Institute for Occupational Safety and Health (NIOSH) intends to employ existing provisions in 42 CFR Part 84 to test and approve air-purifying respirators (APRs) and powered air-purifying respirators (PAPRs) that provide composite multi-gas and particulate protection for inhalation hazards associated with wildland fire-fighting. NIOSH will evaluate candidate respirators for inhalation protections tailored against exposures identified in the National Fire Protection Association (NFPA) 1984 standard on respirators for wildland fire-fighting (WFF) operations. Under 42 CFR Part 84 requirements, NIOSH approval is necessary for the complete evaluation of WFF respirators pursuant to NFPA 1984 (2011).

**SUPPLEMENTARY INFORMATION:**

## Background

Wildland firefighting presents many hazards to firefighters, including inhalation exposure to smoke and other combustion (fire) byproducts. Studies indicate that most wildland firefighters work in smoke levels that are not expected to cause health problems or exceed legal and recommended limits.[1] However, wildland firefighters occasionally experience smoke levels that exceed guidelines recommended by occupational health experts, and are higher than Federal occupational safety and health regulations allow. Because manufacturers have not yet developed respiratory protection for this occupational setting, firefighters battling wild fires often resort to using devices not approved by NIOSH, or NIOSH-approved filtering facepiece respirators which are not designed for this use, or no respiratory protection at all. Without a NIOSH-approved respirator designed to protect against the combination of particulates, gases and vapors generally produced by wildfires, firefighters cannot be sure that they are receiving adequate or any protection at all. Filtering facepiece respirators approved under the current NIOSH standards provide no protection against fire gases or vapors and may structurally fail at the elevated temperatures encountered in wildland firefighting environments.

NIOSH is now accepting applications for respiratory protective devices designed for the inhalation hazards of this occupational setting.

On July 10, 2012 NIOSH issued a letter to manufacturers [2] announcing that NIOSH was prepared to evaluate respirators used for protection against the inhalation hazards identified in the National Fire Protection Association (NFPA) standard 1984 (2011 Edition).[3] This new evaluation will be conducted in accordance with a Memorandum of Understanding between the NIOSH National Personal Protective Technology Laboratory (NPPTL) and the Safety Equipment Institute (SEI), a non-governmental non-profit organization that administers third-party certification programs to certify a broad range of safety and protective products. Under this MOU, NIOSH/NPPTL and SEI will coordinate their certification programs. SEI will evaluate candidate respirators for compliance with NFPA 1984–2011, *Standard on Respirators for Wildland Fire-Fighting Operations,* which includes Tentative Interim Amendment (TIA) No. 11–1.

Under NFPA 1984, the wildland firefighter respirator must be approved by NIOSH as an APR or a PAPR. NIOSH has developed test procedures for a composite particulate and multi-gas protection for APR and PAPR approvals in accordance with 42 CFR 84.60(b); 84.63(a), (b), (c), and (d); 84.110(c); and 84.190(b). The standard test procedures are available upon request and will be available on the NIOSH NPPTL Web site at: *http://www.cdc.gov/niosh/npptl/stps/APresp.html.*

**FOR FURTHER INFORMATION CONTACT:** Tim Rehak, NIOSH National Personal Protective Technology Laboratory (NPPTL), P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236; (412) 386–5200 (this is not a toll-free number).

Dated: November 8, 2012.

**John Howard,**

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

[FR Doc. 2012–27898 Filed 11–15–12; 8:45 am]

**BILLING CODE 4163–19–P**

[1] See: Reinhardt,TE, Ottmar, RD. 2000. Smoke exposure at western wildfires. Res. Pap. PNW–RP–525. Portland, OR: U.S. Department of Agriculture, Forest Service, Pacific Northwest Research Station.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifier CMS–10028, CMS–10180, CMS–R–199 and CMS–10443]**

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

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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 function; (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.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Children's Health Insurance Program (CHIP) Report on Payables and Receivables; *Use:* Collection of CHIP data and the calculation of the CHIP Incurred But Not Reported (IBNR) estimate are pertinent to CMS' financial audit. The CFO auditors have reported the lack of an estimate for CHIP IBNR payables and receivables as a reportable condition in the FY 2005 audit of CMS's financial statements. It is essential that CMS collect the necessary data from State agencies in FY 2006, so that CMS continues to receive an unqualified audit opinion on its financial statements. Program expenditures for the CHIP have increased since its inception; as such, CHIP receivables and payables may materially impact the financial statements. The CHIP Report on Payables and Receivables will provide the information needed to calculate the CHIP IBNR.; *Form Number:* CMS–10180 (OMB#: 0938–0988); Frequency: Reporting—Annually; *Affected Public:* State, Local or Tribal governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 392. (For policy questions regarding this collection contact Michele Myers at 410–786–7911. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Report on Payables and Receivables; *Use:* The Chief Financial Officers (CFO) Act of 1990, as amended by the Government Management Reform Act (GMRA) of 1994, requires government agencies to produce auditable financial statements. Because the Centers for Medicare & Medicaid Services (CMS) fulfills its

mission through its contractors and the States; these entities are the primary source of information for the financial statements. There are three basic categories of data: expenses, payables, and receivables. The CMS–64 is used to collect data on Medicaid expenses. The CMS–R–199 collects Medicaid payable and receivable accounting data from the States. *Form Number:* CMS–R–199 (OMB#: 0938–0697); Frequency: Reporting—Annually; *Affected Public:* State, Local or Tribal governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 336. (For policy questions regarding this collection contact Michele Myers at 410–786–7911. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* State Health Insurance Assistance Program (SHIP) Client Contact Form, Public and Media Activity Report Form, and Resource Report Form. *Use:* Section 4360(f) of the Omnibus Budget Reconciliation Act (OBRA) 1990 requires the Secretary to provide a series of reports to the U.S. Congress on the performance of the program and its impact on beneficiaries and to obtain important informational feedback from beneficiaries. Further, in response to requirements of the Balanced Budget Act of 1997, CMS launched a comprehensive five-year campaign, the National Medicare Education Program (NMEP), to raise awareness among beneficiaries about their Medicare health plan options and help them assess the advantages and disadvantages each choice holds for them. The Medicare Modernization Act (MMA) of 2003 required State Health Insurance Assistance Programs (SHIPs) to be actively engaged in the implementation of the Medicare Prescription Drug Program (Part D). MIPPA legislation and Affordable Care Act legislation required SHIPs to provide enrollment assistance for the Limited Income Subsidy (LIS) and Medicare Savings Program (MSP). The goal is to ensure that beneficiaries are making an informed choice, regardless of whether they stay in Original Medicare or choose new options. CMS is responsible to Congress for demonstrating improvement over time in the level of awareness and understanding beneficiaries have about health plan options. The SHIPs are an integral component of this initiative. The information collected is used to fulfill the reporting requirements described in Section 4360(f) of OBRA 1990. CMS will utilize this data. The data will be accumulated and analyzed to measure SHIP performance in order to determine whether and to what extent the SHIPs have met the goals of improved CMS customer service to beneficiaries and better understanding by beneficiaries of their health insurance options. Further, the information will be used in the administration of the grants, to measure performance and appropriate use of the funds by the state grantees, to identify gaps in services and technical support needed by SHIPs, and to identify and share best practices.

The overall burden of hours and expected number of respondents increase is based on projected future service growth and projected future increases in staffing to accommodate the increased demand to utilize the SHIP network to raise awareness about new CMS policies, outreach initiatives, or both. However, the instruments themselves have not changed. *Form Number:* CMS–10028 (OCN: 0938–0850); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 17,838; *Total Annual Responses:* 2,346,465. *Total Annual Hours:* 195,642. (For policy questions regarding this collection contact Gregory Price at 410–786–4041. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* New collection. *Title of Information Collection:* Transcatheter Valve Therapy Registry and KCCQ–10. *Use:* The data collection is required by the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) entitled, ''Transcatheter Aortic Valve Replacement (TAVR)''. The TAVR device is only covered when specific conditions are met including that the heart team and hospital are submitting data in a prospective, national, audited registry. The data includes patient, practitioner and facility level variables that predict outcomes such as all cause mortality and quality of life. CMS finds that the Society of Thoracic Surgery/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry, one registry overseen by the National Cardiovascular Data Registry, meets the requirements specified in the NCD on TAVR. The TVT Registry will support a national surveillance system to monitor the safety and efficacy of the TAVR technologies for the treatment of aortic stenosis.

The data will also include the variables on the eight item Kansas City Cardiomyopathy Questionnaire (KCCQ–10) to assess heath status, functioning and quality of life. In the KCCQ, an overall summary score can be derived from the physical function, symptoms (frequency and severity), social function and quality of life domains. For each domain, the validity, reproducibility, responsiveness and interpretability have been independently established. Scores are transformed to a range of 0–100, in which higher scores reflect better health status.

The conduct of the STS/ACC TVT Registry and the KCCQ–10 is in accordance with Section 1142 of the Social Security Act (the Act) that describes the authority of the Agency for Healthcare Research and Quality (AHRQ). Under section 1142, research may be conducted and supported on the outcomes, effectiveness, and appropriateness of health care services and procedures to identify the manner in which disease, disorders, and other health conditions can be prevented, diagnosed, treated, and managed clinically. Section 1862(a)(1)(E) of the Act allows Medicare to cover under coverage with evidence development (CED) certain items or services for which the evidence is not adequate to support coverage under section 1862(a)(1)(A) and where additional data gathered in the context of a clinical setting would further clarify the impact of these items and services on the health of beneficiaries.

The data collected and analyzed in the TVT Registry will be used by CMS to determine if the TAVR is reasonable and necessary (e.g., improves health outcomes) for Medicare beneficiaries under Section 1862(a)(1)(A) of the Act. Furthermore, data from the Registry will assist the medical device industry and the Food and Drug Administration (FDA) in surveillance of the quality, safety and efficacy of new medical devices to treat aortic stenosis. For purposes of the TAVR NCD, The TVT Registry has contracted with the Data Analytic Centers to conduct the analyses. In addition, data will be made available for research purposes under the terms of a data use agreement that only provides de-identified datasets. *Form Number:* CMS–10443 (OCN: 0938-New); *Frequency:* Annual; *Affected Public:* Individuals, Households and Private Sector; *Number of Respondents:* 12,000; *Total Annual Responses:* 24,000; *Total Annual Hours:* 7,000. (For policy questions regarding this collection contact JoAnna Baldwin at 410–786–7205. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site

address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on December 17, 2012. OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, Email: *OIRA_submission@omb.eop.gov.*

Dated: November 9, 2012.

**Martique Jones,**

*Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2012–27841 Filed 11–15–12; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–D–0164]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry on Safety Labeling Changes; Implementation of the Federal Food, Drug, and Cosmetic Act

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

**DATES:** Fax written comments on the collection of information by December 17, 2012.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Draft Guidance for Industry on Safety Labeling Changes; Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act.'' Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### Draft Guidance for Industry on Safety Labeling Changes; Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act—(OMB Control Number 0910-New)

This draft guidance provides information on the implementation of section 901 of the Food and Drug Administration Amendments Act of 2007, which authorizes FDA to require certain drug and biological product application holders to make safety related labeling changes based upon new safety information that becomes available after the drug or biological product is approved under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) or the Public Health Service Act. FDA plans to request safety labeling changes by sending a notification letter to the application holder. Under section 505(o)(4)(B) of the FD&C Act (21 U.S.C. 355(o)(4)(B)), the application holder must respond to FDA's notification by submitting a labeling supplement or notifying FDA that the applicant does not believe the labeling change is warranted and submitting a statement detailing the reasons why the application holder does not believe a change is warranted (a rebuttal statement).

The submission of rebuttal statements may result in the collection of information that is not already approved by OMB. Based on FDA's experience thus far with safety labeling changes requirements under section 505(o)(4) of the FD&C Act, FDA estimates that approximately six application holders will elect to submit approximately one rebuttal statement each year and that each rebuttal statement will take approximately 6 hours to prepare.

In addition, in the draft guidance, the Agency states that new labeling prepared in response to a safety labeling change notification should be available on the application holder's Web site within 10 calendar days of approval, which may result in the collection of information that is not already approved by OMB. FDA estimates that approximately 197 application holders will post new labeling one time each year in response to a safety labeling change notification and that the posting of the labeling will take approximately 4 hours to prepare.

In the **Federal Register** of April 13, 2011 (76 FR 20686), FDA published a 60-day notice requesting public comment on the draft version of this guidance. None of the comments we received pertained to the information collection provisions.

FDA estimates the burden of the collections of information that have not already been approved by OMB is as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Rebuttal statement | 6 | 1 | 6 | 6 | 36 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.