(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:* New collection; *Title of Information Collection:* Minimum Data Set for Medicaid Incentives for Prevention of Chronic Diseases Program Grantees; *Use:* The Medicaid Incentives for Prevention of Chronic Diseases (MIPCD) demonstration program provides grants to states to implement programs that provide incentives to Medicaid beneficiaries of all ages who participate in prevention programs and demonstrate changes in health risk and outcomes, including the adoption of healthy behaviors. The prevention programs address at least one of the following prevention goals: tobacco cessation, controlling or reducing weight, lowering cholesterol, lowering blood pressure, and avoiding the onset of diabetes or in the case of a diabetic, improving the management of the condition. The programs are also comprehensive, widely available, easily accessible, and based on relevant evidence-based research and resources, including: the Guide to Community Preventive Services; the Guide to Clinical Preventive Services; and the National Registry of Evidence-Based Programs.

The proposed information collection, the MIPCD Minimum Data Set (MDS), is intended to collect data for program performance monitoring and evaluation. The MDS is a secondary data collection that assembles information already collected by grantees in the course of tracking beneficiary participation and outcomes and performing their own evaluation activities. Data collected through the MDS will be used to report on program implementation and evaluation to CMS and the Congress. *Form Number:* CMS–10444 (OCN: 0938–New); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 10; *Total Annual Responses:* 40; *Total Annual Hours:* 3,467. (For policy questions regarding this collection contact Sherrie Fried at 410–786–6619. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection. *Title of Information Collection:* Medicaid Statistical Information System (MSIS). *Use:* The Balanced Budget Act of 1997 mandated that states report their Medicaid data via MSIS. MSIS is used by states and other jurisdictions to report fundamental statistical data on the operation of their Medicaid program. Data provided on eligibles, beneficiaries, payments and services are vital to those studying and assessing Medicaid policies and costs. Medicaid statistical data are routinely requested by CMS, Department agencies, the Congress and their research offices, state Medicaid agencies, research organizations, social service interest groups, universities and colleges, and the health care industry. The data provides the only national level information available on enrollees, beneficiaries, and expenditures. It also provides the only national level information available on Medicaid utilization. This information is the basis for analyses and for cost savings estimates for the Department's cost sharing legislative initiatives to the Congress. The data is also crucial to CMS and HHS actuarial forecasts. *Form Number:* CMS–R–284 (OCN 0938–0345). *Frequency:* Quarterly. *Affected Public:* State, Local, or Tribal Governments. *Number of Respondents:* 51. *Total Annual Responses:* 204. *Total Annual Hours:* 2,040. (For policy questions regarding this collection contact Kay Spence at 410–786–1617. For all other issues call 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 November 19, 2012.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, Email: *OIRA_submission@omb.eop.gov.*

Dated: October 16, 2012.

Martique Jones,

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

[FR Doc. 2012–25772 Filed 10–18–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3266–FN]

Medicare and Medicaid Programs; Approval of the Community Health Accreditation Program for Continued Deeming Authority for Hospices

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

ACTION: Final notice.

SUMMARY: This notice announces our decision to approve the Community Health Accreditation Program (CHAP) for continued recognition as a national accrediting organization for hospices that wish to participate in the Medicare or Medicaid programs. A hospice that participates in Medicaid must also meet the Medicare conditions of participation (CoPs) as referenced in our regulations.

DATES: *Effective Date:* This final notice is effective November 20, 2012 through November 20, 2018.

FOR FURTHER INFORMATION CONTACT: Lillian Williams, (410) 786–8636.

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)(1) of the Social Security Act (the Act) establishes distinct criteria for entities seeking designation as a hospice program. 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 in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for hospice care.

Generally, to enter into an agreement, a hospice must first be certified by a State survey agency as complying with 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.

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, we 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 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 meet the

Medicare conditions. A national accrediting organization applying for approval of its accreditation program under part 488, subpart A, must provide us 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 reapproval 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 deeming authority every 6 years, or sooner as determined by CMS. CHAP's current term of approval for their hospice accreditation program expires November 20, 2012.

II. Deeming 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 with 210 calendar days after the date of receipt of an application to complete our survey activities and decision-making process. Within 60 days of 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** of approving or denying the application.

III. Provisions of the Proposed Notice

On May 25, 2012, we published a proposed notice (77 FR 31362) announcing CHAP'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 (Application and reapplication procedures for accrediting organizations), we conducted a review of CHAP'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 CHAP'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 CHAP's hospice accreditation standards to our current Medicare conditions of participation.
- A documentation review of CHAP's survey processes to—

++ Determine the composition of the survey team, surveyor qualifications, and the ability of CHAP to provide continuing surveyor training.

++ Compare CHAP's processes to that of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ Evaluate CHAP's procedures for monitoring providers or suppliers found to be out of compliance with CHAP program requirements. The monitoring procedures are used only when the CHAP identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at § 488.7(d).

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

++ Establish CHAP's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of CHAP's survey process.

++ Determine the adequacy of staff and other resources.

++ Review CHAP's ability to provide adequate funding for performing required surveys.

++ Confirm CHAP's policies with respect to whether surveys are announced or unannounced.

++ Obtain CHAP's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the May 25, 2012 proposed notice (77 FR 31362) also solicited public comments regarding whether CHAP's requirements meet or exceed the Medicare CoPs for hospices. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between CHAP's Standards and Requirements for Accreditation and Medicare's Conditions and Survey Requirements

We compared the standards contained in CHAP's accreditation requirements and survey process with the Medicare hospice CoPs and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of CHAP's deeming application, which were conducted as described in section III of this final notice, yielded the following:

- To meet the requirements at § 488.4(a)(4), CHAP implemented a monitoring plan to ensure all personnel files include a current license.
- To meet the requirements at § 488.4(a)(5), CHAP modified its policies and procedures related to the establishment of an accreditation effective date for participation in Medicare.
- To meet the requirements in Appendix M of the SOM, CHAP developed a monitoring plan to ensure the minimum number of medical record reviews with home visits is completed during a survey.
- To meet the requirements at section 2728B of the SOM, CHAP revised its policies to ensure accepted plans of correction include a monitoring plan to ensure deficiencies stay corrected.
- To meet the requirements at section 5075.9 of the SOM, CHAP revised its policies to ensure complaint investigations triaged as non-immediate jeopardy medium are conducted within 45 calendar days following receipt of a complaint.
- To meet the requirements at § 418.54(c)(7), CHAP revised its standards to address the needs of ''other individuals'' in the bereavement assessment. In addition, CHAP included language to ensure ''information gathered from the initial bereavement assessment must be incorporated into the plan of care and considered in the bereavement plan of care.''
- To meet the requirements at § 418.64(b)(3), CHAP revised its standards to include language that addresses the provision of highly specialized nursing services provided so infrequently by direct hospice employees would be impracticable and prohibitively expensive.
- To meet the requirements at § 418.100, CHAP revised its standards to address the hospice's responsibility to ''organize, manage, and administer its resources to provide hospice care and services.''
- To meet the requirements at § 418.100(c), CHAP revised its standards to specify that a hospice must be primarily engaged in providing care and services consistent with accepted standards of practice.
- To meet the requirements at § 418.110(d), CHAP revised its standards to include language that addresses the waiver of space and occupancy and alcohol-based hand rub requirements.
- CHAP revised its crosswalk to ensure that all current CHAP standards

clearly address the following sections of the CFRs: § 418.52, § 418.54(e)(2), § 418.56(a), § 418.56(d), § 418.56(e), § 418.58, § 418.58(a)(2), § 418.58(c)(2), § 418.58(d)(1), § 418.60(b)(2)(ii), § 418.62(b), § 418.62(c), § 418.64(a)(1–3), § 418.64(b)(1), § 418.64(d)(3)(iv), § 418.72, § 418.76(a)(1), § 418.76(b)(3)(i), § 418.76(c), § 418.76(e), § 418.76(h)(1), § 418.76(j)(2), § 418.76(k), § 418.76(k)(2), § 418.100(b), § 418.100(c)(2), § 418.100(f)(1)(i), § 418.100(g)(3), § 418.104(d), § 418.104(f), § 418.106(b)(1), § 418.106(c)(1), § 418.106(e)(1), § 418.108(c)(3), § 418.110(a), § 418.110(c)(1)(i), § 418.110(c)(1)(ii), § 418.110(e), § 418.110(e)(2), § 418.110(f)(1), § 418.110(f)(3)(iv), § 418.110(f)(3)(vi), § 418.112(f), and § 418.116(b)(2).

B. Term of Approval

Based on the review and observations described in section III of this final notice, we have determined that CHAP's accreditation program for hospices meet or exceed our requirements. Therefore, we approve CHAP as a national accreditation organization for hospices that request participation in the Medicare program, effective November 20, 2012 through November 20, 2018.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866, this proposed notice was not reviewed by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: *September 10, 2012.*

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012–25467 Filed 10–18–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Endocrinologic and Metabolic Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Endocrinologic and Metabolic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of October 10, 2012 (77 FR 61609). The amendment is being made to reflect a change in the *Location* and *Procedure* portions of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Paul Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001; FAX: 301–847–8533, email: *EMDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 10, 2012, FDA announced that a meeting of the Endocrinologic and Metabolic Drugs Advisory Committee would be held on November 8, 2012. On page 61609, in the second column, the *Location* portion of the document is changed to read as follows:

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room, (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

On page 61609, in the third column, the *Procedure* portion of the document is changed to read as follows:

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 2, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 25, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 26, 2012.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: October 15, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–25741 Filed 10–18–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Nonprescription Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Nonprescription Drugs Advisory Committee. This meeting was announced in the **Federal Register** of August 30, 2012 (77 FR 52743). The amendment is being made to reflect a change in the *Location* and *Contact Person* portions of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Minh Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Building 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001,