

[www.acf.hhs.gov/programs/ana](http://www.acf.hhs.gov/programs/ana). We encourage interested applicants to sign up for updates on these FOA at HHS Grant Forecast at [www.acf.hhs.gov/hhsgrantsforecast](http://www.acf.hhs.gov/hhsgrantsforecast).

Once ANA's FOAs have been published, the FY 2014 FOAs can be accessed at <http://www.acf.hhs.gov/grants/open/foa/office/ana> or <http://www.acf.hhs.gov/grants/open/foa/>. Synopses and application forms will be available at [www.Grants.gov](http://www.Grants.gov).

**Statutory Authority:** This notice for public comment is required by Section 814 of the Native American Programs Act of 1974 (NAPA), as amended.

**Lillian A. Sparks Robinson,**  
*Commissioner, Administration for Native Americans.*

[FR Doc. 2014-03282 Filed 2-13-14; 8:45 am]

BILLING CODE 4184-34-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0393]

#### Questions and Answers About Electronic Medical Device Reporting; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Questions and Answers About eMDR—Electronic Medical Device Reporting." FDA has published a final rule that requires device manufacturers and importers to submit mandatory reports of individual medical device adverse events, also known as medical device reports (MDRs), to the Agency in an electronic format that FDA can process, review and archive. This guidance provides general information regarding how to prepare and send an electronic postmarket medical device report to the Center for Devices and Radiological Health (CDRH) in FDA. The guidance also identifies where to find more detailed information on the preparation and transmission of the reports.

**DATES:** Submit either electronic or written comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled "Questions and Answers About eMDR—Electronic Medical Device Reporting" to the Division of Small

Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Tahseen Mirza, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2312, Silver Spring, MD 20993-0002, 301-796-7645.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 519 of the Federal Food, Drug and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i) is FDA's authorization to issue a regulation to require mandatory reporting of device-related adverse events. The Medical Device Reporting (MDR) regulation, 21 CFR part 803, effective December 13, 1984, contained reporting requirements for device manufacturers and importers. Amendments to the FD&C Act under the Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992 introduced mandatory reporting by device user facilities and changed the requirements for device manufacturers, importers and distributors. FDA revised the MDR regulation (part 803) effective July 31, 1996, to address the reporting changes. On February 28, 2005, FDA revised the MDR regulation into plain language.

On August 21, 2009, FDA published a proposed rule (74 FR 42203) to amend part 803 to require manufacturers, importers, and user facilities to submit MDRs to the Agency in an electronic format. Because of concerns over the cost of implementation for user facilities, and the relatively low volume of reports FDA receives from such facilities, the final rule does not require user facilities to adopt electronic reporting. Although FDA encourages user facilities to file reports electronically, they may continue to use only paper forms for MDR reporting. The final rule for electronic submission

of MDRs to FDA anticipates that there will be a reduction in costs and time associated with the submission of MDR reports, elimination of transcription errors associated with paper reports, and both expedited access to safety information and enhanced ability to communicate information about suspected problems. This question and answer guidance provides general information on how to prepare and send an electronic postmarket medical device report to FDA and identifies where to find more detailed information on how to prepare and transmit eMDRs.

The draft eMDR guidance document was published in the **Federal Register** of August 21, 2009. No significant comments were received.

##### 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 Agency's current thinking on electronic MDR reporting. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

##### III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive "Questions and Answers about eMDR—Electronic Medical Device Reporting," you may either send an email request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1679 to identify the guidance you are requesting. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>.

##### IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. 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. 3501-3520). The collections of information in 21 CFR part 803 have been approved under OMB control numbers 0910-0291 and 0910-0437.

**V. Comments**

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: February 11, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-03276 Filed 2-13-14; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request**

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review

of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

**DATES:** Comments on this ICR should be received within 30 days of this notice.

**ADDRESSES:** Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-1984.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* The National Health Service Corps and NURSE Corps Interest Capture Form OMB No. 0915-0337—Revision.

*Abstract:* The National Health Service Corps (NHSC) and the NURSE Corps of the Bureau of Clinician Recruitment and Service (BCRS), HRSA, are both committed to improving the health of the nation's underserved by uniting communities in need with caring health professionals and by supporting communities' efforts to build better systems of care. The NHSC and NURSE Corps Interest Capture Form, which will be used when exhibiting at national and regional conferences as well as when presenting on campuses to health profession students, is an optional form that a health profession student, licensed clinician, faculty member, or clinical site administrator can fill out and submit to BCRS representatives at the recruitment event. The purpose of the form is to enable individuals and clinical sites to ask BCRS for periodic program updates and other general

information regarding opportunities with the NHSC and/or the NURSE Corps via email. Completed forms will contain information such as the names of the individual(s), their email address(es), their city and state, the organization where they are employed (or the school which they attend), the year they intend to graduate (if applicable), how they heard about the NHSC and/or the NURSE Corps, and the programs in which they are interested. Assistance in completing the form will be given by the BCRS staff person (or BCRS representative) who is present at the event.

*Need and Proposed Use of the Information:* The need and purpose of this information collection is to share resources and information regarding the NHSC and NURSE Corps programs with interested conference/event participants.

*Likely Respondents:* Conference/event participants interested in the NHSC or NURSE Corps programs.

*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.

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
NHSC and NURSE Corps Interest Capture Form .....	2,400	1	2,400	.025	60
Total .....	2,400	1	2,400	.025	60

Dated: February 7, 2014.

**Jackie Painter,**

*Deputy Director, Division of Policy and Information Coordination.*

[FR Doc. 2014-03239 Filed 2-13-14; 8:45 am]

**BILLING CODE 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings 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