

III. CFSAN's 1999 Program Priorities Document

The meeting announced in this notice, as well as the meeting that took place on June 8, 1999, in Washington, DC, are in response to CFSAN's 1999 Program Priorities document that calls for the development of an overall dietary supplement strategy in conjunction with other agency units and stakeholders. A copy of the priorities document is available on the Internet on FDA's Website at "<http://vm.cfsan.fda.gov/~dms/cfsan199.html>".

The priorities document states that the overall strategy should address all elements of the dietary supplement program including: (1) Boundaries between dietary supplements and conventional foods, between dietary supplements and drugs, and between dietary supplements and cosmetic products; (2) claims; (3) good manufacturing practices; (4) adverse event reporting; (5) laboratory capability; (6) research needs; (7) enforcement; and (8) resource needs. FDA's objective in developing this strategy is to ensure consumer access to safe dietary supplements that are truthfully and not misleadingly labeled. FDA intends to develop this strategy by following a process of openness, flexibility, efficiency, and commitment to public health.

FDA has identified four criteria for priority ranking the tasks encompassed in the strategy. These criteria are: (1) Enhancement of consumer safety, (2) development of health-related product labeling regulation, (3) improvement in efficiency of operation, and (4) closure on unresolved regulatory issues.

This meeting also addresses activity undertaken by the agency to solicit comments in accordance with section 406(b) of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) (21 U.S.C. 393(b)).

IV. Agenda and Goals

To help focus comments for the July 20, 1999, meeting, FDA requests that oral and written input regarding an overall strategy for achieving effective regulation of dietary supplements address the following questions:

1. In addition to ensuring consumer access to safe dietary supplements that are truthfully and not misleadingly labeled, are there other objectives that an overall dietary supplement strategy should include?

2. Are the criteria for prioritizing the tasks within the supplement strategy appropriate? Which specific tasks should FDA undertake first?

3. What factors should FDA consider in determining how best to implement a task (i.e., use of regulations, guidance, etc.)?

4. What tasks should be included under the various dietary supplement program elements in the CFSAN 1999 Program Priorities document?

5. Are there current safety, labeling, or other marketplace issues that FDA should address quickly through enforcement actions to ensure, for example, that consumers have confidence that the products on the market are safe, truthful, and not misleadingly labeled?

6. Toward what type or area of research on dietary supplements should FDA allocate its research resources?

7. Given FDA's limited resources, what mechanisms are available, or should be developed, to leverage FDA's resources to meet effectively the objective of the strategy?

V. Comments

Interested persons may, on or before August 20, 1999, submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may also send comments to the Dockets Management Branch via e-mail to "FDA.Dockets@bangate.fda.gov" or via the FDA Website "<http://www.fda.gov>". You should annotate and organize your comments to identify the specific issues to which they refer. You must submit two copies of comments, identified with the docket number found in brackets in the heading of this document, except that you may submit one copy if you are an individual. You may review received comments in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. Transcripts

You may request transcripts of the meeting in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. You may also examine the transcript of the meeting at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA Website "<http://www.fda.gov>", "<http://vm.cfsan.fda.gov/dms/cfsan199.html>".

Dated: June 11, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-2039-FN]

RIN 0938-AJ41

Medicare Program; Recognition of the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) for Hospices

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

ACTION: Final notice.

SUMMARY: This notice recognizes the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) as a national accreditation organization for hospices that request participation in the Medicare program. We believe that accreditation of hospices by JCAHO demonstrates that all Medicare hospice conditions of participation are met or exceeded. Thus, we grant deemed status to those hospices accredited by JCAHO. The proposed notice included the application from the Community Health Accreditation Program, Inc. (CHAP). The final notice recognizing CHAP as a national accreditation organization for hospices was published on April 20, 1999 at 64 FR 19376.

EFFECTIVE DATE: This final notice is effective June 18, 1999, through June 18, 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.

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 42 CFR part 488 that set forth the procedures 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 Public Law 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 JCAHO application were conducted in accordance with the following factors:

- A determination that JCAHO is a national accreditation body, as required by the Act.
- A determination of the equivalency of JCAHO's requirements for a hospice to our comparable hospice requirements.
- A review of JCAHO's survey processes to determine the following:
 - The comparability of JCAHO'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 JCAHO provides to surveyors.
 - JCAHO's procedures for monitoring providers or suppliers found to be out of compliance with program requirements. (These procedures are used only when JCAHO identifies noncompliance.)

• The composition of JCAHO'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.

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

• JCAHO's procedures for responding to complaints and for coordinating these activities with appropriate licensing bodies and ombudsmen programs.

• JCAHO'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 that JCAHO requests HCFA accept for deeming of hospices.

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

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

• JCAHO'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 to the organization's requirements to changes in Medicare requirements; and
- Permit the organization's 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 JCAHO application, which were conducted as detailed above, yielded the following information.

Differences between the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and Medicare Conditions and Survey Requirements

We compared Medicare requirements with (1) the standards contained in the JCAHO 1997-98 "Comprehensive Accreditation Manual for Home Care" (CAMHC); (2) the survey process outlined in JCAHO's guide entitled "The Complete Guide to the 1997-98 Home Care Survey Process: Home Health, Personal Care, Support and Hospice"; and (3) JCAHO's training materials. We also evaluated the accuracy of JCAHO's cross walk [relational table] between JCAHO standards and Medicare standards. In 16 areas JCAHO has made the following revisions or clarifications:

• *Unannounced surveys.* Our policy requires that all deemed status surveys in Medicare-certified hospices be unannounced (that is, conducted with no advance notice). This policy includes initial accreditation surveys, re-surveys of any kind (regardless of the accreditation category for the deemed hospice service), focused surveys, and complaint surveys. The JCAHO policy for a routine announced, triennial survey of a home care company, including its hospice service, does not meet our requirement; a concurrent survey of the hospice service conducted at the same time as an announced triennial home care survey does not meet our requirement; and any survey with 24-hours advance notice, or any advance notice, does not meet our requirement. Thus, we requested written revision and acceptance of an

unannounced survey process. JCAHO, in response, has agreed that all deemed status hospice surveys will be unannounced:

No advanced notice of any survey will be provided to any hospice electing to use the Joint Commission's accreditation survey to meet Medicare provider requirements as a hospice. This includes all follow-up surveys and surveys to evaluate complaints. If a hospice seeking deemed status is part of a hospital, the hospice survey will be conducted unannounced and not in conjunction with the hospital survey. Specifically, the hospital survey will be announced, but the hospice survey unannounced and definitely not conducted on the dates of the hospital survey.

If a hospice seeking deemed status has other home care services within the hospice organization that are not seeking deemed status, the hospice survey will be unannounced and conducted first. The other home care services will be surveyed for Joint Commission accreditation following the completion of the survey.

- **Core services.** Medicare requires that substantially all core services (nursing care, medical social services, and counseling) be provided directly by hospice employees. Regulations allow for exceptions during times of peak patient loads or under extreme circumstances, and the Balanced Budget Act of 1997 provides exceptions for physicians' services. JCAHO clarified that CAMHC standards LD 2.2 and CC2 include this Medicare standard through cross reference and evaluation against § 418.202, which contains those provisions.

- **Notification issues.** JCAHO failed to clearly indicate in three instances when it would provide us with information regarding the failure of a hospice to meet or maintain Medicare conditions of participation:

- Violations of the Medicare conditions of participation, including routine core services (nursing care, medical social services, and counseling), as required by section 1861(dd)(1) of the Act.

- Changes in accreditation status, such as a decision to preliminarily non-accredit a facility, or any other accreditation status not recognized under this agreement.

- Changes in sites, corporate status, or services not in violation of the Medicare conditions of participation; withdrawal of a provider either voluntarily or involuntarily; and changes of ownership, hospice mergers, or hospice site expansions.

JCAHO clarified its required notification in these three instances, as well as its subsequent notification of us, as follows:

- Accredited organizations must notify JCAHO in writing within 30 days of any changes involving a violation of Medicare conditions of participation, including core services. JCAHO will forward this information in writing to us and to the relevant State agency within 10 days of receiving it.

- We will be notified within 30 days of a decision regarding changes in any accreditation status not accepted under this agreement.

- Accredited organizations must notify JCAHO in writing within 30 days of any changes to sites, corporate status, or services not in violation of the conditions of participation. JCAHO will immediately forward this information to us and to the State agency. JCAHO also stipulates that "the Joint Commission would survey the organization for the changes reported within 30 days. HCFA would be notified within 10 days, and also receive the report of the surveyed changes within 30 days of the completion of the survey."

- **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" (HCFA 855) that the servicing fiscal intermediary has reviewed and approved. JCAHO has specified that it will not conduct a deemed status survey for a hospice until it has received from the applicant either the Medicare provider number or written verification from the fiscal intermediary of submission and approval of HCFA 855.

- **Change of ownership.** Because of our recent experience with changes of ownership and the difficulty in recovering overpayments from facilities not transferring a provider ID from previous owners, we questioned when (that is, before or after making an accreditation award to the new owner of a home care company) JCAHO would survey a Medicare-certified hospice that is undergoing a change of ownership and that has not accepted assignment of the former owner's provider agreement (including Medicare-certified hospices that are part of an accredited home care company). Medicare providers that change ownership and do not accept assignment of the former owner's provider agreement are treated by us as new applicants to the Medicare program. JCAHO has stipulated in writing that "when a new provider number is being issued, the Joint Commission would not transfer its

accreditation of the old organization to the new. A complete new survey would have to be conducted."

- **Survey process.** JCAHO's hospice program standards are a subset of the CAMHC, containing requirements for both home health agencies and hospices. These two facility types are often part of the same organization. It is possible that one facility would be under a deeming program and the other would not, resulting in one announced and one unannounced survey. Because of this combined presentation, we initially had some difficulty in understanding how JCAHO would conduct a hospice survey separate from a related home care organization. Therefore, we recommended that JCAHO develop a deemed status survey protocol for Medicare-certified hospices in the near future and indicate if and when this process would be completed. In the meantime, we held discussions with JCAHO to ensure that our expectations of hospice programs were verified by JCAHO's interpretation of its standards and procedures.

JCAHO provided us with written verification that its hospice survey process encompasses all sites of care, including inpatient and respite care, where hospice services are provided. JCAHO specified that it evaluates contracted organizations, including those providing pharmaceutical and home medical equipment services, during the hospice survey. If the contracted organization is already accredited by JCAHO, some standards that have already been evaluated during the facility's own JCAHO survey, such as performance improvement activities or environmental safety plan, may not be assessed during the on-site survey of the facility. The survey of the non-accredited organizations, as well as those accredited by another accreditor, consists of on-site evaluation of all applicable JCAHO standards and corresponding Medicare conditions of participation, including the Life Safety Codes.

JCAHO would conduct the deemed status survey of a Medicare-certified hospice separately and provide a separate report. If home care services other than hospice are part of the JCAHO survey, JCAHO would survey those other services for its purposes on separate days and would not conduct the survey concurrently with the hospice deemed status survey. JCAHO would conduct the hospice deemed status survey first, followed by a survey of the other home care services. The deemed status survey would remain unannounced. This is the current method used to conduct the JCAHO

deemed status process for home health agencies when the same organization also provides services that are not Medicare-certified.

For example, if a Medicare-certified hospice also had within its business a licensed home health organization that is not Medicare-certified, JCAHO would survey both for accreditation. According to JCAHO procedures, the survey provided might total 5 days, and the survey would be conducted as follows. The survey conducted for the entire organization would be unannounced. JCAHO would survey the hospice first, at the end of which time (in this scenario, let us assume 3 days), JCAHO would issue a report for only the hospice Medicare deemed status compliance. On the subsequent days, JCAHO would survey the licensed home health agency, and on the final survey day, JCAHO would present its report, comprising both the hospice and licensed agency, to the organization. JCAHO's detailed survey process can be found in its application under tab 3ii, and in Exhibit 5, "The Complete Guide to the 1997-98 Home Care Survey Process: Home Health, Personal Care, Support and Hospice."

- *Data systems.* We recommended that JCAHO provide assurance that it can and will produce a plan indicating when and how they will be able to produce validation data such as outcome trends, especially deficiency types for regions and States; resolution time frames for deficiencies; and complaints for comparative Medicare purposes. JCAHO provided the detail for all the data described in our recommendation, including outcome trends (deficiency types for regions and States) and time frames. These reports, tables, and other displays indicate that JCAHO has the capability of producing resolution time frames for deficiencies and complaints.

- *Conditional accreditation.* We were concerned about the JCAHO request to consider the category called Conditional Accreditation as acceptable for deemed status and certification of facilities under Medicare. To clarify how conditional accreditation might be applied to a Medicare-certified hospice, we asked the following questions:

- What is the meaning (with examples, if necessary) of the first part of the category's definition, which states that "an organization is not in substantial compliance with Joint Commission standards?"
- What criteria would JCAHO use to determine that a Medicare-certified hospice would not be in "substantial compliance" with JCAHO standards

and would be placed in this category called Conditional Accreditation?

- What is the meaning (with examples, if necessary) of the rest of the definition, which states that "one or more adverse clinical events that potentially reflect underlying systems issues?"
- What are some "worst case" scenarios in which a Medicare-certified hospice could have had "one or more adverse clinical events that potentially affect underlying systems issues," and would be placed in this category?

In response to these questions, JCAHO has indicated that it will not accept, for deeming purposes, hospices with a decision of conditional accreditation, with one exception: those cases in which the hospice was not found to be the cause of the conditional decision. JCAHO awards the lowest score given when an organization bridges more than one facility type. Thus, a provider-based hospice may receive a conditional accreditation based on a deficiency outside the scope of its survey. A specific example would be a hospice organization that also includes a home health agency that is not Medicare-certified. In this case, if the home health agency's compliance with the JCAHO standards creates the conditional decision, but the hospice is found in compliance with all Medicare conditions of participation, HCFA would determine that the hospice is eligible for deemed status. JCAHO has agreed to provide us with a letter explaining any conditional accreditation decision, in addition to a copy of the deemed status hospice report, so that "HCFA may validate the status of compliance." JCAHO has also agreed to supply us with quarterly lists of all its home care customers and companies that include a deemed hospice service for validation to assure that all non-deemed hospices in these settings are subject to State agency survey.

- *Information sharing.* It is important that we be able to differentiate between JCAHO's regular home care customers and those that include a deemed hospice service, since regular home care customers with hospice services that have not elected the deemed status option still require the State agency survey. JCAHO has agreed that we should receive complete and timely lists of all deemed hospice services in an unambiguous format.

- *Electronic data exchange.*

- We requested a single contact who would have the authority to comply with requests for any new data and format revisions for validation submissions. JCAHO has supplied the

names of contacts with the authority to make decisions regarding the release of validation information.

- Additionally, we requested JCAHO's plan to ensure that electronic exchanges and internal data collection can proceed uninterrupted into the Year 2000 (Y2K). JCAHO has appointed a corporate-wide task force of key staff and has assigned this task force the responsibility for monitoring the implementation of JCAHO's plans for Y2K compliance. A major national consulting firm is assisting the task force in this effort. To date, JCAHO's implementation plans are proceeding as scheduled.
- We required assurances from JCAHO that it has the ability to provide us with timely electronic survey data and requested validation of survey findings for all Medicare-certified hospices that have elected the deemed status option. JCAHO has provided a description of its data systems and has stipulated that it has the ability to provide us electronically with survey findings for validation.

- *Millennium updates.* We requested that JCAHO indicate how it plans to assure that deemed hospices maintain equipment and systems to sustain the quality of patient care through the millennium updates. JCAHO stipulates that in 1998 and 1999, initial and resurveys conducted for HCFA's hospice applicants include in the "Management of Information" chapter of the 1997-98 CAMHC several standards that are used to address Y2K issues: CAMHC IM 1, "The organization plans and designs information-management processes to meet its internal and external information needs"; IM 2, "Confidentiality, security and integrity of data and information are maintained"; and IM 3.1, "The organization takes steps to ensure that the data are complete, reliable, valid, and accurate on an ongoing basis." Surveyors request information from the hospice to determine the organization's awareness of the Y2K issue and the steps being taken to assure compliance. In the year 2000, the compliance with these standards will be validated during the on-site survey process. Non-compliance that affects the quality of patient care would be addressed in other standards and could potentially lead to loss of accreditation.

- *JCAHO scoring of its standards.* We were concerned that JCAHO puts limits or "caps" on scores given to new requirements or standards for providers; that is, according to JCAHO policy, new requirements cannot be cited from level 3 (partial compliance) to level 5

(noncompliance). This practice often prevents new standards from being cited as deficiencies within JCAHO's system, which is computer-driven and aggregates scores within an area of performance. Scores from 3 to 5, as explained in the following table, are likely to result in the citing of a deficiency or type I recommendation, defined by JCAHO as "a recommendation or group of recommendations that addresses insufficient or unsatisfactory standards compliance in a specific performance area."

JCAHO SCORING SCALE/LEVELS OF COMPLIANCE

Score	Level of compliance	Definition
1	Substantial compliance.	The organization consistently meets all major provisions of the standard and its intent.
2	Significant compliance.	The organization meets most provisions of the standard and its intent.
3	Partial compliance.	The organization meets some provisions of the standard and its intent.
4	Minimal compliance.	The organization meets few provisions of the standard and its intent.
5	Noncompliance.	The organization fails to meet the provisions of the standard and its intent.

HCFA requires that scoring of all standards for hospices wishing to participate in Medicare, including any new standards that may be added to meet Medicare conditions of participation in this notice, be allowed through level 5. JCAHO has agreed that "No hospice standards will be 'capped' and therefore all may be cited through all levels." JCAHO has also agreed to notify all currently accredited hospices through individual letters, and to notify the public through JCAHO's periodicals, website, and the next issuance of its manual, that the scoring of hospice standards will not be limited or capped.

- **Hospice medical director.**

Medicare's conditions of participation require that the hospice medical director be a doctor of medicine or osteopathy. As written, the JCAHO standard reads only that qualified individuals be responsible for directing patient care and services. It was not clear to us that this standard met Medicare conditions of participation for hospices. JCAHO has assured us,

however, that its deemed hospice standard cross references the Medicare requirement and that "the Medicare condition would be evaluated as acceptable only if the medical director were a director of medicine or osteopathy."

- **Interdisciplinary Group.**

—Medicare's standards require that the Interdisciplinary Group (IDG) provide or supervise the provision of care and participate in the establishment and periodic review of the patient's plan of care. JCAHO's standards include the appropriate composition of the IDG and the appropriate process for care planning, but do not appear to link the IDG with the care planning processes. JCAHO standards simply require the "organization" to be responsible for care planning. JCAHO clarified that its CAMHC standard TX 1 includes the requirement consistent with the Medicare standard that the IDG establishes and is responsible for the plan of care. TX-1.3 specifically requires the IDG to participate in the review and updating of this plan.

—We questioned whether JCAHO standards clearly indicate that the IDG is responsible for designating a registered nurse to coordinate the implementation of the plan of care, and thus meet Medicare standards. JCAHO demonstrated that CAMHC standard CC 4, which assigns "appropriately qualified staff member(s) to coordinate patient care services," addresses and repeats this Medicare standard verbatim.

- **Volunteer staff.** The Medicare standard requires that hospices maintain a volunteer staff sufficient to provide administrative or direct patient care in an amount that, at a minimum, equals 5 percent of the total patient care hours of all paid hospice employees and contract staff. JCAHO stipulates that the intent of its standard at CAMHC HR 3.1 is that Medicare-certified providers must maintain and document that volunteer staff hours are equal to at least 5 percent of patient care hours.

- **Inpatient care.**

—The Medicare standard requires, at § 418.98(c), that inpatient care days may 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. JCAHO clarified that this standard is met through CAMHC standard LD 5, which discusses patient care and services appropriate to the care plan, and standard LD 8, which, under 8.2, discusses the organization's compliance with the

applicable law and regulation. JCAHO has specified that they—

have specifically listed 418.98(c) as a cross walked standard for deemed purposes. Instructions in the application indicate that in all circumstances for deemed surveys, the cross walked standards and conditions are utilized as an adjunct to the Joint Commission standard and intents. In other words, the Joint Commission surveyor evaluates compliance with all listed cross walked Medicare conditions of participation and standards when evaluating the referenced Joint Commission standard. Therefore, the requirement that any 12 month period preceding a certification survey for hospices may not exceed 20% of the total number of hospice days would be evaluated as the surveyor was surveying compliance with LD 5 and LD 8.

—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. JCAHO provided evidence that this standard was included in its requirements at CAMHC TX 1.2, which implements interventions identified in the care plan; at CC2, which provides for 24-hours-a-day, 7-days-a-week registered nursing; and at LD 2.2, which discusses the use of systematic planning consistent with the patient's needs.

III. Results of Evaluation

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

national accreditation organization for hospices that request participation in the Medicare program, effective June 18, 1999, through June 18, 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) (Pub. 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 JCAHO 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. The increase in the number of facilities is less than the number of initial surveys because of mergers, withdrawals, and closures during the year.

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. The increase in the number of facilities is less than the number of initial surveys because of mergers, withdrawals, and closures during the year.

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). Hospices accredited by JCAHO 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 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 reviewed by OMB.

Authority: Sec. 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: May 3, 1999.

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

[FR Doc. 99-15500 Filed 6-17-99; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4432-N-24]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

EFFECTIVE DATE: June 18, 1999.

FOR FURTHER INFORMATION CONTACT: Mark Johnston, Department of Housing and Urban Development, Room 7256, 451 Seventh Street SW, Washington, DC 20410; telephone (202) 708-1226; TTY number for the hearing- and speech-impaired (202) 708-2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1-800-927-7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless v. Veterans Administration*, No. 88-2503-OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: June 11, 1999.

Fred Karnas, Jr.,

Deputy Assistant Secretary for Economic Development.

[FR Doc. 99-15221 Filed 6-17-99; 8:45 am]

BILLING CODE 4210-29-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Availability of a Technical/Agency Draft Revised Puerto Rican Parrot (*Amazona vittata*) Recovery Plan for Review and Comment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of document availability and public comment period.

SUMMARY: We, the Fish and Wildlife Service, announce the availability for public review of the technical/agency