abbreviated version of the RFI rating system consistent with the Board's practice for BHCs outlined in SR 13–21. An offsite review of the SLHC will be conducted upon receipt of the lead depository institution's report of examination. The supervisory cycle will be determined by the examination frequency of the lead depository institution and the SLHC will be assigned only a risk management rating and a composite rating.

Moreover, SLHCs have been subject to the RFI rating system on indicative basis for the past seven years, which has provided SLHCs the opportunity to adjust to the RFI rating system. The full application of the RFI rating system to small non-commercial and non-insurance SLHCs will not create any new economic impact on small entities.

In light of the foregoing, the Board does not believe that this final rule will have a significant economic impact on any small entities and therefore believes that there are no significant alternatives that would reduce the economic impact on small entities.

By order of the Board of Governors of the Federal Reserve System, November 2, 2018.

Ann Misback,

Secretary of the Board.

[FR Doc. 2018–24496 Filed 11–8–18; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Decision to Designate a Class of Employees From the Sandia National Laboratories in Albuquerque, New Mexico, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: HHS gives notice of a decision to designate a class of employees from the Sandia National Laboratories in Albuquerque, New Mexico, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, NIOSH, 1090 Tusculum Avenue, MS C–46, Cincinnati, OH 45226–1938, Telephone 1–877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV*.

SUPPLEMENTARY INFORMATION:

Authority: 42 U.S.C. 7384q(b). 42 U.S.C. 7384*l*(14)(C).

On October 18, 2018, as provided for under 42 U.S.C. 7384*l*(14)(C), the Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of the Department of Energy, its predecessor agencies, and its contractors or subcontractors who worked in any area at the Sandia National Laboratories in Albuquerque, New Mexico, during the period from January 1, 1995, through December 31, 1996, for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees included in the Special Exposure Cohort.

This designation will become effective on November 17, 2018, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

John J. Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2018–24530 Filed 11–8–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–R–240 and CMS–10164]

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 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 must be received by January 8, 2019.

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' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

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: William Parham at (410) 786–4669.

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–R–240 Prospective Payments for Hospital Outpatient Services

CMS–10164 Medicare EDI Enrollment Form and EDI Registration

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:* Reinstatement of a previously approved collection; *Title of Information Collection:* Prospective Payments for Hospital Outpatient Services; *Use:* Section 1833(t) of the Act, as added by section 4523 of the Balanced Budget Act of 1997 (the BBA) requires the Secretary to establish a prospective payment system (PPS) for hospital outpatient services. Successful implementation of an outpatient PPS requires that CMS distinguish facilities or organizations that function as departments of hospitals from those that are freestanding, so that CMS can determine which services should be paid under the OPPS, the clinical laboratory fee schedule, or other payment provisions applicable to services furnished to hospital outpatients. Information from the reports required under sections 413.65(b)(3) and (c) is needed to make these determinations. In addition, section 1866(b)(2) of the Act authorizes hospitals and other providers to impose deductible and coinsurance charges for facility services, but does not allow such charges by facilities or organizations which are not provider-based. Implementation of this provision requires that CMS have information from the required reports, so it can determine which facilities are provider-based. *Form Number:* CMS–R–240 (OMB control number: 0938–0798); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 750; *Total Annual Responses:* 13,649,150; *Total Annual Hours:* 680,920 (For policy questions regarding this collection contact Emily Lipkin at 410–786–3633.)

2. *Type of Information Collection Request:* Reinstatement of a previously approved collection; *Title of Information Collection:* Medicare EDI Enrollment Form and EDI Registration; *Use:* The Congress, recognizing the need to simplify the administration of health care transactions, enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191, on August 21, 1996. Title II, Subtitle F of this legislation directs the Secretary of the Department of Health and Human Services to develop unique standards for specified electronic transactions and code sets for those transactions. The purpose of this Subtitle is to improve the Medicare and Medicaid programs in particular and the efficiency and effectiveness of the health care industry in general through the establishment of standards and requirements to facilitate the electronic transmission of certain health information. This Subtitle also requires that the Secretary adopt standards for financial and administrative transactions, and data elements for those transactions to enable health information to be exchanged electronically. The Standards for Electronic Transactions final rule, 45 CFR part 162 Subpart K § 162.1101 through Subpart R § 162.1802, (hereinafter referred to as ''Transactions Rule'') published August 17, 2000 adopted standards for health care transactions and code sets. Subsequent to the Transactions Rule, CMS–0003–P and CMS–0005–P proposed modifications to the adopted standards essential to permit initial implementation of the standards throughout the entire healthcare industry.

Currently, Medicare contractors have a process in place to enroll providers for electronic billing and other EDI transactions. In support of the HIPAA Transactions Rule, the purpose of this Paperwork Reduction Act (PRA) request is to establish a common form that is sufficient to address all HIPAA transactions. *Form Number:* CMS–10164 (OMB control number: 0938–0983); *Frequency:* Hourly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 193,268; *Number of Responses:* 193,268; *Total Annual Hours:* 64,423. (For policy questions regarding this collection, contact Matt Klischer at 410–786–7488.)

Dated: November 6, 2018.

William N. Parham, III,

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

[FR Doc. 2018–24592 Filed 11–8–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4099]

Tedor Pharma, Inc., et al.; Withdrawal of Approval of 10 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 10 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of December 10, 2018.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945, *Trang.Tran@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.