

will publish a final notice in the **Federal Register** announcing the result of our evaluation. In accordance with the provisions of Executive Order 12866, the Office of Management and Budget did not review this proposed notice.

V. Regulatory Impact Statement

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

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: September 10, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 04-21196 Filed 9-23-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-4077-PN]

RIN 0928-ZA59

Medicare and Medicaid Programs; Application by the National Committee for Quality Assurance Preferred Provider Organization for Deeming Authority for Medicare Advantage

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

ACTION: Proposed notice.

SUMMARY: This proposed notice announces the receipt of an application from the National Committee for Quality Assurance for recognition as a national accreditation program for preferred provider organizations that wish to participate in the Medicare Advantage program. The statute requires that within 60 days of receipt of an organization's complete application, we will announce our receipt of the accreditation organization's application for approval, describe the criteria we will use in evaluating the application, and provide 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 October 25, 2004.

ADDRESSES: In commenting, please refer to file code CMS-4077-PN. Because of staff and resource limitations, we cannot

accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/regulations/ecomments>. (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By 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-4077-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 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) 786-3159 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: Heidi Adams, (410) 786-1094.

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-4077-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. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public website. Comments received timely will 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 (410) 786-7195.

This **Federal Register** document is available from the **Federal Register** online database through *GPO Access*, a service of the U.S. Government Printing Office. The web site address is: <http://www.gpoaccess.gov/fr/index.html>.

I. Background

[If you choose to comment on issues in this section, please include the caption "Background" at the beginning of your comments.]

Under the Medicare program, eligible beneficiaries may receive covered services through a managed care organization (MCO) that has a Medicare Advantage (MA) (formerly, Medicare+Choice) contract with the Centers for Medicare & Medicaid Services (CMS). The regulations specifying the Medicare requirements that must be met in order for an MCO to enter into an MA 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 MCO 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 pertaining to the provision of services by Medicare certified providers and suppliers.

Generally, for an organization to enter into an MA contract, the organization must be licensed by the State as a risk bearing organization as set forth in part 422 of our regulations. Additionally, the organization must file an application demonstrating that it meets other Medicare requirements in part 422 of our regulations. Following approval of the contract, we engage in routine monitoring and oversight audits of the MA organization to ensure continuing compliance. The monitoring and

oversight audit process is comprehensive and incorporates ongoing analysis of various performance data in addition to biennial audits by CMS staff who use a written protocol that itemizes the Medicare requirements the MA organization must meet.

As an alternative for meeting some Medicare requirements, an MA organization may be exempt from CMS monitoring of certain requirements in subsets listed in section 1852(e)(4)(B) of the Act as a result of an MA organization's accreditation by a CMS-approved accrediting organization (AO). In essence, the Secretary deems that the Medicare requirements are met based on a determination that the AO's standards are at least as stringent as Medicare requirements. As we specify at § 422.157(b)(2) of our regulations, the term for which an AO may be approved by CMS may not exceed 6 years. For continuing approval, the AO will have to re-apply to CMS.

The applicant organization is generally recognized as an entity that accredits MCOs that are licensed as a health maintenance organization (HMO) or a preferred provider organization (PPO).

II. Approval of Deeming Organizations

[If you choose to comment on issues in this section, please include the caption "Approval of Deeming Organizations" at the beginning of your comments.]

Section 1852(e)(4)(C) of the Act requires that within 210 days of receipt of an application, the Secretary shall determine whether the applicant meets criteria specified in section 1865(b)(2) of the Act. Under these criteria, the Secretary will consider for a national accreditation body, its requirements for accreditation, its survey procedures, its ability to provide adequate resources for conducting required surveys and supplying information for use in enforcement activities, its monitoring procedures for provider entities found out of compliance with the conditions or requirements, and its ability to provide the Secretary with necessary data for validation.

Section 1865(b)(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 accreditation 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 our receipt of a completed application to publish approval or denial of the application.

The purpose of this notice is to inform the public of our consideration of National Committee for Quality

Assurance's (NCQA's) application for approval of deeming authority of MA organizations that are licensed as a PPO for the following six categories:

- Quality improvement.
- Access to services.
- Antidiscrimination.
- Information on advance directives.
- Provider participation rules.
- Confidentiality and accuracy of enrollees' records.

This notice also solicits public comment on the ability of the applicant's accreditation program to meet or exceed the Medicare requirements for which it seeks authority to deem.

III. Evaluation of Deeming Request

[If you choose to comment on issues in this section, please include the caption "Evaluation of Deeming Request" at the beginning of your comments.]

On August 4, 2004, NCQA submitted all the necessary information to permit us to make a determination concerning its request for approval as a deeming authority for MA organizations that are licensed as a PPO. Under § 422.158(a) of the regulations, our review and evaluation of a national accreditation organization will consider, but not necessarily be limited to, the following information and criteria:

- The equivalency of NCQA's requirements for PPOs to CMS's comparable MA organization requirements.
- NCQA's survey process, to determine the following:
 - + The frequency of surveys.
 - + The types of forms, guidelines, and instructions used by surveyors.
 - + Descriptions of the accreditation decision making process, deficiency notification and monitoring process, and compliance enforcement process.
- Detailed information about individuals who perform accreditation surveys including—
 - + Size and composition of the survey team;
 - + Education and experience requirements for the surveyors;
 - + In-service training required for surveyor personnel;
 - + Surveyor performance evaluation systems; and
 - + Conflict of interest policies relating to individuals in the survey and accreditation decision process.
- Descriptions of the organization's—
 - + Data management and analysis system;
 - + Policies and procedures for investigating and responding to complaints against accredited organizations; and
 - + Types and categories of accreditation offered and MA

organizations currently accredited within those types and categories.

In accordance with § 422.158(b) of our regulations, the applicant must provide documentation relating to—

- Its ability to provide data in a CMS-compatible format;
- The adequacy of personnel and other resources necessary to perform the required surveys and other activities; and
- Assurances that it will comply with ongoing responsibility requirements specified in § 422.157(c) of our regulations.

Additionally, the accrediting organization must provide CMS the opportunity to observe its accreditation process on site at a managed care organization and must provide any other information that CMS requires to prepare for an onsite visit to the AO's offices. These site visits will help to verify that the information presented in the application is correct and to make a determination on the application.

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. Regulatory Impact Statement

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

Authority: Section 1852 and 1865 of the Social Security Act (42 U.S.C. 1395w-23 and 1395bbb).

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

Dated: September 8, 2004.

Mark B. McClellan,
Administrator, Centers for Medicare & Medicaid Services.

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