

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-2872]

#### Medical Device User Fee Amendments; Public Meeting; Request for Comments; Extension of Comment Period

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

**ACTION:** Notice of public meeting; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending the comment period for the Medical Device User Fee Amendments (MDUFA) reauthorization draft recommendations that were announced in the **Federal Register** on October 7, 2016. In that **Federal Register** notice, FDA requested comments on the draft recommendations related to the reauthorization of the medical device user fee amendments. The Agency is taking this action to allow interested persons the statutorily required 30 days to submit comments.

**DATES:** FDA is extending the comment period on the MDUFA reauthorization draft recommendations published October 7, 2016 (81 FR 69829). Submit either electronic or written comments by November 28, 2016.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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-N-2872 for "Medical Device User Fee Amendments; Public Meeting; Request for Comments; Extension of Comment Period." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### **FOR FURTHER INFORMATION CONTACT:**

Aaron Josephson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5449, Silver Spring, MD 20993, 301-796-5178, [Aaron.Josephson@fda.hhs.gov](mailto:Aaron.Josephson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 7, 2016, FDA published a request for comments with a 30-day comment period beginning October 14, 2016, to request comments on MDUFA reauthorization draft recommendations.

Because the Agency was unable to post the draft recommendations until October 25, 2016, and the statute requires a period of 30 days be provided for the public to provide comments on the draft recommendations, FDA is extending the comment period for the MDUFA reauthorization draft recommendations until November 28, 2016.

Dated: October 27, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**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; Nurse Anesthetist Traineeship Program Specific Data Forms

**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 (Section 3506(c)(2)(A) 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 must be received no later than January 3, 2017.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto: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](mailto:paperwork@hrsa.gov) or call 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: Nurse Anesthetist Traineeship (NAT) Program Specific Data Forms (Application).

OMB No. 0915-0374—Revision.

**Abstract:** HRSA provides advanced education nursing training grants to educational institutions to increase the numbers of Nurse Anesthetists through the NAT Program. The NAT Program is authorized by Section 811 of the Public Health Service (PHS) Act (42 U.S.C. 296j). The NAT Tables request information on program participants such as the number of enrollees, number of enrollees/trainees supported, number of graduates, number of graduates supported, projected data on the number of enrollees/trainees and graduates for the previous fiscal year, the types of programs the Nurse Anesthesia student trainees are enrolling into and/or from which

enrollees/trainees are graduating, and the distribution of Nurse Anesthetists who practice in underserved, rural, or public health practice settings.

Need and Proposed Use of the Information: Funds appropriated for the NAT Program are distributed among eligible institutions based on a formula, as permitted by PHS Act section 806(e)(1). HRSA uses the data from the NAT Tables to determine the award amount, to ensure compliance with programmatic and grant requirements, and to provide information to the public and Congress.

HRSA is streamlining the data collection forms from three tables to two tables by making the following changes:

- Table 1—NAT: Enrollment, Traineeship Support, Graduates, Graduates Supported and Projected Data will no longer capture data by students in first 12 months of study and students beyond first 12 months of study the program. Data will continue to be captured by Master's and Doctoral students.

- Table 2A—NAT: Graduate Data—Rural, Underserved, or Public Health is now Table 2 due to the elimination of Table 2B. There are no other changes to this form.

- Table 2B—NAT: Graduates Supported by Traineeship Data—Rural, Underserved, or Public Health (7/01/15–6/30/16) will be discontinued as of 07/01/18.

**Rationale:** The NAT Program Specific Data Forms will be revised to streamline the process and capture only essential data for use in the formula calculation, ensure grantee compliance, and measure and evaluate the program.

**Likely Respondents:** Eligible applicants are education programs that

provide registered nurses with full-time nurse anesthesia education and are accredited by the Council on Accreditation (COA) of Nurse Anesthesia Educational Programs. Such programs may include schools of nursing, nursing centers, academic health centers, state or local governments, and other public or private nonprofit entities authorized by the Secretary to confer degrees to registered nurses for full-time nurse anesthesia education. Faith-based and community-based organizations, Tribes, and tribal organizations may apply for these funds if otherwise eligible. In addition to the 50 states, only the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, American Samoa, the U.S. Virgin Islands, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau may apply.

**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
Table 1—NAT: Enrollment, Traineeship Support, Graduate, Graduates Supported and Projected Data .....	100	1	100	3.4	340
Table 2—NAT: Graduate Data—Rural, Underserved, or Public Health .....	100	1	100	2.8	280
Total .....	*100	.....	100	.....	620

\* The same respondents are completing Tables 1 and Table 2.

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.

**Jason E. Bennett,**

*Director, Division of the Executive Secretariat.*

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