

The panel is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: November 18, 2010.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2010-29945 Filed 11-26-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-4154-PN]

Medicare and Medicaid Programs; Renewal of Deeming Authority of the National Committee for Quality Assurance for Medicare Advantage Health Maintenance Organizations and Local Preferred Provider Organizations

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice announces the receipt of an application to renew the Medicare Advantage Deeming Authority of the National Committee for Quality Assurance (NCQA) for Health Maintenance Organizations and Preferred Provider Organizations for a term of 4 years. The new term of approval would begin October 19, 2010, and would end October 18, 2014. In addition, this proposed notice announces a 30-day public comment period on the renewal of the application.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 28, 2011.

ADDRESSES: In commenting, please refer to file code CMS-4154-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

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-4154-PN, P.O. Box 8010, Baltimore, MD 21244-1850.

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-4154-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) 786-9994 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: Caroline L. Baker (410) 786-0116.

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 through a Medicare Advantage (MA) organization that contracts with the Centers for Medicare & Medicaid Services (CMS). The regulations specifying the Medicare requirements that must be met in order for an Medicare Advantage Organization (MAO) to enter into a contract with CMS are located at 42 CFR part 422. These regulations implement Part C of Title XVIII of the Social Security Act (the Act), which specifies the services that an MAO must provide and the requirements that the organization must meet to be an MA contractor. Other relevant sections of the Act are Parts A and B of Title XVIII and Part A of Title XI of the Act pertaining to the provision of services by Medicare certified providers and suppliers.

Generally, for an entity to be an MA organization, the organization must be licensed by the State as a risk bearing organization as set forth in Part 422 of our regulations.

To assure compliance with certain Medicare requirements, an MA organization may choose to become accredited by a CMS approved accrediting organization (AO). By doing so, the MA organization may be "deemed" compliant in one or more of 6 requirements set forth in section 1852(e)(4)(B) of the Act. In order for an AO to be able to "deem" an MA plan as compliant with these MA requirements, the AO must prove to CMS that its standards are at least as stringent as Medicare requirements. MA organizations that are licensed as health maintenance organizations (HMOs) or preferred provider organizations (PPOs) and are accredited by an approved accrediting organization may receive, at their request, deemed status for CMS requirements in the following six MA survey areas: (1) Quality Improvement, (2) Antidiscrimination, Access to Services, (3) Confidentiality and Accuracy of Enrollee Records, (4) Information on Advanced Directives, and Provider Participation Rules. (See 42 CFR 422.156(b).) We note that at this

time, deeming does not include the Part D areas of review listed in § 422.156(b).

Organizations that apply for MA deeming authority are generally recognized by the health care industry as entities that accredit HMOs and PPOs. As we specified in § 422.157(b)(2), the term for which an AO may be approved by CMS may not exceed 6 years. For continuing approval, the AO must renew their application with CMS.

The National Committee for Quality Assurance (NCQA) was approved as an accrediting organization for MA deeming of HMOs from January 19, 2002 through January 18, 2008. The NCQA was reapproved as an accrediting organization for MA deeming of HMOs on January 18, 2008, for a term of 6 years, which was set to expire on January 17, 2014.

The NCQA was approved for MA deeming of PPOs from October 20, 2004 through October 19, 2010. On July 20, 2010, the NCQA submitted an application to renew their deeming authority which, at the request of CMS for administrative simplification purposes, combined their HMO and PPO deeming authority. On July 20, 2010, the NCQA also submitted all of the prerequisite materials as specified in § 422.158(a) for receiving CMS deeming program approval. This information was previously submitted to CMS by NCQA as a part of their initial HMO and PPO applications.

II. Approval of Deeming Organizations

Section 1852(e)(4)(C) of the Act provides a statutory timetable to ensure that our review of deeming applications in 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 application review process. At the end of the 210 day period, we must publish an approval or denial of the application in the **Federal Register**.

III. Evaluation of Deeming Authority Request

As set forth in § 1852(e)(4) of the Act and our regulations at § 422.158, the review and evaluation of NCQA's accreditation program (including its standards and monitoring protocol) were compared to the requirements set forth in part 422 for the MA program.

A. Components of the Review Process

The review of NCQA's application for approval of MA deeming authority included the following components:

- The types of MA plans that it would review as part of its accreditation process.

- A detailed comparison of the organization's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk).

- Detailed information about the organization's survey process, including—

- ++ Frequency of surveys and whether surveys are announced or unannounced.

- ++ Copies of survey forms, and guidelines and instructions to surveyors.

- ++ Description of The survey review process and the accreditation status decision making process;

- ++ The procedures used to notify accredited MA organizations of deficiencies and to monitor the correction of those deficiencies; and

- ++ The procedures used to enforce compliance with accreditation requirements.

- Detailed information about the individuals who perform surveys for the accreditation organization, including—

- ++ The size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process.

- ++ The education and experience requirements surveyors must meet.

- ++ The content and frequency of the in-service training provided to survey personnel.

- ++ The evaluation systems used to monitor the performance of individual surveyors and survey teams.

- The organization's policies and practice with respect to the participation, in surveys or in the accreditation decision process by an individual who is professionally or financially affiliated with the entity being surveyed.

- A description of the organization's data management and analysis system with respect to its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

- A description of the organization's procedures for responding to and investigating complaints against accredited organizations, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.

- A description of the organization's policies and procedures with respect to the withholding or removal of accreditation for failure to meet the accreditation organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

- A description of all types (for example, full and partial) and categories

(for example, provisional, conditional, and temporary) of accreditation offered by the organization, the duration of each type and category of accreditation, and a statement identifying the types and categories that would serve as a basis for accreditation if CMS approves the accreditation organization.

- A list of all currently accredited MA organizations and the type, category, and expiration date of the accreditation held by each of them.

- A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization as requested by CMS.

- The name and address of each person with an ownership or control interest in the accreditation organization.

- The NCQA's past performance in the deeming program and results of recent deeming validation reviews, or look-behind audits conducted as part of continuing Federal oversight of the deeming program under § 422.157(d).

B. Results of the Review Process

Using the information listed in section III.A. of this proposed notice, we determined that NCQA's current accreditation program for HMO and PPO MA plans continues to be at least as stringent as the MA requirements contained in the six categories specified in section 1852(e)(4)(C) of the Act and our methods of evaluation for those areas.

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 notice, 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, 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]

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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.