

all nonfatal assaults occurring in private industry are experienced in healthcare. Six states have enacted laws to reduce violence against healthcare workers by requiring workplace violence prevention programs. However, little is understood about how effective these laws are in reducing violence against healthcare workers.

The long-term goal of the proposed project is to reduce violence against healthcare workers. The objective of the proposed study is: (1) To examine nursing home compliance with the New Jersey Violence Prevention in Health Care Facilities Act, and (2) to evaluate the effectiveness of the regulations in this Act in reducing assault injuries to

nursing home workers. Our central hypothesis is that nursing homes with high compliance with the regulations will have lower rates of employee violence-related injury.

Previously under this OMB Control number, NIOSH received OMB approval to evaluate the legislation at 50 hospitals and at 40 nursing homes, to conduct a nurse survey, and to conduct a home healthcare aide survey (HHCAS). NIOSH completed the data collection activities for the hospitals, the nurse survey, and the HHCAS. However, NIOSH only completed 20 out of 40 nursing home interviews.

NIOSH seeks to conduct face-to-face interviews with the Chairs of the

Violence Prevention Committees in 20 nursing homes (10 in New Jersey and 10 in Virginia) who are in charge of overseeing compliance efforts. The purpose of the interviews is to measure compliance to the state regulations: Violence prevention policies, reporting systems for violent events, violence prevention committee, written violence prevention plan, violence risk assessments, post incident response and violence prevention training. A contractor will conduct the interviews.

There are no costs to respondents other than their time. The total estimated burden hours are 40.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Nursing Home Administrators	Interview	20	1	1	20
Nursing Home Administrators	Abstraction form	20	1	1	20
Total	40

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 Medicare & Medicaid Services

[Document Identifiers: CMS-10123 and CMS-10124]

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

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human 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 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 December 22, 2017.

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 Web site 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: 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:* Extension of a currently approved collection; *Title of Information Collection:* Fast Track Appeals Notices: NOMNC/DENC; *Use:* Providers shall deliver a Notice of Medicare (Provider) Non-Coverage (NOMNC) to beneficiaries, enrollees, or both beneficiaries and enrollees no later than two days prior to the end of Medicare-covered services in skilled nursing facilities, home health agencies, comprehensive outpatient rehabilitation facilities, and hospices. Beneficiaries, enrollees or both beneficiaries and enrollees will use this information to determine whether they want to appeal the service termination to their Quality Improvement Organization (QIO). If the beneficiaries, enrollees or both beneficiaries decide to appeal, the Medicare provider or health plan will send the QIO and appellant a Detailed Explanation of Non-Coverage (DENC) detailing the rationale for the termination decision. *Form Number:* CMS-10123 and CMS-10124 (OMB control number: 0938-0953); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 28,177; *Total Annual Responses:* 6,017,832; *Total Annual Hours:* 1,111,196. (For policy questions regarding this collection contact Janet Miller at 404-562-1799.)

Dated: November 17, 2017.

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-2013-N-0227]

Tobacco Product Manufacturing Practice; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting public input on updated recommendations for regulations on good manufacturing practice for electronic nicotine delivery systems (ENDS) that were submitted to FDA by a group of 13 tobacco companies

(tobacco companies' ENDS recommendations). FDA is providing an opportunity for interested parties to comment on the tobacco companies' ENDS recommendations.

DATES: Submit electronic or written comments on the tobacco companies' ENDS recommendations by December 22, 2017.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 22, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of December 22, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management

Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2013-N-0227 for "Tobacco Product Manufacturing Practice; Establishment of a Public Docket." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Matthew Brenner, Center for Tobacco