

VI. Regulatory Impact Statement

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

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program).

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

Dated: November 18, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2010–29959 Filed 11–26–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–2332–PN]

Medicare Program; Application by the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) for Deeming Authority for Providers of Outpatient Physical Therapy and Speech-Language Pathology Services.

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice acknowledges the receipt of a deeming application from the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) for recognition as a national accrediting organization for providers of outpatient physical therapy and speech-language pathology services 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, the Secretary of the Department of Health and Human Services 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 December 29, 2010.

ADDRESSES: In commenting, please refer to file code CMS–2332–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 specific issues in this regulation to <http://www.regulations.gov>. Click on the link “Submit electronic comments on CMS regulations with an open comment period.” (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. By regular mail. You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–2332–PN, P.O. Box 8010, Baltimore, MD 21244–8010.

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 (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–2332–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 (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH 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.)

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: L. Alexis Prete, (410) 786–0375.

Patricia Chmielewski, (410) 786–6899.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this proposed notice to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–2332–PN and the specific “issue identifier” that precedes the section on which you choose to comment.

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>. Click on the link “Electronic Comments on CMS Regulations” 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 outpatient physical therapy services (OPT) from a provider of services, a clinic, a rehabilitation agency, a public health agency, or by others under an arrangement with and under the supervision of such provider, clinic, rehabilitation agency, or public health agency (collectively, “organizations”), provided certain requirements are met. Section 1861(p)(4) of the Social Security Act (the Act) establishes distinct criteria for organizations seeking approval to provide OPT services. 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. Our regulations at 42 CFR part 485, subpart H specify the conditions that an organization providing OPT services must meet in order to participate in the Medicare program.

Generally, in order to enter into a provider agreement with the Medicare program, an organization offering OPT services must first be certified by a State survey agency as complying with the applicable conditions or requirements set forth in part 42 CFR part 485.

Thereafter, the organization 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 State certification and surveys by State agencies, as a means to enter into a Medicare provider agreement. Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a national accrediting organization approved by the Secretary, 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 of participation. The regulations at § 488.8(d)(3) require accrediting organizations to reapply for continued deeming authority every six years or sooner, as determined by the Secretary.

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 approval 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 the Secretary with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that the Secretary 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. The Secretary has 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 AAAASF's request for deeming authority for organizations providing OPT services. This notice also solicits public comment on whether AAAASF's requirements meet or exceed the Medicare conditions for participation for such organizations.

III. Evaluation of Deeming Authority Request

AAAASF submitted all the necessary materials to enable us to make a determination concerning its request for approval as a deeming organization for organizations providing OPT services. This application was determined to be complete on October 15, 2010. Under Section 1865(a)(2) of the Act and our regulations at § 488.8 (Federal review of accrediting organizations), our review and evaluation of AAAASF will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of AAAASF's standards for an organization providing OPT services, as compared with CMS' OPT organizations' conditions of participation.
- AAAASF'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 AAAASF's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.
- AAAASF's processes and procedures for monitoring OPTs found out of compliance with the AAAASF's program requirements. These monitoring procedures are used only when AAAASF identifies noncompliance. If noncompliance is identified through validation reviews, the State survey agency will monitor corrections as specified at § 488.7(d).
- AAAASF's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.
- AAAASF's capacity to provide the Secretary with electronic data and reports necessary for effective validation and assessment of the organization's survey process.
- The adequacy of AAAASF's staff and other resources, and its financial viability.
- AAAASF's capacity to adequately fund required surveys.

—AAAASF's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

—AAAASF'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 Comments

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.

(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: November 17, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

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