debarred individual if the agency finds that: (1) The debarred individual has provided substantial assistance in the investigation or prosecution of offenses described in subsections (a) or (b) of section 306 of the act or relating to a matter under FDA's jurisdiction; (2) termination of the debarment serves the interest of justice; and (3) termination of the debarment does not threaten the integrity of the drug approval process. Special termination of debarment is discretionary with FDA.

FDA considers a determination by the Department of Justice concerning the substantial assistance of a debarred individual conclusive in most cases. Dr. Perkal cooperated with the Department of Justice investigations and prosecutions of others, as substantiated by the testimony of the Assistant U.S. Attorney at Dr. Perkal's sentencing. Accordingly, FDA finds that Dr. Perkal provided substantial assistance as required by section 306(d)(4)(C) of the act.

The additional requisite showings that termination of debarment serves the interest of justice and poses no threat to the integrity of the drug approval process are difficult standards to satisfy. In determining whether these have been met, the agency weighs the significance of all favorable and unfavorable factors in light of the remedial, public health-related purposes underlying debarment. Termination of debarment will not be granted unless, weighing all favorable and unfavorable information, there is a high level of assurance that the conduct that formed the basis for the debarment has not recurred and will not recur, and that the individual will not otherwise pose a threat to the integrity of the drug approval process.

The evidence presented to FDA in support of termination shows that Dr. Perkal was convicted for a first offense; that he has no prior or subsequent convictions for conduct described under the GDEA and has committed no other wrongful acts affecting the drug approval process; and that his character and scientific ability are highly regarded by his professional peers. The evidence presented supports the conclusion that the conduct upon which Dr. Perkal's debarment was based is unlikely to recur. For these reasons, the agency finds that termination of Dr. Perkal's debarment serves the interest of justice and will not pose a threat to the integrity of the drug approval process.

Under section 306(d)(4)(D) of the act, the period of debarment of an individual who qualifies for special termination may be limited to less than permanent but to no less than 1 year. Dr. Perkal's period of debarment has lasted more than 1 year. Accordingly, the Deputy Commissioner for Operations, under section 306(d)(4) of the act and under authority delegated to him (21 CFR 5.20), finds that Mark Perkal's application for special termination of debarment should be granted, and that the period of debarment should terminate immediately, thereby allowing him to provide services in any capacity to a person with an approved or pending drug product application. The Deputy Commissioner for Operations further finds that because the agency is granting Dr. Perkal's application, an informal hearing under section 306(d)(4)(C) of the act is unnecessary.

As a result of the foregoing findings, Dr. Mark Perkal's debarment is terminated effective September 11, 1998 (21 U.S.C. 335a(d)(4)(C) and (d)(4)(D)).

Dated: September 2, 1998.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

[FR Doc. 98–24375 Filed 9–10–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[Document Identifier: HCFA–R–0050 and HCFA–1515/1572]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medical Records Review Under PPS and Supporting Regulations in 42 CFR 412.40–412.52; *Form No.:* HCFA–R–0050 (OMB# 0938–0359); *Use:* Peer Review Organizations (PRO) are authorized to conduct medical review activities under the Prospective Payment System (PPS). In order to conduct the medical review activities we depend upon hospitals to make available medical records. PROs ensure that admissions are medically necessary, provided in the appropriate setting, and that they meet acceptable standards of quality.; *Frequency:* When records are reviewed; *Affected Public:* Business or other for profit; *Number of Respondents:* 6,412; *Total Annual Responses:* 746,681; *Total Annual Hours:* 27,096.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Home Health Agency Survey and Deficiencies Report, Home Health Functional Assessment Instrument and Supporting Regulations in 42 CFR Part 484–1—484.52; *Form No.:* HCFA–1515/1572 (OMB#0938–0355); *Use:* In order to participate in the Medicare program as a Home Health Agency (HHA) provider, the HHA must meet Federal Standards. These forms are used to record information about patients' health and provider compliance with requirements.; *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 9,942; *Total Annual Responses:* 19,884; *Total Annual Hours:* 19,884.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Louis Blank, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850

Dated: September 2, 1998.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*

[FR Doc. 98–24436 Filed 9–10–98; 8:45 am]

**BILLING CODE 4120–03–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[HCFA–2029–PN]**

**RIN 0938–AI69**

## Medicare and Medicaid Programs; Recognition of the Community Health Accreditation Program, Inc. (CHAP) and Joint Commission for Accreditation of Healthcare Organizations (JCAHO) for Hospices

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Proposed notice.

**SUMMARY:** This notice announces the receipt of applications from CHAP and JCAHO for recognition as national accreditation programs for hospices that wish to participate in the Medicare or Medicaid programs. The Social Security Act requires that the Secretary publish a notice identifying the national accreditation body making the request, describing the nature of the request, and providing a 30-day public comment period.

**DATES:** Written comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on or before October 13, 1998.

**ADDRESSES:** Mail written comments (one original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services,

Attention: HCFA–2029–PN, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

If you prefer, you may deliver your written comments (one original and three copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Because of staffing and resource limitations, we cannot accept audio, visual, or facsimile (FAX) copies of comments. In commenting, please refer to file code HCFA–2029-PN. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in room 309G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (Phone: (202) 690–7890).

**FOR FURTHER INFORMATION CONTACT:** Joan C. Berry, (410) 786–7233.

**SUPPLEMENTARY INFORMATION:**

### I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a hospice provided certain requirements are met. The regulations specifying the Medicare conditions of participation for hospice care are located in 42 CFR part 418. These conditions implement section 1861(dd) of the Social Security Act (the Act), which specifies services covered as hospice care and the conditions that a hospice program must meet in order to participate in the Medicare program. Other relevant sections of the Act are sections 1812(a)(4) and (d) which specify eligibility requirements for the individual and the benefit periods; section 1813(a)(4) which specifies coinsurance amounts; sections 1814(a)(7) and 1814 (i)(1)(A) which contain conditions and limitation on coverage of, and payment for, hospice care; and sections 1862(a)(1), (6), (9) which establish limits on hospice coverage.

Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to the activities relating to the survey and certification of facilities are at 42 CFR part 488. Our 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 facility services.

Generally, in order to enter into an agreement, a hospice must first be certified by a State survey agency as complying with the conditions or standards 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(b)(1) of the Act permits ''accredited'' hospices to be exempt from routine surveys by State survey agencies to determine compliance with Medicare conditions of participation. Section 1865(b)(1) of the Act provides that if the Secretary finds that accreditation of a provider entity by a national accreditation body demonstrates that all applicable conditions are met or exceeded, the Secretary ''deems'' those requirements to be met by the hospice. Our regulations concerning approval of accrediting organizations are set forth at §§ 488.6 and 488.8. To date, we have not recognized any organization as an accreditation organization for hospices.

### II. Approval of Deeming Organizations

Section 1865(b)(2) of the Act further requires that the Secretary's findings concerning review and approval of national accrediting organizations consider, among other factors, the applying accreditation organization's requirements for accreditation, its survey procedures, its ability to provide adequate resources for conducting required surveys and ability to supply 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 requires that the Secretary publish, within 60 days of the 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. Subsequently, the Secretary has 210 days from the receipt of the request to publish a finding of approval or denial of the application.

The purpose of this notice is to notify the public of the request of CHAP and of JCAHO for approval of their requests that the Secretary find that their separate accreditation programs for hospice care meet or exceed the Medicare conditions. This notice also solicits public comment on the ability of each body's requirements to meet or exceed the Medicare conditions of participation.

### III. Evaluation of Deeming Request

On July 6, 1998, CHAP and JCAHO submitted all the necessary information concerning their request to be approved as deeming organizations for hospices to permit us to make a determination. Under section 1865(b)(2) of the Act and our regulations at § 488.8 (''Federal review of accreditation organizations'') our review and evaluation of a national accreditation organization will be conducted in accordance with, but not necessarily limited to, the following factors: