

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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: July 21, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9-17626 Filed 7-23-09; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0650]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; General Administrative Procedures; Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezuto, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of March 10, 2009 (74 FR 10255), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0183. The approval expires on May 31, 2012. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: July 16, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-17621 Filed 7-23-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request of Public Comment: 60-Day Proposed Information Collection; Indian Health Service Forms To Implement the Privacy Rule (45 CFR Parts 160 and 164); Correction

ACTION: Notice; correction.

SUMMARY: The Indian Health Service published a document in the *Federal Register* (FR) on June 24, 2009. The document contained two errors.

FOR FURTHER INFORMATION CONTACT: Ms. Betty Gould, Regulations Officer, 801 Thompson Avenue, TMP, Suite 450, Rockville, MD 20852, Telephone (301) 443-7899. (This is not a toll-free number.)

Correction

In the *Federal Register* of June 24, 2009 in FR Doc. E9-14841, on page 30095, in the third column, second line, 45 CFR 164.522: change 164.522(a)(2)(1) to 164.522(a)(2); and on page 30095, in the table 45 CFR Section/IHS form, change 164.506, IHS-810 to 164.508, IHS-810.

Dated: July 17, 2009.

Yvette Roubideaux,

Director, Indian Health Service.

[FR Doc. E9-17452 Filed 7-23-09; 8:45 am]

BILLING CODE 4165-16-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS-2305-PN]

Medicare and Medicaid Programs; Application of the Accreditation Commission for Health Care for Deeming Authority for Hospices

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice acknowledges the receipt of a deeming application from the Accreditation Commission for Health Care (ACHC) for recognition as a national accrediting

organization for hospices that wish to participate in the Medicare or Medicaid programs. Section 1865(a)(3)(A) of the Social Security Act requires that within 60 days of receipt of an organization's complete application, we publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 24, 2009.

ADDRESSES: In commenting, please refer to file code CMS-2305-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2305-PN, P.O. Box 8016, Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2305-PN, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

(If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786–0310. Patricia Chmielewski, (410) 786–6899.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a hospice provided certain requirements are met. Section 1861(dd)(2) of the Social Security Act (the Act) establish distinct criteria for facilities 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 hospices.

Generally, in order to enter into a provider agreement with the Medicare program, a hospice must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 418 of our CMS regulations. Thereafter, the hospice is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(a)(1) of the Act (as redesignated under section 125 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275)) 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 deeming authority 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 the 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 deeming authority every six years or sooner as we determine.

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.8(a) require that our findings concerning review and reapproval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization's: Requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of ACHC's request for deeming authority for hospices. This notice also solicits public comment on whether ACHC's requirements meet or exceed the Medicare conditions for participation for hospices.

III. Evaluation of Deeming Authority Request

ACHC submitted all the necessary materials to enable us to make a determination concerning its request for approval as a deeming organization for hospices. This application was determined to be complete on May 25, 2009. Under Section 1865(a)(2) of the Act and our regulations at § 488.8 (Federal review of accrediting organizations), our review and evaluation of ACHC will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of ACHC's standards for a hospice as compared with CMS' hospice conditions of participation.
- ACHC's survey process to determine the following:
 - The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.
 - The comparability of ACHC's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.
 - ACHC's processes and procedures for monitoring hospices found out of compliance with ACHC's program requirements. These 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 capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.
 - ACHC's capacity to provide us with electronic data and reports necessary for effective validation and

assessment of the organization's survey process.

- The adequacy of ACHC's staff and other resources, and its financial viability.
- ACHC's capacity to adequately fund required surveys.
- ACHC's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.
- ACHC's agreement to provide us 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).

IV. Response to Public Comments and Notice Upon Completion of Evaluation

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

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, the Office of Management and Budget did not review this proposed notice.

In accordance with Executive Order 13132, we have determined that this proposed notice would not have a significant effect on the rights of States, local or Tribal governments.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

(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: July 9, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E9-17611 Filed 7-23-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-5050-N]

Medicare and Medicaid Programs; Resolicitation of Proposals for the Private, For-Profit Demonstration Project for the Program of All-Inclusive Care for the Elderly (PACE) and Announcement of Closing Date

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

ACTION: Notice.

SUMMARY: This notice resolicits proposals for the private, for-profit demonstration project for the Program of All-Inclusive Care for the Elderly (PACE) and announces a closing date for the solicitation. We previously solicited proposals from private, for-profit organizations for a fully capitated joint Medicare and Medicaid demonstration.

DATES: *Closing Date:* Proposals must be submitted by July 26, 2010.

ADDRESSES: Proposals should be mailed to the following by the date specified in the **DATES** section of this notice:
Attention: Michael Henesch, Office of Research, Development, and Information, Centers for Medicare and Medicaid Services, *Mailstop:* C4-17-27, 7500 Security Boulevard, Baltimore, MD 21244-1850.

FOR FURTHER INFORMATION CONTACT: Michael Henesch, 410-786-6685.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 1894(h)(1) and 1934(h)(1) of the Social Security Act (the Act) state that the Secretary shall grant waivers to enable up to ten private, for-profit Programs of All-Inclusive Care for the Elderly (PACE) demonstration projects to provide medical assistance to PACE program eligible individuals who are 55 years of age or older, require the level of care required for coverage of nursing facility services, and reside in the PACE program service area. The for-profit demonstration provision requires that, except for the numerical limitation of ten demonstration waivers, the operation of a PACE program by a provider shall be the same as those for

PACE providers that are not-for-profit, private organizations. The purpose of this notice is to resolicit proposals for the private, for-profit demonstration project for the PACE and announces a closing date for the solicitation. A previous notice of solicitation to for-profit organizations (66 FR 42229) was published in the August 10, 2001 **Federal Register**. The purpose of the August 2001 notice was to determine whether the risk-based long-term care model employed by the nonprofit PACE can be replicated successfully by for-profit organizations.

Section 4804(b) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33) requires issuance of a report that includes findings as to whether—

- The number of covered lives enrolled in for-profit PACE demonstration projects are statistically sufficient to make the findings described below;
- The population enrolled in for-profit PACE demonstration projects is less frail than the population enrolled with other PACE providers;
- Access to or quality of care for individuals enrolled with for-profit PACE programs is lower than for those enrolled in other PACE programs; and
- For-profit demonstration projects resulted in increased expenditures under Medicare or Medicaid programs above those incurred by other PACE providers.

The August 2001 **Federal Register** (66 FR 42229), solicited proposals from for-profit entities to demonstrate that they can successfully provide comprehensive coordinated care for the frail elderly under a prepaid fully-capitated payment system. That notice specified that we would—(1) consider proposals only from for-profit organizations; and (2) operate the demonstration for 3 years.

To date, there are only two for-profit PACE demonstration projects in place, both of which began in 2007.

II. Provisions of the Notice

This notice resolicits proposals for the private, for-profit demonstration project for the PACE and announces a closing date for this solicitation. We publish this notice to—

- Encourage for-profit entities to submit proposals to conduct projects to demonstrate the for-profit PACE concept over a 3 year period, and to further encourage that they do so within the next year by establishing a closing date to the solicitation; and
- Increase the number of covered enrollees across all for-profit demonstration sites.

Therefore, this notice provides an additional opportunity for interested