information collection documents from the General Services Administration, Regulatory Secretariat Division, 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755.

Please cite OMB Control No. 3090–0205, Environmental Conservation, Occupational Safety, and Drug-Free Workplace, in all correspondence.

Dated: May 12, 2015.

Jeffrey A Koses,

Director, Office of Acquisition Policy, Senior Procurement Executive.

[FR Doc. 2015–11749 Filed 5–14–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–437A & CMS–437B]

Agency Information Collection Activities: Proposed Collection; 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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (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.

DATES: Comments must be received by July 14, 2015.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

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:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–437A & CMS–437B State Agency Sheets for Verifying Exclusions From the Inpatient Prospective Payment System and Supporting Regulations

Under the 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 requires federal agencies to publish a 60-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.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection. *Title of Information Collection:* State Agency Sheets for Verifying Exclusions from the Inpatient Prospective Payment System and Supporting Regulations *Use:* For first time verification requests for exclusion from the Inpatient Prospective Payment System (IPPS), a hospital/unit must notify the Regional Office (RO) servicing the State in which it is located that it believes it meets the criteria for exclusion from the IPPS. Currently, all new inpatient rehabilitation facilities (IRFs) must provide written certification that the inpatient population it intends to serve will meet the requirements of the IPPS exclusion criteria for IRFs. They must also complete the Form CMS–437A if they are a rehabilitation unit or complete Form CMS–437B if they are a rehabilitation hospital. This information is submitted to the State Agency (SA) no later than 5 months before the date the hospital/unit would become subject to IRF–PPS.

We propose to continue to use the Criteria Worksheets (Forms CMS–437A and CMS–437B) for verifying first-time exclusions from the IPPS, 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 IPPS-excluded rehabilitation units and rehabilitation hospitals.

For rehabilitation hospitals and rehabilitation units already excluded from the IPPS, annual onsite re-verification surveys by the SA are not required. These hospitals and units will be provided with a copy of the appropriate CMS–437 Worksheet at least 5-months prior to the beginning of its cost reporting period, so that the hospital/unit official may complete and sign an attestation statement and complete and return the appropriate CMS–437A or CMS–437B at least 5-months prior to the beginning of its cost reporting period. Fiscal Intermediaries will continue to verify, on an annual basis, compliance with the 60 percent rule (42 CFR 412.29(b)(2)) for rehabilitation hospitals and rehabilitation units through a sample of medical records and the SA will verify the medical director requirement.

The SA will maintain the documents unless instructed otherwise by the RO.

The SA will notify the RO at least 60 days prior to the end of the rehabilitation hospital's/unit's cost reporting period of the IRF's compliance or non-compliance with the payment requirements. The information collected on these forms, along with other information submitted by the IRF is necessary for determining exclusion from the IPPS. Hospitals and units that have already been excluded need not reapply for exclusion. These facilities will automatically be reevaluated yearly to determine whether they continue to meet the exclusion criteria.

Form Number: CMS–437A and CMS–437B (OMB Control Number: 0938–0986); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits); *Number of Respondents:* 478; *Total Annual Responses:* 478; *Total Annual Hours:* 120. (For policy questions regarding this collection contact James Cowher at 410–786–1948).

Dated: May 12, 2015.

William N. Parham, III

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

[FR Doc. 2015–11798 Filed 5–14–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1484]

Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators.'' The purpose of this guidance is to assist sponsor-investigators in preparing and submitting complete investigational new drug applications (INDs) to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) at FDA. Although not an exhaustive step-by-step instruction manual, this guidance highlights certain elements of this process to facilitate a sponsor-investigator's successful submission of an IND. This guidance also discusses the IND review process and general responsibilities of sponsor-investigators related to clinical investigations. Details of the informational content of an IND as well as information needed to complete required forms also are provided throughout this guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 14, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft 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.

FOR FURTHER INFORMATION CONTACT: Amalia Himaya, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6439, Silver Spring, MD 20993–0002, 301–796–0700; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators.'' The purpose of this guidance is to assist investigators in preparing and submitting complete INDs to CDER and CBER at FDA. Sponsor-investigators seeking to do clinical research often do not have the regulatory knowledge or the resources to hire experts to help them with the IND submission process. Although not an exhaustive step-by-step instruction manual, this guidance highlights certain elements of this process to facilitate a sponsor-investigator's successful submission of an IND. This guidance also discusses the IND review process and general responsibilities of sponsor-investigators related to clinical investigations. The guidance does not include discussions of all of the requirements that apply to the IND submission and review process or to conducting clinical research.

This guidance is directed primarily at those sponsor-investigators who are seeking to evaluate a drug that is either currently approved or is being investigated under an existing IND for a different indication. This guidance is not intended for sponsor-investigators who are developing a drug for commercial purposes (*i.e.,* seeking market approval or licensure). This guidance does not apply to clinical trials that do not need to be conducted under an IND (*i.e.,* that qualify for an IND exemption). The guidance also is not intended to address expanded access INDs or biologic devices.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on INDs prepared and submitted by sponsor-investigators. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 312 have been approved under OMB control number 0910–0014.

III. 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