

factory or warehouse. The survey design protocol must address short-, medium-, and long-term smokeless tobacco product variability (e.g., variability over time and from container to container of the tobacco product) in a manner equivalent to that described for cigarette sampling in Annex C of ISO Protocol 8243. Information accompanying results for each sample should include, but not be limited to:

1. For each product—manufacturer and variety (including brand families and brand variations) and brand name (e.g., Skoal Bandits, Skoal Long Cut Cherry, Skoal Long Cut Wintergreen, etc.) information.

2. Product “category,” e.g., loose leaf, plug, twist, dry snuff, moist (wet) snuff, etc.

3. Lot number.

4. Lot size.

5. Number of randomly sampled, sealed, packaged (so as to be representative of the product that is sold to the public) smokeless tobacco products selected (sampling fraction) for nicotine, moisture, and pH determination.

6. Documentation of method used for random sample selection.

7. “Age” of product when received by testing facility and storage conditions prior to analysis.

12. Extraction of nicotine and pH determination must be performed with reagents and samples at a room temperature of 22–25 °C. Room temperature should not vary more than 1 °C during extraction of nicotine or pH determination.

13. Use non-glass 10 mL repipette for transferring NaOH solution.

14. Use 50 mL repipette for transferring MTBE.

15. For dry snuff, use  $0.500 \pm 0.010$  gram sample.

16. The testing facility is referred to ISO Procedure 8243 for a discussion of sample size and the effect of variability on the precision of the mean of the sample (ISO 8243, 1991).

17. When analyzing new smokeless tobacco products, extract product without IS to determine if any components co-elute with the IS or impurities in the IS. This interference could artificially lower calculated values for nicotine.

18. The calculated nicotine values for all samples must fall within the low and high nicotine values used for the calibration curve. If not, prepare a fresh nicotine standard solution and an appropriate series of standard nicotine dilutions. Determine the detector response for each standard using chromatographic conditions described in I.E.

19. The testing frequency for each smokeless tobacco brand name (e.g., Skoal Bandits Wintergreen, Skoal Long Cut Cherry, Skoal Long Cut Wintergreen, etc.) is based on the manufacturing duration (refer to table below). Each smokeless tobacco brand name will be sampled and tested for nicotine, total moisture, and pH no fewer than twice and no more than four times during a calendar year.

Manufacturing duration in weeks	Test frequency*
Up to and including 4 .....	2
Up to and including 28 .....	3
Up to and including 52 .....	4

\* Use a statistical program to determine random sampling dates based on the total manufacturing duration during a calendar year. Sampling dates should fall on actual manufacturing days for the product when test material that is representative of the product that is sold to the public (consisting of sealed, packaged samples) is available. If a statistically determined sampling date falls on a day that does not meet this criterion, sample the product on the next date that does meet the criteria.

For smokeless tobacco brand names with episodic production during a calendar year, the total number of sampling dates is determined by the sum of the individual test frequencies, not to exceed four. For the purpose of the Protocol, episodic production is defined as manufacturing intervals separated by periods of 30 or more days when the smokeless tobacco brand name is not manufactured.

*Example 1:* Within a single calendar year a smokeless tobacco brand name is manufactured from January 1 to March 31 and from September 1 to December 15. The testing frequency for the first manufacturing interval is 3 and for the second manufacturing interval is 3. The Protocol allows that each smokeless tobacco brand name be tested for nicotine, total moisture, and pH no more than four times during a calendar year. Therefore, 4 random sampling dates, as described in the footnote to the above table, are determined for the smokeless tobacco brand name. The values for nicotine, moisture, and pH determinations, and unionized (free) nicotine calculations and the mean of the 4 data points for that smokeless tobacco brand name are reported.

*Example 2:* Within a single calendar year a smokeless tobacco brand name is manufactured from April 5 to May 3 and from September 1 to December 15. The testing frequency for the first manufacturing interval is 2 and for the second manufacturing interval is 3. The values for nicotine, moisture, and pH determinations, and unionized (free) nicotine calculations and the mean of the 4 data points for that smokeless tobacco brand name are reported.

*Example 3:* Within a single calendar year a smokeless tobacco brand name is manufactured from January 1 to January 15 and from September 1 to September 22. The testing frequency for the first manufacturing interval is 2 and for the second manufacturing interval is 2. Four random sampling dates are selected to fall within the

6 weeks of manufacturing for the smokeless tobacco brand name. The values for nicotine, moisture, and pH determinations, and unionized (free) nicotine calculations and the mean of the 4 data points for that smokeless tobacco brand name are reported.

20. The method is a modification of AOAC Method 966.02 (1990) in that the ground tobacco passes through a 4 mm screen rather than a 1 mm screen.

21. When drying samples, do not dry different products (e.g., moist (wet) snuff, dry snuff, loose leaf) in the oven at the same time since this will produce errors in the moisture determinations.

22. The method is a modification of a method published by Henningfield *et al.* (1995).

## References

- AOAC (Association of Official Analytical Chemists). Official Methods of Analysis. 966.02: Moisture in Tobacco. (1990) Fifth Edition. K. Helrich (ed). Association of Official Analytical Chemists, Inc. Suite 400, 2200 Wilson Boulevard, Arlington, Virginia 22201 USA.
- CORESTA (Centre de Coopération pour les Recherches Scientifiques relatives au Tabac). Recommended Method No. 39: Determination of the purity of nicotine and nicotine salts by gravimetric analysis—Tungstosilic acid method November, 1994. 87–90.
- CRC Handbook of Chemistry and Physics. R.C. Weast, D.R. Lide, M.J. Astle, and W.H. Beyer (eds). 70th ed. Boca Raton, Florida: CRC Press (1989–1990) D–162.
- Henningfield, J.E., Radzius A., Cone E.J. (1995). Estimation of available nicotine content of six smokeless tobacco products. Tobacco Control 4:57–61.
- ISO (International Organization for Standardization). IOS 8243: Cigarettes—Sampling. (1991). Second Edition. Prepared by Technical Committee ISO/TC 126, Tobacco and tobacco products. International Organization for Standardization, Case Postale 56, CH–1211 Genève 20, Switzerland.
- Westgard J.O., Barry P., Hunt M., and Groth T. (1981). A multi-rule Shewhart chart for quality control in clinical chemistry. Clinical Chemistry 27:493.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–268 and CMS–222]

### 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:** Revision of currently approved collection; **Title of Information Collection:** Survey Tool for <http://www.medicare.gov> and <http://www.cms.hhs.gov>; **Use:** The purpose of this submission is to request a revision of 0938-0756 (CMS-R-268) to continue to collect information from Internet users as they exit from the Websites [Medicare.gov](http://www.medicare.gov) and [CMS.hhs.gov](http://www.cms.hhs.gov). As part of the revised collection we are combining the content from the collection 0938-0900 that was discontinued on 5/31/2007. The packages are being combined to eliminate a duplication of effort. We are requesting a three-year clearance, so that the feedback received through the survey can be used continually to update and improve the sites. To ensure that we gather information about user reactions to the Websites, we have developed a survey tool that users can complete when they exit either site or by accessing a link on the bottom bar on the page. The responses on this survey tool will help CMS to make appropriate changes to the Web sites in the future. The survey tool contains questions about the information that visitors are seeking from the sites, the degree to which either site was useful to them, the improvements that they would like to see in the sites, and their general comments. **Form Number:** CMS-R-268 (OMB# 0938-0756); **Frequency:** On occasion; **Affected Public:** Individuals and households, Private sector—Business or other for-profit; **Number of Respondents:** 7,000; **Total Annual Responses:** 7,000; **Total Annual Hours:** 1,167.

#### 2. *Type of Information Collection*

**Request:** Extension of currently

approved collection; **Title of Information Collection:** Independent Rural Health Center/Freestanding Federally Qualified Health Center Cost Report and Supporting Regulations 42 CFR 413.20 and 42 CFR 413.24; **Use:** Providers of service in the Medicare program are required to submit annual information to achieve reimbursement for healthcare services rendered to Medicare beneficiaries.

The Form CMS-222 cost report is needed to determine the amount of reasonable cost due to the providers for furnishing medical services to Medicare beneficiaries; **Form Number:** CMS-222 (OMB# 0938-0107); **Frequency:** Yearly; **Affected Public:** Business or other for-profit and Not-for-profit institutions; **Number of Respondents:** 3,159; **Total Annual Responses:** 3,159; **Total Annual Hours:** 157,950.

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 e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto: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 April 14, 2008: OMB Human Resources and Housing Branch, Attention: Carolyn Raffaelli, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395-6974.

Dated: March 7, 2008.

**Michelle Shortt,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifier: CMS-R-211, CMS-10258, CMS-209, CMS-10259, and CMS-R-266]**

#### **Agency Information Collection Activities: Proposed Collection; 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) 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 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.

#### 1. *Type of Information Collection*

**Request:** Extension of a currently approved collection; **Title of Information Collection:** Model Application Template for State Child Health Plan Under Title XXI of the Social Security Act, State Children's Health Insurance Program, Instructions for Model Application Template; **Use:** States are required to submit Title XXI plans and amendments for approval by the Secretary pursuant to section 2102 of the Social Security Act in order to receive funds for initiating and expanding health insurance coverage for uninsured children. The model application template is used to assist States in submitting a State Child Health Plan and amendments to that plan. **Form Number:** CMS-R-211 (OMB# 0938-0707); **Frequency:** Yearly and occasionally; **Affected Public:** State, Local or Tribal Governments; **Number of Respondents:** 56; **Total Annual Responses:** 40; **Total Annual Hours:** 3,200.

#### 2. *Type of Information Collection*

**Request:** New collection; **Title of Information Collection:** Survey of State Medicaid Agencies: Innovative Approaches to Collecting Citizenship Documentation; **Use:** The purpose of the survey is to collect information from State Medicaid agencies on innovative approaches used to collect citizenship documentation from Medicaid applicants and recipients. Prior to the Deficit Reduction Act of 2005 (DRA), Medicaid applicants could self-attest to citizenship. As of July 1, 2006, applicants and recipients are required to provide original documentation of citizenship. For some states, this new requirement is challenging because there has been a general movement towards virtual applications by phone,