

information is aircraft traveling within the United States.

This revision makes several modification to this information collection. They are as follows:

- In current practice, CDC does not process applications for travel permits. The issuance of travel restrictions is a collaborative process between public health partners, e.g., state health departments, the Department of Homeland Security, and CDC. There is no standardized collection of information involved. This change results in the removal of the Ill Person Travel Permit from the list of information collections as well as the removal of the associated burden.

- Reports of communicable disease or death from domestic conveyances are

almost always submitted electronically via radio, so the current Master of Vessel or Conveyance Illness Report has been rendered obsolete. In addition, CDC has issued guidance stating that reports to CDC, instead of local health authorities, regarding domestic reports of communicable disease or death on board conveyances meet the requirements of the regulation; therefore, information collections related to copies sent to state health departments are no longer necessary. This primary concerns interstate flights.

- CDC is also requesting an adjustment to the burden associated with reports of communicable disease or death from domestic conveyances. CDC is reducing the burden from 15 minutes per report to 7 minutes. This is due to

the facilitation of reporting using electronic means, i.e., Air Traffic Control and the Domestic Events Network for domestic flights.

The resulting change in burden is a reduction of 3,678 hours.

For reports of death or communicable disease made by master of a vessel or person in charge of a conveyance engaged in interstate traffic, the requested burden is approximately 23 hours. This total is estimated from 200 respondents submitting domestic reports of death or communicable disease a year, with an average burden of 7 minutes per report. This totals 23 hours. There is no burden to respondents other than the time required to make the report of illness or death.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondent | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|---|---|-----------------------|------------------------------------|--|-------------------------|
| Master of a vessel or person in charge of a conveyance. | 42 CFR 70.4 Report by the master of a vessel or person in charge of conveyance of the incidence of a communicable disease occurring while in interstate travel. | 200 | 1 | 7/60 | 23 |
| Total | | | | | 23 |

Leroy A. Richardson,
Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC-2015-0075, Docket Number NIOSH-288]

A Vapor Containment Performance Protocol for Closed System Transfer Devices Used During Pharmacy Compounding and Administration of Hazardous Drugs; Request for Comment

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

ACTION: Notice of draft document available for public comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the availability of the following draft document for public comment entitled *A Vapor Containment Performance Protocol for Closed System Transfer Devices Used During Pharmacy Compounding and Administration of Hazardous Drugs*. The document and instructions for submitting comments can be found at www.regulations.gov.

This guidance document does not have the force and effect of law.

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DATES: Electronic or written comments must be received by November 9, 2015.

ADDRESSES: You may submit comments, identified by CDC-2015-0075 and Docket Number NIOSH-288, by either of the two following methods:

- *Federal eRulemaking Portal:* www.regulations.gov Follow the instructions for submitting comments.
- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, 1090 Tusculum

Avenue, MS-C34, Cincinnati, Ohio 45226.

Instructions: All information received in response to this notice must include the agency name and the docket number (CDC-2015-0075; NIOSH-288). All relevant comments received will be posted without change to www.regulations.gov, including any personal information provided. All electronic comments should be formatted as Microsoft Word. Please make reference to CDC-2015-0075 and Docket Number NIOSH-288. All information received in response to this notice will also be available for public examination and copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 155, Cincinnati, OH 45226-1998.

FOR FURTHER INFORMATION CONTACT: Deborah V. Hirst, NIOSH, Division of Applied Research and Technology, Alice Hamilton Laboratories, 1090 Tusculum Avenue, MS R-5, Cincinnati, Ohio 45226, (513) 841-4141 (not a toll free number), Email: hazardousdrugs@cdc.gov.

SUPPLEMENTARY INFORMATION: The purpose of the protocol is to test a closed system transfer device's (CSTD) capability to perform as a closed system. During an evaluation of the protocol,

registered pharmacists, familiar with the use of CSTDs, tested the protocol's prescribed compounding and administration tasks using five commercially available CSTDs. They also performed the assigned tasks using a negative control condition without a CSTD. Prescribed tasks were performed in a NIOSH-developed environmental test chamber with 70% isopropyl alcohol (IPA) as the challenge agent. A highly specific gas analyzer, with measurement capabilities specific to IPA and with a low limit of detection (LOD), was used to detect vapor concentrations of escaped IPA during the tasks. The protocol is not intended for CSTDs designed to operate using air-cleaning technologies. This protocol has multiple applications and can be used by manufacturers to evaluate prototype CSTDs, by consumers to compare CSTD products, or by jurisdictions wishing to adopt the protocol for a CSTD performance certification procedure.

A panel consisting of peer reviewers and stakeholders was asked to review and comment on the draft guidance document and protocol. NIOSH reviewed the recommendations of the peer reviewers and stakeholders then made the final determination regarding document content as well as the decision not to propose a specific pass/fail performance threshold. The protocol is being published for comment in CDC-2015-0075 and Docket Number NIOSH-288 and can be found at www.regulations.gov.

Dated: September 1, 2015.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10221]

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

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: (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 on the collection(s) of information must be received by the OMB desk officer by October 8, 2015.

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:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Site Investigation for Independent Diagnostic Testing Facilities (IDTFs); *Use:* We enroll Independent Diagnostic Testing Facilities (IDTFs) into the Medicare program via a uniform application, the CMS 855B. Implementation of enhanced procedures for verifying the enrollment information has improved the enrollment process as well as identified and prevented fraudulent IDTFs from entering the Medicare program. As part of this process, verification of compliance with IDTF performance standards is necessary. The primary function of the site investigation form for IDTFs is to provide a standardized, uniform tool to gather information from an IDTF that tells us whether it meets certain standards to be a IDTF (as found in 42 CFR 410.33(g)) and where it practices or renders its services. The site investigation form has been used in the past to aid in verifying compliance with the required performance standards found in 42 CFR 410.33(g). No revisions have been made to this form since the last submission for OMB approval. *Form Number:* CMS-10221 (OMB Control Number: 0938-1029); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 900; *Total Annual Responses:* 900; *Total Annual Hours:* 1,800. (For policy questions regarding this collection contact Kim McPhillips at 410-786-5374).

Dated: September 2, 2015.

William N. Parham, III,

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

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