water by company contact through an address or phone number on the label is an appropriate and feasible method. We believe that the combination approach (providing some content information on the label along with a company contact) is an appropriate and feasible method of providing customers with information and, in addition, has the benefit of delivering certain pieces of information to customers at the point of purchase. The agency also believes that it would be an appropriate method and is feasible for bulk deliverers to provide an information package with a bill or an invoice.

The agency has tentatively determined that certain methods are not appropriate and feasible for informing customers of the contents of bottled water. We believe that placing all of the information analogous to that contained in a CCR on the label of bottled water is not feasible. Moreover, there is a potential economic burden of frequent label changes if the particular information that is placed on the label requires frequent label changes as a result of ongoing monitoring of contaminants. We have the same concerns regarding changing test results for information provided in a pamphlet at point of purchase. We also question the practicality of ensuring that pamphlets are consistently available at retail. Further, the agency does not believe that the Internet may be appropriate as the sole method of providing information on the contents of bottled water to customers because not all customers may have access to it.

Comments received on this draft report will be evaluated and considered in preparation of the final report on the feasibility of appropriate methods, if any, for providing information about the contents of bottled water to customers. Based on the comments received, the agency plans to discuss the possibility of further action on this subject, if any is necessary, in the final report.

Dated: February 11, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–4025 Filed 2–18–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1060–N2]

RIN 0938–AJ57

Medicaid Program; Additional Comment Period for the Schedules of Per-Visit and Per-Beneficiary Limitations on Home Health Agency Costs for Cost Reporting Periods Beginning on or After October 1, 1999 and Portions of Cost Reporting Periods Beginning October 1, 2000

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

ACTION: Notice of an additional 15-day comment period for notice with comment period.

SUMMARY: This notice announces an additional 15-day comment period for a notice with comment period published in the **Federal Register** on August 5, 1999 (64 FR 42766). In that notice, we set forth cost limitations for cost reporting periods beginning on or after October 1, 1999 and portions of cost reporting periods beginning before October 1, 2000.

DATE: The comment period closes 5 p.m. On March 8, 2000.

ADDRESSESES: Mail written comments (one original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1060–NC, P.O. Box 8018, Baltimore, Maryland 21207–8018

If you prefer, you may deliver your written comments (one original and three copies) to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, D.C. 20201, or

Room C5–16–03, Central Building, 7500 Security Boulevard, Baltimore, Maryland 21244–1850

Comments may also be submitted electronically to the following E-mail address: HCFA1060NC@hcfa.gov. E-mail comments must include the full name and address of the sender and must be submitted to the reference address in order to be considered. All comments must be incorporated in the E-mail message because we may not be able to access attachments.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to the file code HCFA–1060–NC. 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 443–G of the Department's offices at 200 Independence Avenue, SW., Washington, D.C., on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (Phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT: Michael Bussacca, (410) 786–4602.

SUPPLEMENTARY INFORMATION: On August 5, 1999, we published a notice with comment period in the **Federal Register** (64 FR 42766) setting forth revised schedules of limitations on home health agency costs that may be paid under the Medicare program for cost reporting periods beginning on or after October 1, 1999 and portions of cost reporting periods beginning before October 1, 2000. These limitations replaced the limitations that were set forth in our August 11, 1998 notice with comment period (63 FR 42912). Under the August 5, 1999 notice with comment period, written or electronic comments were acceptable. The comment period ended on October 4, 1999. Due to technical difficulties, however, it is unclear whether or not we received all of the electronic comments that may have been submitted to us. Therefore, we are announcing an additional 15-day comment period from the date of publication of this notice (that is, March 8, 2000.

Authority: Section 1861 (v)(1)(L) of the Social Security Act (42 U.S.C. 1395x(v)(1)(L)); section 4207(d) of Pub. L. 101–508 (42 U.S.C. 1395x (note)).

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

Dated: December 6, 1999.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 00–4071 Filed 2–18–00; 8:45 am]

BILLING CODE 4120–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–2058–FN]

RIN 0938–AJ68

Medicare and Medicaid Programs; Reapproval of the Deeming Authority of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for Home Health Agencies (HHAs)

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

ACTION: Final notice.

SUMMARY: This notice announces the reapproval of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as a national accreditation organization for home health agencies (HHAs) that request participation in the Medicare program. We have found that JCAHO's standards for HHAs meet or exceed those established by the Medicare program. Therefore, HHAs accredited by JCAHO will be granted deemed status under the Medicare program.

EFFECTIVE DATE: This final notice is effective February 22, 2000, through March 31, 2005.

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

SUPPLEMENTARY INFORMATION:

I. Background

Sections 1861(o) and 1891 of the Social Security Act (the Act) and part 484 of the Medicare regulations specify the conditions that a home health agency (HHA) must meet in order to participate in the Medicare program. Generally, in order to enter into an agreement with Medicare, an HHA must first be certified by a State survey agency as complying with the conditions or standards set forth in part 484 of the regulations. Then, the HHA 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'' HHAs 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 under a set of standards that meet or exceed the Medicare conditions, the Secretary can ''deem'' that HHA as having met the Medicare requirements for those conditions.

Our regulations concerning reapproval of accrediting organizations are set forth at 42 CFR 488.4 and 488.8(d)(3). Section 488.8(d)(3) requires reapplication at least every 6 years and permits the Secretary to determine the required materials from those enumerated in § 488.4, as well as the deadline to reapply for continued approval of deeming authority. We have determined that the procedures set out in section 1865(b)(3)(A) of the Act for initial applications for deeming authority should apply to renewals as well. These procedures require us to—(1) 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 continue to meet or exceed Medicare requirements; (2) identify in the notice the organization and the nature of the request and allow a 30-day public comment period; and (3) publish a notice of our approval or disapproval within 210 days after we receive the organization's application and complete package of information.

II. Provisions of the Proposed Notice

On September 10, 1999, we published a proposed notice in the **Federal Register** (64 FR 49197) announcing the receipt of an application from JCAHO for renewal of its privileges as a national accreditation organization for HHAs. In the proposed notice, we detailed the factors on which we would base our evaluation. Under section 1865(b)(2) of the Act and our regulations at § 488.8(d)(3)(i), our review and evaluation of the JCAHO application were conducted in accordance with the following procedures:

- An on-site administrative review of the following: (1) The accrediting organization's corporate policies; (2) its financial and human resources available to accomplish the proposed surveys; (3) the training, monitoring, and evaluation of its surveyors, (4) its ability to investigate and respond appropriately to complaints against accredited facilities; and (5) its survey review and decision-making process for accreditation.
- A determination of the equivalency of JCAHO's standards for an HHA to our comparable HHA conditions of participation.
- A review, both through documentation and on-site observation, of JCAHO's survey processes to determine the following:

—The comparability of JCAHO's processes to those of State agencies, including survey frequency and whether surveys are announced or unannounced;
—The adequacy of the guidance and instructions and survey forms JCAHO provides to surveyors; and
—JCAHO's procedures for monitoring providers or suppliers found to be out of compliance with our requirements (these procedures are used when JCAHO identifies noncompliance).

- JCAHO's procedures for responding to complaints and for coordinating these activities with appropriate Federal, State, and local licensing bodies and ombudsmen programs.
- JCAHO's policies and procedures for identifying potential fraud and abuse, and its coordination with or reporting to us.
- JCAHO's survey team, 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
—Provide us with electronic data and new statistical validation information including—

+ The number, accreditation status, and resurvey cycle for facilities;
+ The number, types, and resolution times for follow-up when deficiencies are detected during surveys;
+ The 10 most common deficiencies found in surveyed HHAs; and
+ The number of actionable cases of noncompliance and an indication of the method and timeframe for resolution including plans of correction, if any.

- A review of all types of accreditation status JCAHO offers and the extent to which each type corresponds with HCFA's standards of compliance.
- 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 situations of 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.

In accordance with section 1865(b)(3)(A) of the Act the proposed notice also solicited public comment regarding whether JCAHO's requirements meet or exceed the Medicare conditions of participation for HHAs. We received no public comments in response to our proposed notice.

III. Provisions of the Final Notice

A. Differences between JCAHO and Medicare's Conditions and Survey Requirements

Our review and evaluation of the JCAHO application, which were conducted as detailed in section II of

this notice, yielded the following information.

We compared the standards contained in JCAHO's ''1999–2000 Comprehensive Accreditation Manual for Home Care'' and its ''Deemed Status Education Program'' supplemented by flow charts comparing the survey process, deficiency resolution, complaint monitoring, and accreditation decision making with the Medicare conditions of participation and our ''State and Regional Operations Manual.''

Under its current authority, JCAHO had used informal procedures and its technical advisory groups to inform us in advance of potential changes to its standards. It had routinely provided us with its updated manuals after, rather than before, the effective date as required by § 488.4(b)(3)(iii). In response to our request, JCAHO put procedures in place which would require a more formal submission of proposed manual changes to our director of the Center for Medicaid and State Operations (CMSO) 30 days in advance of their effective dates to fully meet the requirements of § 488.4(b)(3)(iii). JCAHO has also agreed to provide us with an updated crosswalk (a table showing the match between their standards and our standards) any time changes are made in the substance or numbering of its standards that changes the mapping to Medicare requirements.

In 11 areas JCAHO has made the following revisions or clarifications:

• *Ownership information.* JCAHO has revised its policies to retain detailed ownership information encompassing the names and addresses of all persons with an ownership or controlling interest in the HHA. In addition, JCAHO has created new forms for use by its surveyors to validate and document ownership information, and requires the surveyors to send any changes to the JCAHO central office to update its files.

• *Crosswalk references.* JCAHO has submitted evidence of changes to its crosswalk references, to assure that incorrect advertisement of services by a provider, or decisions by a provider not to provide certified services because of reimbursements, are correctly cited and reported to our regional offices.

• *Group of professional personnel.* JCAHO has changed its survey requirements and submitted appropriate documentation of this change through a policy letter, to review not only the composition of the professional group participating in the HHA, but also to evaluate the attendance, participation of all required disciplines, and the appropriate exercise of the professional group's advisory functions.

• *Comprehensive assessment condition.* JCAHO has clarified that ''When a Joint Commission standard is 'cross walked', the interpretation of that standard is supplanted *exactly* by the Medicare Condition of Participation or standard.'' This makes the Medicare interpretation the one used by the JCAHO. Specifically, standards governing patient eligibility for home health care (including home bound status) and the incorporation of data management requirements found in § 484.55 are crosswalked, to comply with our interpretation of the requirements. They state, ''you may consider that we add to the evaluation of the Joint Commission's standard and intent, the exact wording of the Medicare condition or standard.'' The evaluation of such standards becomes the sum of the requirements, not one set or the other. Both sets of criteria must be met.

• *Early survey option.* When an HHA elects to use the JCAHO's Early Survey Option II approved by us, the HHA must provide skilled nursing and at least one other therapeutic service. JCAHO standards require that the HHA must serve at least ten patients. JCAHO has added to its standard that seven active patients must be receiving at least one skilled service (nursing assessments do not count as a skilled service). These requirements conform to our policy. In addition, JCAHO has provided documentation that it requires its surveyors to perform home visits using the HCFA's sampling methodology to select the correct number of home visits, as JCAHO does on standard deemed status HHA surveys.

• *Corrective action timeframes.* JCAHO's timeframes for corrective actions have been revised to conform to those limits set by statute and the our State Operations Manual.

—JCAHO has provided documentation that its administrative and survey procedures state that *all* findings of immediate and serious jeopardy, as defined by us, must be reported to the appropriate regional office within 24 hours of discovery. These incidents would include any ''sentinel events'' that meet the definition of immediate and serious threats to health or safety.

—JCAHO will provide the listings of facilities and the letters containing the results of surveys to the appropriate HCFA regional office and to our CMSO contact when the notification goes to the facility.

—JCAHO has revised its notification letter to the facility to indicate any Medicare condition or standard level deficiencies separate from any Type I recommendations (JCAHO accreditation deficiencies). This will allow our staff in the central office or the regional office to identify clearly the level and type of Medicare deficiency, and initiate action to resolve condition level deficiencies as we judge necessary.

—JCAHO has explained the process by which its preliminary nonaccreditation (PNA) decisions are validated and the timeframes for doing so.

—JCAHO has created a Medicare timeframe for resolution of deficiencies in its deemed status facilities and supplied us with a clear outline of this process, that includes timeframes for all steps. This new procedure provides a more efficient process and includes sending all relevant communications to our regional offices in accordance the policy parameters found in our policies and procedures. JCAHO has clarified that it will use the Medicare timeframe for evaluating survey findings (for both Medicare and JCAHO standards) and processing letters to deemed status agencies. This new process eliminates the situation where a finding would be identified after a listing of Medicare deficiencies had been sent to us and cited only in the JCAHO portion of the report, even when the finding was relevant to Medicare. JCAHO's commitment to a 30-day maximum for each follow-up cycle until correction (of all Type I recommendations) is achieved (within the procedural limits of 6 months set by Medicare) meets our requirements.

• *Documentation of deficiencies.* JCAHO has revised its documentation requirements by adding the language ''all relevant scope and severity information, including a description of the findings, to present a clear picture of events and outcomes. Documentation will be consistent with Medicare regulation, and a demonstration of investigative techniques.'' This addition to JCAHO's documentation requirements makes these rules comparable to the Medicare requirements. To validate this goal JCAHO has provided training materials and an agenda for January 2000 training of HHA deemed status surveyors which instructs that the documentation of its surveyors will meet or exceed our 1999 ''Principles of Documentation.''

• *Systemic problems.* JCAHO has clarified that its philosophy and process are directed at identifying underlying systemic problems and then securing correction. This is accomplished for accreditation standards through the use of a computerized algorithm which weighs and combines compliance with

standards to create an overall ''score.'' Surveyors evaluate and document the Medicare requirements by hand-entering data on printed forms, while the JCAHO standards are evaluated using data entry into a computerized algorithm. JCAHO is reinforcing correct identification and documentation of Medicare problems by its surveyors in its January 2000 training. These Medicare findings are supported and expanded by the results of the JCAHO computerized assessment, which aids in the identification of systemic problems. Validation of these systemic problems is done through appropriate follow-up, either by on-site survey or through documented evidence, as appropriate, within 30 days.

• *Complaint process.* JCAHO has provided us with detailed information about its current definitions of and criteria for determining the severity of complaints and the process for handling complaints for each severity level. This process does not include any routine reporting of such complaints to us. JCAHO appropriately is postponing changing this complaint process so that its changes will conform to our new requirements for an improved complaint interface process, currently under development, as soon as it is promulgated.

• *State and local requirements.* JCAHO has clarified that ''[w]hen any Joint Commission standard has the phrase, 'applicable law and regulation' included within the standard or intent, surveyors are instructed that the requirements of the most stringent law or regulation are those to be followed and surveyed for compliance.'' It has also provided us with the procedures it uses to instruct its surveyors to apply when they are unsure of whether or not a facility meets these requirements.

• *Fraud and abuse identification and reporting.* JCAHO confirmed that its ''survey process specifically evaluates the billing and eligibility practices of organizations, as well as ethical behaviors.'' Any violation would be included in the routine reports subsequent to any survey to the regional office within 10 days of the last survey.

In addition to these changes, JCAHO provided a revised crosswalk incorporating all the changes necessitated by our requests.

B. Term of Approval

Based on the review and observations described in section III.A of this notice we have determined that JCAHO's requirements for HHAs meet or exceed our requirements. Therefore, we recognize JCAHO as a national accreditation organization for HHAs that request participation in the Medicare program, effective February 22, 2000, through March 31, 2005.

IV. Paperwork Reduction Act

This document does not impose any information collection and recordkeeping 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, codified in 42 CFR part 488, ''Survey, Certification, and Enforcement Procedures,'' are currently approved by OMB under OMB approval number 0938–0690, with an expiration date of June 30, 2002.

V. Regulatory Impact Statement

We have examined the impact of this notice as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 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 recognizes JCAHO as a national accreditation organization for HHAs that request participation in the Medicare program. 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 an effort to better assure the health, safety, and services of beneficiaries in HHAs already certified, as well as to provide relief to State budgets in this time of tight fiscal constraints, we deem HHAs 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 OMB.

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:** 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)
(Catalog of Federal Domestic Assistance Program No. 93.778—Medical Assistance Programs)

Dated: February 7, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 00–4155 Filed 2–18–00; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–2059–FN]

RIN 0938–AJ69

Medicare and Medicaid Programs; Reapproval of the Deeming Authority of the Community Health Accreditation Program, Incorporated (CHAP) for Home Health Agencies (HHAs)

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

ACTION: Final notice.

SUMMARY: This notice announces the reapproval of the Community Health Accreditation Program, Incorporated (CHAP) as a national accreditation organization for home health agencies (HHAs) that request participation in the Medicare program. We have found that CHAP's standards for HHAs meet or exceed those established by the Medicare program. Therefore, HHAs accredited by CHAP will be granted deemed status under the Medicare program.