

whether such items are in written form, in the form of computer data, or in any other form, for a period of three years after final payment. This information is necessary for examination and audit of contract surveillance, verification of contract pricing, and to provide reimbursement of contractor costs, where applicable. The records retention period is required by the statutory authorities at 10 U.S.C. 2313, 41 U.S.C. 254, and 10 U.S.C. 2306, and are implemented through the following clauses: Audit and Records-Negotiation clause, 52.215-2; Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items clause, 52.212-5; and Audit and Records-Sealed Bidding clause, 52.214-26. This information collection does not require contractors to create or maintain any records that the contractor does not normally maintain in its usual course of business.

B. Annual Reporting Burden

Respondents: 14,830.

Responses per Respondent: 10.

Total number of responses: 148,300.

Hours per Response: 1.0.

Total Burden Hours: 148,300.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulation (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology and ways to enhance the quality, utility, and clarity of the information to be collected.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202-501-4755. Please cite OMB Control Number 9000-0034, Examination of Records by Comptroller General and Contract Audit, in all correspondence.

Dated: September 6, 2016.

Lorin S. Curit,

Director, Federal Acquisition Policy, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10328]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: The necessity and utility of the proposed information collection for the proper performance of the agency's functions; the accuracy of the estimated burden; ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by October 11, 2016.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 OR Email: OIRA_submission@omb.eop.gov.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. Email your request, including your address, phone number, OMB number,

and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT:

Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Self-Referral Disclosure Protocol; *Use:* The Affordable Care Act ("ACA") was enacted on March 23, 2010. Section 6409 of the ACA requires the Secretary of the Department of Health and Human Services (the "Secretary"), in cooperation with the Office of Inspector General of the Department of Health and Human Services, to establish a Medicare self-referral disclosure protocol ("SRDP"). The SRDP enables providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral statute, section 1877 of the Social Security Act (the "Act"). Section 6409(b) of the ACA gives the Secretary the authority to reduce the amount due and owing for all violations of section 1877 of the Act. In establishing the amount by which an overpayment may be reduced, the Secretary may consider: the nature and extent of the improper or illegal practice; the timeliness of the self-disclosure; the cooperation in providing additional information related to the disclosure; and such other factors as the Secretary considers appropriate.

In accordance with the ACA, CMS established the SRDP on September 23, 2010, and information concerning how

to disclose an actual or potential violation of section 1877 of the Act was posted on the CMS Web site. The most recent approval of this information collection request ("ICR") was issued by the Office of Management and Budget on August 26, 2014.

We are now seeking approval to revise the currently approved ICR. Under the currently approved collection, a party must provide a financial analysis of overpayments arising from actual or potential violations of section 1877 of the Act based on a 4-year lookback period. On February 12, 2016, CMS published a final rule on the reporting and returning of overpayments. See CMS-6037-F, Medicare Program; Reporting and Returning of Overpayments, 81 FR 7654 (Feb. 12, 2016) (the "final overpayment rule"). The final overpayment rule establishes a 6-year lookback period for reporting and returning overpayments. We are revising the information collection for the SRDP to reflect the 6-year lookback period established by the final overpayment rule. The revision is necessary to ensure that parties submitting self-disclosures to the SRDP report overpayments for the entire 6-year lookback period. The 6-year lookback period applies *only* to submissions to the SRDP received *on or after* March 14, 2016, the effective date of the final overpayment rule; parties submitting self-disclosures to the SRDP prior to March 14, 2016 need only provide a financial analysis of potential overpayments based on a 4-year lookback period.

We are also taking the opportunity to streamline and simplify the SRDP by issuing a required form for SRDP submissions. The SRDP Form will reduce the burden on disclosing parties by reducing the amount of information that is required for submissions to the SRDP and providing a streamlined and standardized format for the presentation of the required information. *Form Number:* CMS-10328 (OMB control number: 0938-1106); *Frequency:* Annually and semi-annually; *Affected Public:* Private sector (Business or other for-profits and Not-for-profits); *Number of Respondents:* 200; *Total Annual Responses:* 200; *Total Annual Hours:* 5,000. (For policy questions regarding this collection contact Matt Edgar at 410-786-0698).

Dated: September 2, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Blood Products Advisory Committee Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Blood Products Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on November 17, 2016, from 8 a.m. to 5:30 p.m. and on November 18, 2016, from 8:30 a.m. to 1 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD, 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT:

LCDR Bryan Emery or Joanne Lipkind, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, Bldg. 71, Rm. 6132, at 240-402-8054, bryan.emery@fda.hhs.gov and 240-402-8106, joanne.lipkind@fda.hhs.gov, respectively, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting. For those unable to attend in person, the meeting will also be

available via Webcast. The Webcast will be available at the following link for both days: <https://collaboration.fda.gov/bpac1116/>.

SUPPLEMENTARY INFORMATION:

Agenda: On the morning of November 17, 2016, the Committee will meet in open session to discuss strategies to manage iron deficiency associated with blood donation. The Committee will also discuss proposed procedures for assuring donor safety for collections of blood from female donors with hemoglobin values of 12.0–12.4g/dL or a hematocrit value between 36 and 38. In the afternoon, the Committee will meet in open session to discuss adverse reactions related to blood donation in teenage (16 to 18 years) donors, and the effectiveness of several mitigation measures. On November 18, 2016, the Committee will meet in open session to hear an informational session on Zika virus and blood safety in the United States. Following the informational session, the Committee will hear presentations on the following topics: (1) The Transfusion Transmissible Infections Monitoring System; (2) a summary of the FDA workshop on new methods to predict the immunogenicity of therapeutic coagulation proteins; and (3) a summary of the FDA workshop on preclinical evaluation of red blood cells for transfusion.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 4, 2016. Oral presentations from the public will be scheduled between approximately 11 a.m. to 11:45 a.m. and 4 p.m. to 4:30 p.m. on November 17, 2016. Oral presentations from the public will also be scheduled between approximately 10:30 a.m. and 11 a.m. and 12:30 p.m. to 1 p.m. on November 18, 2016. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief