

Form No.: HCFA-R-70 (OMB# 0938-0426);

Use: "Medicare Disclosure Information, Regulatory" The Peer Review Improvement Act of 1982 authorizes PRO's to acquire information necessary to fulfill their duties and functions and places limits on disclosure of the information. These requirements are on the PRO to provide notices to the affected parties when disclosing information about them. These requirements serve to protect the rights of the affected parties;

Frequency: On occasion;

Affected Public: Business or other for-profit, Individuals or Households, and Not-for-profit institutions;

Number of Respondents: 53;

Total Annual Responses: 53;

Total Annual Hours: 30,789.

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: Dawn Willingham, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: April 12, 1999.

John P. Burke III,

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

[FR Doc. 99-9804 Filed 4-19-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-2029-FN]

RIN 0938-AJ42

Medicare Program; Recognition of the Community Health Accreditation Program, Inc. (CHAP) for Hospices

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

ACTION: Final notice.

SUMMARY: This notice recognizes the Community Health Accreditation Program, Inc. (CHAP) as a national accreditation organization for hospices that request participation in the Medicare program. We believe that accreditation of hospices by CHAP demonstrates that all Medicare hospice conditions of participation are met or exceeded. Thus, we grant deemed status to those hospices accredited by CHAP. The proposed notice included the application from the Joint Commission for Accreditation of Healthcare Organizations (JCAHO). We have separated the final notices to appropriately process each application and will issue a separate final notice containing the decision for JCAHO under HCFA-2039-FN.

EFFECTIVE DATE: This final notice is effective April 20, 1999 through November 20, 2003.

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

SUPPLEMENTARY INFORMATION:

I. Background

A. Laws and Regulations

Under the Medicare program, eligible beneficiaries may receive covered palliative 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.

Generally, in order to enter into an agreement with Medicare, a hospice must first be certified by a State survey agency as complying with the conditions or standards set forth in part 418 of the regulations. Then, the hospice is subject to routine surveys by a State survey agency to determine whether it continues to meet Medicare requirements. There is an alternative, however, to surveys by State agencies.

Current 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. Accreditation by an accreditation organization is voluntary and is not required for Medicare certification. Section 1865(b)(1) of the Act provides that, if a provider is accredited by a national accreditation body that has standards that meet or exceed the Medicare conditions, the Secretary can "deem" that hospice as having met the Medicare requirements.

We have rules at part 488 that set forth the procedure we use to review applications submitted by national accreditation organizations requesting our approval. A national accreditation organization applying for approval must furnish to us information and materials listed in the regulations at § 488.4. The regulations at § 488.8 ("Federal review of accreditation organizations") detail the Federal review and approval process of applications for recognition as an accrediting organization. On April 26, 1996, however, new legislation entitled "Omnibus Consolidated Rescissions and Appropriations Act of 1996" (Pub. L. 104-134) was enacted.

Section 1865(b)(3)(A) of the Act, as amended by section 516 of Pub. L. 104-134, requires us to publish a notice in the **Federal Register** within 60 days after receiving an accreditation organization's written request that we make a determination regarding whether its accreditation requirements meet or exceed Medicare requirements. Section 1865(b)(3)(A) of the Act also requires that we identify in the notice the organization and the nature of the request and allow a 30-day comment period. This section further requires that we publish a notice of our approval or disapproval within 210 days after we receive a complete package of information and the organization's application.

B. Proposed Notice

On September 11, 1998, we published a proposed notice (63 FR 48735) announcing the requests of CHAP and JCAHO for our approval as national accreditation organizations for hospices. In the notice, we detailed the factors on which we would base our evaluation. (We inadvertently gave the citation for the regulations governing our evaluation as § 488.8, "Federal review of accreditation organizations," rather than as § 488.4, "Application and reapplication procedures for accreditation organizations.") Under section 1865(b)(2) of the Act and our regulations at § 488.4, our review and evaluation of the CHAP application were conducted in accordance with the following factors:

- A determination that CHAP is a national accreditation body, as required by the Act.
- A determination of the equivalency of CHAP's requirements for a hospice to our comparable hospice requirements.
- A review of CHAP's survey processes to determine the following:
 - The comparability of CHAP's processes to those of State agencies, including survey frequency; its ability to investigate and respond

appropriately to complaints against accredited facilities; whether surveys are announced or unannounced; and the survey review and decision-making process for accreditation.

—The adequacy of the guidance and instructions and survey forms CHAP provides to surveyors.

—CHAP's procedures for monitoring providers or suppliers found to be out of compliance with program requirements. (These procedures are used only when CHAP identifies noncompliance.)

- The composition of CHAP's survey team, surveyor qualifications, the content and frequency of the in-service training provided, the evaluation systems used to assess the performance of surveyors, and potential conflict-of-interest policies and procedures.

- CHAP's data management system and reports used to assess its surveys and accreditation decisions, and its ability to provide us with electronic data.

- CHAP's procedures for responding to complaints and for coordinating these activities with appropriate licensing bodies and ombudsman programs.

- CHAP's policies and procedures for withholding or removing accreditation from a facility that fails to meet its standards or requirements.

- A review of all types of accreditation status CHAP offers and an assessment of the appropriateness of those for which CHAP seeks deemed status.

- A review of the pattern of CHAP's deemed facilities (that is, types and duration of accreditation and its schedule of all planned full and partial surveys).

- The adequacy of CHAP's staff and other resources to perform the surveys, and its financial viability.

- CHAP's written agreement to—

- Meet our requirements to provide to all relevant parties timely notifications of changes to accreditation status or ownership, to report to all relevant parties remedial actions or immediate jeopardy, and to conform its requirements to changes in Medicare requirements; and

- Permit its surveyors to serve as witnesses for us in adverse actions against its accredited facilities.

We received no comments on our proposed notice.

II. Review and Evaluation

Our review and evaluation of the CHAP application, which were conducted as detailed above, yielded the following information.

Differences between the Community Health Care Program, Inc. (CHAP) and Medicare Conditions and Survey Requirements

We compared the standards contained in the CHAP 1997 "Standards of Excellence for Hospice Organizations" with CHAP's survey process outlined in its training materials and "Hospice Surveyor Operations Manual," which incorporates our 1994 guidelines to the Medicare hospice conditions and survey procedures. In 13 areas CHAP has made the following revisions or clarifications:

- *No surveys prior to enrollment form verification.* State survey agencies do not conduct health and safety inspections until a hospice has submitted a "Medicare and Other Federal Health Care Program General Enrollment Health Care Provider/Supplier Application" (Form HCFA-855) that the servicing fiscal intermediary has reviewed and approved. CHAP has provided written assurance that "It is CHAP's policy not to conduct a deemed status accreditation survey until an organization is properly enrolled in the Medicare program." In addition, CHAP has added a blanket statement that an organization must meet not only "All state licensure laws, Certificate of Need (CON) requirements or other state regulations and standards," but "Federal requirements" as well.

- *Unannounced surveys (Reference S 488.4(a)(3)(v)).* Current CHAP procedures contain the following statement regarding unannounced surveys for Medicare-certified home health agencies: "All visits to Medicare home health agencies will be unannounced. The specific timing of the visit is determined by the CHAP's Board of Review and no one from the applicant organization will be informed of the dates." We expect that a similar statement will be added for Medicare-certified hospices that elect the deemed status option. CHAP has agreed to add this language to its hospice procedures.

- *Core services.* Medicare requires that substantially all core services (nursing, medical social services, and counseling services) be provided directly by hospice employees, the only exception being during times of peak patient loads or under extraordinary circumstances. CHAP responded by revising its standards to require that a hospice program employ sufficient staff to provide all core services or provide documentation describing unusual or extraordinary circumstances necessitating the use of contracted staff for these services.

- *Notification when required services are not provided.* Medicare-certified hospices are required by section 1861(dd)(1) of the Act to provide routinely the following services: nursing care, medical social services, and counseling. CHAP has agreed that when it becomes aware that any Medicare-certified hospice is not providing one or more of these core services, we shall be promptly notified.

- *Change of status notification.* We require prompt notification from the accreditation organizations regarding hospice changes of ownership, hospice mergers, hospice site expansions, withdrawals from accreditation, and involuntary terminations from accreditation by the accreditation organization, because those actions require certification and enrollment actions by us, the fiscal intermediary, or the State survey agency. CHAP has stipulated in writing that its "home care policy and practice to provide prompt notification to HCFA of changes in ownership, mergers, site expansion, withdrawals or involuntary termination" will be applied to the hospice program.

- *Accreditation survey review and decision-making process (Reference S 488.4(a)(3)(iii)).* CHAP has responded to two requests we made for clarification regarding current CHAP terminology in its accreditation application under the heading, "CHAP Accreditation Policies and Procedures":

- Deferral of action.* CHAP has confirmed that facilities in deferral are not considered accredited.

- Warnings.* CHAP has confirmed that it issues a warning to an accredited entity that "has made limited progress regarding required actions and recommendations or has demonstrated a decline in meeting CHAP standards since the last appraisal based on a site visit or progress report." We have also received assurance that the time frames for reaching a decision on whether or not to withdraw accreditation for these entities are comparable to those we use for State-surveyed facilities.

- *Contracted services.*

- Some of the requirements in § 418.56 did not appear to be included in CHAP standards. CHAP provided clarifying cross references and revised pages, demonstrating that its standards do incorporate all of the requested requirements.

- The requirement for retaining fiscal responsibility needed to be included for all contracted services, not just inpatient care contracts. CHAP revised its standard to read, "the hospice program retains professional

management and fiscal responsibilities for patient care when services are provided under arrangement with contractors."

- *Millennium updates.* CHAP has provided us with its plans to ensure that deemed hospices maintain equipment and systems to sustain the quality of patient care through the millennium updates.

- *Data exchange.* CHAP has assured us that it has the ability to provide us with timely electronic survey data and validation of survey findings for all Medicare-certified hospices that have elected the deemed status option.

- *Qualified social worker.* Medicare requires that medical social services be provided by a qualified social worker under the direction of a physician. Medicare defines a hospice social worker at § 418.3 as "a person who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education." CHAP's standard required that social work services be provided by a qualified social worker or social worker assistant. CHAP has provided revised language for its related standard to require that "social work services are provided under the direction of a physician by a person who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education" and that the services are in agreement with the patient's plan of care.

- *Home health aide supervision.* Medicare requires at § 418.94(a) that a registered nurse visit the home site at least every 2 weeks when aide services are being provided and that the visit include an assessment of the aide services. In addition, Medicare requires that a registered nurse provide written instructions for patient care. CHAP's standard required that nursing and home health aide services always be provided under the supervision of a qualified registered nurse, available at all times, but made no reference to biweekly, direct (in-person) supervision and assessment. CHAP responded by clarifying how these requirements were covered at HIII.1d4(c) in its "Standards of Excellence for Hospice Organizations": "Written instructions prepared by an RN are provided to paraprofessional staff for care plan compliance." CHAP further stipulates at HIII.1d4(b) that a home health aide's performance is evaluated by a registered nurse every 2 weeks.

- *Inpatient care.*

The Medicare standard requires at § 418.98(c) that the total number of inpatient care days used by Medicare

beneficiaries not exceed 20 percent of the total number of hospice days for this group of beneficiaries in any 12-month period preceding a certification survey. We could not find this standard in the application. CHAP responded by clarifying how this requirement was covered at HIII.6.a1 in its "Standards for Excellence for Hospice Organizations": "The hospice program reviews total inpatient days routinely in any 12 month period to prevent Medicare clients from exceeding 20% of the total number of hospice days."

—Another Medicare standard requires at § 418.100(a) that hospices providing inpatient care directly provide 24-hour nursing services that are sufficient to meet total nursing needs and that are in accordance with the patient's plan of skilled care. We asked CHAP to provide evidence that this standard was included in its requirements. CHAP responded by clarifying how this requirement was covered at Item 17 of HIII.1i in its "Standards for Excellence for Hospice Organizations": "Inpatient facilities provide 24 hour nursing services, including a registered nurse on each shift, which are sufficient to meet total nursing needs and which are in accordance with the patient plan of care."

- *Storage of drugs.* Medicare standards require at § 418.100(k)(6) that separately locked compartments be provided for storage of Schedule II drugs and other drugs subject to abuse. CHAP's standard did not include "other drugs subject to abuse" in the list of drugs to be stored in separately locked compartments. CHAP revised its standard by adding "Separately locked compartment for Schedule II drugs and other drugs subject to abuse (multidose containers)" at H.III.4 in CHAP's "Standards of Excellence for Hospice Organizations."

In addition to these changes, CHAP provided a revised crosswalk (table showing the match between CHAP's standards and ours) incorporating all the changes necessitated by our requests.

III. Results of Evaluation

We completed a standard-by-standard comparison of CHAP's conditions or requirements for hospices to determine whether they met or exceeded Medicare requirements. We found that, after requested revisions were made, CHAP's requirements for hospices did meet or exceed our requirements. In addition, we visited the corporate headquarters of CHAP to validate the information it

submitted and to verify that its administrative systems could adequately monitor compliance with its standards and survey processes and that its decision-making documentation and processes met our standards. We also observed a survey in real time to see that it met or exceeded our standards. As a result of our review of the documents and observations, we requested certain clarifications to CHAP's survey and communications processes. These clarifications were provided as indicated above, and changes were made to the documentation in the applications. Therefore, we recognize CHAP as a national accreditation organization for hospices that request participation in the Medicare program, effective April 20, 1999 through November 20, 2003.

IV. Paperwork Reduction Act

This document 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, codified in part 488, "Survey, Certification, and Enforcement Procedures," are currently approved by OMB under OMB approval number 0938-0690, with an expiration date of August 31, 1999.

V. Regulatory Impact Statement

We have examined the impacts of this notice as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (P.L. 96-354). 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 50 beds.

This notice merely recognizes CHAP as a national accreditation organization for hospices that request participation in the Medicare program. As evidenced by the following data for the cost of surveys, 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.

Therefore, 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 fiscal year 1996, there were 2,148 certified hospices participating in the Medicare program. We conducted 258 initial surveys, 322 recertification surveys (both at a cost of \$634,904), and 145 complaint surveys.

In fiscal year 1997, there were 2,270 certified hospices. This was an increase of 122 facilities. We conducted 180 initial surveys, 354 recertification surveys (both at a cost of \$330,686), and 237 complaint surveys.

In fiscal year 1998, there were 2,290 certified hospices. This was an increase of 20 facilities. We conducted 126 initial surveys, 196 recertification surveys (both at a cost of \$360,783), and 201 complaint surveys.

As the data above indicate, the number of hospices and the cost for conducting hospice surveys by State agencies are increasing. There was a 6.6 percent increase in hospices within 3 years (fiscal years 1996 through 1998). The fiscal year 1999 appropriation for hospice survey activities was not increased, and these surveys were included within the lowest priority category. This appropriation does not allow sufficient resources for some regions to meet the survey demand, especially for resurvey activity, which remains a small proportion of eligible facilities (less than 9 percent for a maximum resurvey once every 12 years). Hospices accredited by CHAP would be surveyed every 3 years. The numbers of participating providers continue to increase. In an effort to better assure the health, safety, and services of beneficiaries in hospices already certified, as well as to provide relief to State budgets in this time of tight fiscal constraints, we deem hospices accredited by CHAP 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 reviewed by OMB.

Authority: Section 1865(b)(3)(A) of the Social Security Act (42 U.S.C. 1395bb(b)(3)(A)).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance)

Dated: March 1, 1999.

Nancy-Ann Min DeParle,
Administrator, Health Care Financing Administration.

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BILLING CODE 4120-01-P

described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: April 15, 1999.

David S. Cristy,
Director, ISP and Management.

Title of Proposal: Consolidated Plan.

Office: Community Planning and Development.

OMB Approval Number: 2506-0117.

Description of the Need for the Information and its Proposed Use: Based on 24 CFR Parts 91 et. al. each jurisdiction receiving formula allocated funds under the Community Development Block Grant (CDBG), HOME Investment Partnerships (HOME) Program, the Emergency Shelter Grants (ESG), or Housing Opportunities for Persons with HIV/AIDS (HOPWA) program, must submit a Consolidated Plan establishing an overall three- to five-year strategy for use of these funds and a one year action plan detailing individual projects. The information collection includes narrative requirements such as statements of goals, objectives, and priorities for funds, and tabular information describing priorities for funds, and tabular information describing priority housing, homeless and community development needs. Information is also collected regarding programmatic accomplishments and annual performance of States and localities receiving formula allocated funds under these programs in accordance with statutory and regulatory requirements found in Title I of the HCDA of 1974,

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4441-N-21]

Submission for OMB Review: Comment Request

AGENCY: Office of the Assistant Secretary for Administration HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due date: May 20, 1999.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within thirty (30) days from the date of this Notice. Comments should refer to the proposal by name and/or OMB approval number and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708-1305. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as