

Dated: May 23, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2177-FN]

Medicare and Medicaid Programs; Approval of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for Deeming Authority for Hospices

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This notice announces our decision to re-approve the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for continued recognition as a national accreditation program for hospice facilities seeking to participate in the Medicare or Medicaid programs.

EFFECTIVE DATE: This final notice is effective June 19, 2003 through June 19, 2009.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786-0310.

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. 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. The regulations at 42 CFR part 418 specify the conditions that a hospice facility must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for hospice care.

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 facility 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(b)(1) of the Act 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. 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 assurances 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 us. The JCAHO's term of approval as a recognized accreditation program for hospice facilities expires June 18, 2003.

II. Deeming Applications Approval Process

Section 1865(b)(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. Provisions of the Proposed Notice

On January 24, 2003, we published a proposed notice in the **Federal Register** (68 FR 3532) announcing the JCAHO's request for reapproval as a deeming organization for hospices. In this notice, we specified in detail our evaluation

criteria. Pursuant to section 1865(b)(2) of the Act and our regulations at § 488.4, we conducted a review of the JCAHO application in accordance with the criteria specified in our regulation, which include, but are not limited to the following:

- An onsite administrative review of JCAHO's (1) corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (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 JCAHO's hospice accreditation standards to our current Medicare hospice conditions for participation.

- A documentation review of JCAHO's survey processes to:

- + Determine the composition of the survey team, surveyor qualifications, and the ability of JCAHO to provide continuing surveyor training.
- + Compare JCAHO's processes to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.
- + Evaluate JCAHO's procedures for monitoring providers or suppliers found to be out of compliance with JCAHO program requirements. The monitoring procedures are used only when JCAHO identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at § 488.7(d).

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

- + Establish JCAHO's ability to provide us with electronic data in ASCII-comparable code and reports necessary for effective validation and assessment of JCAHO's survey process.

- + Determine the adequacy of staff and other resources.

- + Review JCAHO's ability to provide adequate funding for performing required surveys.

- + Confirm JCAHO's policies for whether surveys are announced or unannounced.

- + Obtain JCAHO'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(b)(3)(A) of the Act, the proposed notice also solicited public comments regarding whether JCAHO'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 JCAHO and Medicare's Conditions and Survey Requirements

We compared the standards contained in JCAHO's "Comprehensive Accreditation Manual for Home Care" (CAMHC) and its survey process in the "Request for Continued Deeming for Hospice Handbook" with the Medicare hospice conditions for participation and our State and Regional Operations Manual. Our review and evaluation of JCAHO's deeming application, which were conducted as described in section III of this notice yielded the following:

- In order to meet the requirements of § 488.4(a)(4)(v), JCAHO provided a copy of their Conflict of Interest and Financial Integrity policy that is required to be signed by all JCAHO surveyors.
- JCAHO provided a list of all full and partial hospice accreditation surveys scheduled to be performed by the organization in 2002 and 2003 to satisfy our requirements at § 488.4(a)(10).
- To satisfy the requirements of § 488.4(b)(3)(v), JCAHO provided documentation that allows its surveyors to serve as witnesses if we take an adverse action based on accreditation findings.
- In order to comply with § 418.100(k)(2)(i), JCAHO agreed to add to its "intent" statement that Medicare certified hospice, facilities require that a physician must order all medications for the patient.
- To comply with § 418.22(b), JCAHO agreed to add to their "intent" statement that in a Medicare certified hospice "terminally ill" means that the individual has a medical prognosis that his or her life expectancy is 6 months or less if the terminal illness runs its normal course.

B. Term of Approval

Based on the review and observations described in section IV of this final notice, we have determined that JCAHO's requirements for hospices meet or exceed our requirements. Therefore, we recognize the JCAHO as a national accreditation organization for hospices that request participation in the Medicare program, effective June 19, 2003 through June 19, 2009.

V. Collection of Information Requirements

This final 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 granting and withdrawal of deeming authority to national accreditation organizations, specified in 42 CFR part 488, "Survey, Certification, and Enforcement Procedures," are currently approved by OMB under OMB approval number 0938-0690.

VI. Regulatory Impact Statement

We have examined the impact of this notice as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Pub. L. 98-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The RFA requires agencies to analyze options for regulatory relief for small businesses. For purposes of the RFA, States and individuals are not considered small entities.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any notice that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we consider a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

This final notice recognizes JCAHO as a national accreditation organization for hospices that request participation in the Medicare and Medicaid programs. There are neither significant costs nor savings for the program and administrative budgets of Medicare. Therefore, this notice is not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866. We have determined, and the Secretary certifies, that this notice will not result in a significant impact on a substantial number of small entities and will not have a significant effect on the operations of a substantial number of small rural hospitals. Therefore, we are

not preparing analyses for either the RFA or section 1102(b) of the Act.

In an effort to better assure the health, safety, and services of beneficiaries in hospices already certified as well as provide relief to State budgets in this time of tight fiscal restraints, we deem hospices accredited by JCAHO as meeting our Medicare requirements. Thus, we continue our focus on assuring the health and safety of services by providers and suppliers already certified for participation in a cost-effective manner.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget. In accordance with Executive Order 13132, we have determined that this notice will not significantly affect 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—Supplemental Medical Insurance Program)

Dated: April 18, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0201]

Minimizing Medication Errors—Methods for Evaluating Proprietary Names for Their Confusion Potential; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA), in cooperation with the Pharmaceutical Research and Manufacturers Association (PhRMA) and the Institute for Safe Medication Practices (ISMP), is announcing a public meeting to explore current methods being used to evaluate proprietary drug names to reduce medication errors due to similarity in drug names. The goal of the meeting is to solicit views on a recommendation by the Department of Health and Human Services (HHS) that drug manufacturers perform proprietary name testing prior to submitting new