verification is required for psychiatric hospitals. Some verification is needed, however, to ensure that other types of hospitals and units meet the criteria for exclusion. Consequently, we instructed the Fiscal Intermediaries (FIs) and SAs to perform certain verification activities, beginning in October 1983 when PPS was implemented. We originally developed the CMS–437 as an SA Worksheet for verifying exclusions from PPS for psychiatric units.

Since April 9, 1994, PPS-excluded psychiatric units already excluded from the PPS have met CMS's annual requirement for PPS-exclusion by self-attesting that they remain in compliance with the PPS exclusion criteria. Under the current procedure, all psychiatric units applying for first-time exclusion are surveyed by the SAs. The SAs also perform surveys to investigate complaint allegations and conduct annual sample reverification surveys on 5 percent of all psychiatric units. The aforementioned exclusions continue to exist and thus we propose to continue to use the Criteria Worksheet, Forms CMS–437, for verifying first-time exclusions from the PPS, for complaint surveys, for its annual 5 percent validation sample, and for facility self-attestation. These forms are related to the survey and certification and Medicare approval of the PPS-excluded units. *Form Number:* CMS–437 (OCN: 0938–0358); *Frequency:* Annually; *Affected Public:* Private sector—Business or other for-profits; *Number of Respondents:* 1,614; *Total Annual Responses:* 1,614; *Total Annual Hours:* 404. (For policy questions regarding this collection contact Donald Howard at 410–786–6764.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Disclosure for the In-Office Ancillary Services Exception; *Use:* Physicians who provide certain imaging services (magnetic resonance imaging, computed tomography, and positron emission tomography) under the in-office ancillary services exception to the physician self-referral prohibition are required to create the disclosure notice as well as the list of other imaging suppliers to be provided to the patient. The patient will then be able to use the disclosure notice and list of suppliers in making an informed decision about his or her course of care for the imaging service. The physician must maintain a record of the disclosure in the patient's medical record. If we were investigating the referrals of a physician providing advanced imaging services under the in-office ancillary services exception, we would review the written disclosure in order to determine if the physician satisfied the requirement. *Form Number:* CMS–10332 (OCN: 0938–1133); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profits; *Number of Respondents:* 71,000; *Total Annual Responses:* 71,106; *Total Annual Hours:* 125,383. (For policy questions regarding this collection contact Jacqueline Proctor at 410–786–8852).

Dated: April 1, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–07582 Filed 4–3–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request Proposed Projects

Title: Family Violence Prevention and Services: Grants to States; Native American Tribes and Alaskan Native Villages; and State Domestic Violence Coalitions

OMB No.: 0970–0280

Description: The Family Violence Prevention and Services Act (FVPSA), 42 U.S.C. 10401 *et seq.,* authorizes the Department of Health and Human Services to award grants to States, Tribes—and Tribal Organizations, and State Domestic Violence Coalitions for family violence prevention and intervention activities. The proposed information collection activities will be used to make grant award decisions and to monitor grant performance.

Respondents: State Agencies Administering FVPSA Grants; Tribal Governments and Tribal Organizations; and State Domestic Violence Coalitions.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Grant Application	53	1	10	530
Tribal Grant Application	150	1	5	750
State Domestic Violence Coalition Application	56	1	10	560
State FVPSA Grant Performance Progress Report	53	1	10	530
Tribal FVPSA Grant Performance Progress Report	150	1	10	1,500
State Domestic Violence Coalition Performance Progress Report	56	1	10	560
Estimated Total Annual Burden Hours				4,430

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–07530 Filed 4–3–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0147]

Types of Communication During the Review of Medical Device Submissions; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Types of Communication During the Review of Medical Device Submissions.'' The purpose of this guidance is to update the Agency's approach to Interactive Review and other additional types of communication, to reflect FDA's implementation of the Medical Device User Fee Act of 2007 (MDUFA II) Commitment Letters and of undertakings agreed to in connection with the Medical Device User Fee Amendments of 2012 (MDUFA III). These new Agency communication commitments are to increase the efficiency of the review process.

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: 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 single copies of the guidance document entitled ''Types of Communication During the Review of Medical Device Submissions'' to the Office of the Center Director, 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 or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. 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: Samie Allen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1533, Silver Spring, MD 20993–0002, 301–796–6055, or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the letters dated September 27, 2007, from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the U.S. Senate and the Chairman of the Committee on Energy and Commerce of the U.S. House of Representatives setting out the goals of section 201(c) of MDUFA II, Title II of the Food and Drug Administration Amendments of 2007 (FDAAA) (21 U.S.C. 379i note), FDA committed to developing a guidance document that describes an interactive review process between FDA and industry for specific medical device premarket submissions. Further, during discussions with representatives of the medical device industry in the development of the Agency's recommendations for MDUFA III, Title II of the Food and Drug Administration Safety and Innovation Act, Public Law 112–144 (July 9, 2012) (21 U.S.C. 301 note), the Agency proposed process improvements to provide further transparency into the review process, including new communication commitments.

In the **Federal Register** on March 5, 2013 (78 FR 14305), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by June 3, 2013. Four comments were received and, in general, were supportive of the guidance. However, the comments contained multiple recommendations pertaining to the content of the guidance and the need for clarification, particularly for the Interactive Review section. In response to these comments, FDA revised the guidance document to restructure the Interactive Review section to clarify how this process works and to include references to additional submission types for which Interactive Review pertains. Although several commenters expressed concern about FDA's intention to limit the last round of Interactive Review to 7 days, we did not modify the guidance because this approach is needed in order to appropriately balance the intent of interactive review with FDA's commitment to meet the performance goals agreed upon as part of MDUFA III. In response to comments regarding our intention to limit the issuance of second Additional Information (AI) letters for 510(k) submissions, the guidance was modified slightly to clarify the circumstances in which a second AI letter might be issued, but remains unchanged in explaining that these circumstances will remain limited and at FDA's discretion. FDA will continually assess any impacts that the limited use of a second AI letter may have, and, if needed, may consider modifications to this approach. In addition to modifications to the Interactive Review section, we clarified other items throughout the guidance, and included Pre-Submissions as a submission type subject to Acceptance Communication. This document supersedes ''Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements'' dated February 28, 2008.

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 communication during a medical device premarket submission review to provide further transparency into, and to increase the efficiency of, the review process. 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. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/*