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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day-14-0210]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to CDC, LeRoy Richardson, 1600 Clifton Road, MS D-74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques

or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products (OMB No. 0920-0210, exp. 2/28/2014)—Extension—Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Cigarette smoking is the leading preventable cause of premature death and disability in the United States. Each year, more than 443,000 premature deaths occur as the result of diseases related to cigarette smoking. The Centers for Disease Control and Prevention (CDC), Office on Smoking and Health (OSH) has the primary responsibility for the Department of Health and Human Services (HHS) smoking and health program. HHS's overall goal is to reduce death and disability resulting from cigarette smoking and other forms of tobacco use through programs of information, education and research.

The Comprehensive Smoking Education Act of 1984 (CSEA, 15 U.S.C. 1336 or Pub. L. 98-474) requires each person who manufactures, packages, or imports cigarettes to provide the Secretary of HHS with a list of ingredients added to tobacco in the manufacture of cigarettes. The legislation also authorizes HHS to undertake research, and to report to the Congress (as deemed appropriate) discussing the health effects of these ingredients.

HHS has delegated responsibility for implementing the CSEA's ingredient reporting requirements to CDC's OSH. OSH has collected ingredient reports on cigarette products since 1986.

Respondents are commercial cigarette manufacturers, packagers, or importers, or their designated representatives. Respondents are not required to submit specific forms; however, they are required to submit a list of all ingredients used in their products. CDC requires the ingredient report to be submitted by chemical name and Chemical Abstract Service (CAS) Registration Number, consistent with accepted reporting practices for other companies currently required to report ingredients added to other consumer products. Typically, respondents submit a summary report to CDC with the ingredient information for multiple products, or a statement that there are no changes to their previously submitted ingredient report. The estimated burden per response is 6.5 hours. The total estimated annualized burden hours are 501.

Ingredient reports for new products are due at the time of first importation. Thereafter, ingredient reports are due annually on March 31. Information is submitted to OSH by mailing a written report on the respondent's letterhead, which may be accompanied by a compact disk (CD), three-inch floppy disk, or thumb drive. Annual ingredient reports should be mailed to: Office on Smoking and Health, Attention: FCLAA Program Manager, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, NE., MS F-79 Atlanta, GA 30341-3717. Electronic mail submissions are not accepted. Upon receipt and verification of the annual ingredient report, OSH issues a Certificate of Compliance to the respondent.

There are no costs to respondents other than their time. Office of Management and Budget (OMB) approval is requested for three years.

Estimated Annualized Burden Hours

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Cigarette Manufacturers, Packagers, and Importers	77	1	6.5	501

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3110-FN]

Medicare & Medicaid Programs: Application From the Accreditation Commission for Health Care for Continued CMS-Approval of Its Hospice Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the Accreditation Commission for Health Care (ACHC) for continued recognition as a national accrediting organization for hospices that wish to participate in the Medicare or Medicaid programs.

DATES: *Effective:* This final notice is effective November 27, 2013 through November 27, 2019.

FOR FURTHER INFORMATION CONTACT: Valarie Lazerowich, (410) 786-4750. Cindy Melanson, (410) 786-0310. Patricia Chmielewski, (410) 786-6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a hospice provided certain requirements are met. Section 1861(dd) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as a hospice. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 418 specify the conditions that a hospice must meet to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for hospices.

Generally, to enter into an agreement, a hospice must first be certified by a state survey agency as complying with the conditions or requirements set forth in part 418. Thereafter, the hospice is subject to regular surveys by a state survey agency to determine whether it

continues to meet these requirements. However, there is an alternative to surveys by state agencies. Certification by a nationally recognized accreditation program can substitute for ongoing state review.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, CMS will deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary of the Department of Health and Human Services as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to have met the Medicare conditions. A national accrediting organization applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions.

Our regulations concerning the approval of accrediting organizations are set forth at § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require accrediting organizations to reapply for continued approval of its accreditation program every 6 years or sooner as determined by CMS.

The ACHC's current term of approval for their hospice accreditation program expires November 27, 2013.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

On May 3, 2013, we published a proposed notice in the **Federal Register** (78 FR 26036) announcing Accreditation Commission for Health Care's request for approval of its hospice accreditation program. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.4 and § 488.8, we conducted a review of ACHC's application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite administrative review of ACHC's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and (5) survey review and decision-making process for accreditation.

- The comparison of ACHC's accreditation requirements to our current Medicare hospice conditions of participation.

- A documentation review of ACHC's survey process to determine the following:

- ++ The composition of the survey team, surveyor qualifications, and ACHC's ability to provide continuing survey or training.

- ++ Comparability of ACHC's processes to those of state survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

- ++ ACHC's procedures for monitoring hospices out of compliance with ACHC's program requirements. The monitoring procedures are used only when ACHC identifies noncompliance. If noncompliance is identified through validation reviews, the State survey agency monitors corrections as specified at § 488.7(d).

- ++ ACHC's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

- ++ ACHC's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

- ++ The adequacy of staff and other resources.

- ++ ACHC's ability to provide adequate funding for performing required surveys.

- ++ ACHC's policies with respect to whether surveys are announced or unannounced.