

timeframe. CLIA regulations do not have this requirement.

H. Subpart R—Enforcement Procedures

The CAP meets the requirements of subpart R to the extent that they apply to accreditation organizations. The CAP policy stipulates the actions it takes when laboratories it accredits do not comply with its requirements and standards for accreditation. As demonstrated during its first two periods of approval, the CAP denies accreditation to a laboratory when appropriate, and reports the denial to CMS within 30 days. The CAP also provides an appeal process for laboratories that have had accreditation denied.

Some specific actions the CAP takes in response to non-compliance or violation of its requirements or standards for accreditation include:

- The enrollment monitoring process runs continuously throughout the year. When no enrollment data or incomplete enrollment data are received based on the laboratory's test menu, letters are sent notifying the laboratory of its missing enrollments. If no enrollment is found after 60 days, the laboratory is sent a "cease testing" letter for the analytes not properly enrolled in PT.
- For all analytes listed in subpart I that the CAP accredited laboratories perform, the CAP technical staff reviews such testing to verify two previous PT performances, reviews PT evaluation to detect trends and repeats failures, contacts the laboratory to alert them if the status is critical, and issues cease testing letters when appropriate.
- When an accredited laboratory has unsatisfactory performance, a letter is sent instructing it to investigate and document the cause of the erroneous result and the corrective actions it takes to prevent recurrence.
- When there is an initial unsuccessful performance, the laboratory may either provide documentation of investigation and corrective action or the laboratory is given the option to voluntarily cease testing the unsuccessful analyte(s).
- If the laboratory indicates it will permanently cease testing of a non-initial unsuccessful PT performance, the activity is removed from the laboratory's test menu. If the laboratory wishes to resume testing at a later date, it must successfully perform two consecutive re-instatement PT testing events.
- When the CAP becomes aware of a problem in an accredited laboratory that is so severe and extensive that it

could cause a serious risk of harm (an immediate jeopardy situation), an expedited evaluation is immediately undertaken by the Chair and Vice Chair of the Accreditation Committee, the Regional Commissioner and the Director of the Laboratory Accreditation Program. If it is determined that an immediate jeopardy situation exists, the laboratory is required to remove the jeopardy situation immediately or accreditation would be revoked and reported to CMS. An on-site focused re-inspection may be performed to verify that the immediate jeopardy no longer exists. These actions are similar to CMS actions for immediate jeopardy.

- The CAP requires its accredited laboratories to correct all deficiencies within 30 days. CLIA deficiencies that are not condition level must be corrected in a timeframe that is acceptable to CMS, but no longer than 12 months. CLIA deficiencies that are condition level that are not considered immediate jeopardy must be corrected in an acceptable timeframe; however, CMS may impose one or more alternate sanctions or a principal sanction to motivate laboratories to correct these deficiencies. The CAP timeframe for correction of deficiencies, when taken as a whole, is more stringent than CLIA.

We have determined that the CAP's laboratory enforcement and policies are equivalent to the requirements of this subpart as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of laboratories accredited by the CAP may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or our agents, the State survey agencies, will be our principal means for verifying that the laboratories accredited by CAP remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide that we may rescind the approval of an accreditation organization, such as that of the CAP, for cause, before the end of the effective date of approval. If we determine that

the CAP has failed to adopt, maintain and enforce requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its monitoring, inspection or enforcement processes, we may impose a probationary period, not to exceed 1 year, in which the CAP would be allowed to address any identified issues. Should the CAP be unable to address the identified issues within that time frame, CMS may, in accordance with the applicable regulations, revoke CAP's deeming authority under CLIA.

Should circumstances result in our withdrawal of the CAP's approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

VI. Collection of Information Requirements

This notice does not impose any information collection and record keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA. The requirements associated with the accreditation process for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program, and the implementing regulations in 42 CFR part 493, subpart E, are currently approved under OMB control number 0938–0686.

Authority: Section 353(p) of the Public Health Service Act (42 U.S.C. 263a).

Dated: February 26, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E9–6903 Filed 3–26–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2294–FN]

Medicare and Medicaid Programs; Approval of the Joint Commission for Continued Deeming Authority for Hospices

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

ACTION: Final notice.

SUMMARY: This final notice announces the approval of a deeming application from the Joint Commission for continued recognition as a national

accreditation program for hospices that request participation in the Medicare or Medicaid programs.

EFFECTIVE DATE: This final notice is effective June 18, 2009 through June 18, 2015.

FOR FURTHER INFORMATION CONTACT:

Alexis Prete, (410) 786-0375.

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 facilities seeking designation as a hospice program. Under this authority, 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. Provider agreement regulations are located in 42 CFR part 489 and regulations pertaining to the survey and certification of facilities are located in 42 CFR part 488.

Generally, in order to enter into an agreement, a hospice facility must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 418 of our regulations. Then, 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 accreditation organization that all applicable Medicare conditions are met or exceeded, we would "deem" those provider entities as having met the requirements. (We note that section 125 of MIPPA redesignated subsections (b) and (e) of subsection 1865 of the Act as (a) and (d) respectively.) Accreditation by an accreditation organization is voluntary and is not required for Medicare participation.

If an accreditation 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

accreditation organization applying for approval of deeming authority under part 488, subpart A must provide us with reasonable assurance that the accreditation 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 accreditation organizations to reapply for continued approval of deeming authority every 6 years or sooner as determined by CMS. The Joint Commission's term of approval as a recognized accreditation program for Hospice facilities expires June 18, 2009.

II. Deeming Applications Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of deeming applications 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 application review process. Within 60 days of receiving a completed application, we must publish a notice in the **Federal Register** that identifies the national accreditation 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 our approval or denial of the application.

III. Proposed Notice

On November 28, 2008 we published a proposed notice (73 FR 72487) announcing the Joint Commission's request for reapproval as a deeming organization for hospices. In this notice we specified in detail our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.4 (Application and reapplication procedures for accreditation organizations), we conducted a review of the Joint Commission's application in accordance with the criteria specified in our regulation, which include, but are not limited to the following:

- An onsite administrative review of the Joint Commissions—(1) corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyor; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and (5) survey review and decision-making process for accreditation.

- A comparison of the Joint Commission's hospice accreditation standards to our current Medicare conditions for participation.

- A documentation review of the Joint Commission's survey processes to:
 - Determine the composition of the survey team, surveyor qualifications, and the ability of the Joint Commission to provide continuing surveyor training.
 - Compare the Joint Commission'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 the Joint Commission's procedures for monitoring providers or suppliers found to be out of compliance with the Joint Commission program requirements. The monitoring procedures are used only with the Joint Commission identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at § 488.7(d).

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

- Establish the Joint Commission's ability to provide us with electronic data and reports necessary for effective validation and assessment of the Joint Commission's survey process.

- Determine the adequacy of staff and other resources.

- Review the Joint Commission's ability to provide adequate funding for performing required surveys.

- Confirm the Joint Commission's policies with respect to whether surveys are announced or unannounced.

- Obtain the Joint Commission'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.

In accordance with section 1865(a)(3)(A) of the Act, the November 28, 2008 proposed notice (73 FR 72487) also solicited public comments regarding whether the Joint Commission's requirements met or exceeded the Medicare conditions of participation for hospices. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between the Joint Commission Standards and Requirements and Medicare's Conditions and Survey Requirements

We compared the standards contained in the Joint Commission's

“Comprehensive Accreditation Manual for Home Care” (CAMHC) and its survey process in the “Surveyor Activity Guide” with the Medicare hospice conditions for participation and our State Operations Manual (SOM). Our review and evaluation of the Joint Commission’s deeming application, which were conducted as described in section III of this notice yielded the following:

- On June 5, 2008, CMS published a final rule (73 FR 32088) that revised the existing conditions of participation that hospices must meet to participate in the Medicare and Medicaid Program. In accordance with the regulations at § 488.4(a)(3)(iv), the Joint Commission updated and revised their standards and survey procedures to meet the Medicare requirements.

- To meet the Medicare requirements at section 2728 of the SOM, the Joint Commission modified its policies for posting the deemed status survey results within 10 days onto its extranet site.

- The Joint Commission will conduct all for-cause surveys on an unannounced basis.

- The Joint Commission modified its executive summary statement to clearly indicate that providers must meet all accreditation standards in order to be recommended for deemed status.

B. Term of Approval

Based on the review and observations described in section III of this final notice, we have determined that the Joint Commission’s requirements for hospices meet or exceed our requirements. Therefore, we recognize the Joint Commission as a national accreditation organization for hospices that request participation in the Medicare program, effective June 18, 2009 through June 18, 2015.

V. Collection of Information Requirements

This final notice does not impose any information collection and record keeping requirements. Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

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

Dated: March 4, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E9–6775 Filed 3–26–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3212–N]

Medicare Program; Request for Nominations for Members for the Medicare Evidence Development & Coverage Advisory Committee

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

ACTION: Notice.

SUMMARY: This notice announces a request for nominations for consideration for membership on the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). Among other things, the MEDCAC advises the Secretary of the Department of Health and Human Services (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services on whether medical items and services are “reasonable and necessary” and therefore eligible for coverage under Title XVIII of the Social Security Act.

We are requesting nominations for both voting and nonvoting members to serve on the MEDCAC. Nominees are selected based upon their individual qualifications and not as representatives of professional associations or societies. We have a special interest in ensuring that women, minority groups, and physically challenged individuals are adequately represented on the MEDCAC. Therefore, we encourage nominations of qualified candidates from these groups.

The MEDCAC reviews and evaluates medical literature, reviews technology assessments, and examines data and information on the effectiveness and appropriateness of medical items and services that are covered or eligible for coverage under Medicare.

DATES: Nominations for membership will be considered if postmarked by April 27, 2009 and mailed to the contact person specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice to the designated address, as provided in the **ADDRESSES** section of this notice.

ADDRESSES: You may mail nominations for membership to the following:

Attention: Maria Ellis, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop: C1–09–06, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT:

Maria Ellis, Executive Secretary for MEDCAC, Centers for Medicare & Medicaid Services OCSQ—Coverage and Analysis Group, Mailstop: C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244, or contact Ms. Ellis by phone at 410–786–0309; or via e-mail at Maria.Ellis@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) announcing establishment of the Medicare Coverage Advisory Committee (MCAC). The Secretary signed the initial charter for the Medicare Coverage Advisory Committee on November 24, 1998. On January 26, 2007 the Secretary published a notice in the **Federal Register** (72FR 3853), changing the Committee’s name to the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC). The charter for the committee was renewed by the Secretary and will terminate on November 24, 2010, unless renewed again by the Secretary.

The MEDCAC is governed by provisions of the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C. App. 2), which sets forth standards for the formulation and use of advisory committees, and is authorized by section 222 of the Public Health Service Act as amended (42 U.S.C. 217a).

The MEDCAC consists of a pool of 100 appointed members including: 6 patient advocates, who are standard voting members, and 6 representatives of industry interests, who are nonvoting members. Members are selected from among authorities in clinical medicine of all specialties, administrative medicine, public health, biologic and physical sciences, health care data and information management and analysis, patient advocacy, the economics of health care, medical ethics, and other related professions such as epidemiology and biostatistics, and methodology of trial design.

The MEDCAC functions on a committee basis. The Committee reviews and evaluates medical literature, reviews technology assessments, and examines data and information on the effectiveness and appropriateness of medical items and services that are covered or eligible for coverage under Medicare. The