

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