

conditions of participation and our "State and Regional Operations Manual." In six areas CHAP has made the following revisions or clarifications:

- CHAP incorporated language to address the provisions of § 484.10(d) (Privacy Act provisions that apply when gathering OASIS data on patients).

- CHAP added specificity to its crosswalk covering provisions of § 484.14(f) and (h), to indicate that during each survey they assess contracts for services or personnel provided under arrangement. Where clinical services are supplied, CHAP clarified that it reviews an HHA's certifications and competencies as well as its backup procedures.

- CHAP provided us with revised pages to its "Core" standards reflecting the requirements at § 484.55, setting out the way in which the collection, use, and reporting of OASIS data in home health agencies will be assessed by surveyors for compliance with the regulation.

- CHAP provided us with additional information from its revised policy and procedure manual specifying its procedures and timeframes for withdrawals and involuntary termination of deemed accreditation, its requirements for reporting such withdrawals to HCFA, and when an HHA may reapply for deemed status accreditation.

- CHAP provided evidence that its fraud and abuse policy and training programs, both through teleconference updates and annual training, provide opportunities for surveyors to discuss how to identify and appropriately report instances of potential Medicare fraud and abuse.

- CHAP provided us with additional materials with respect to its appraisal of surveyor or visitor performance including the information covered, who conducts the appraisals and when, and how site visitor weaknesses are identified and corrected to assure consistency and quality in the survey process.

In addition to these changes, CHAP 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 CHAP's requirements for HHAs meet or exceed our requirements. Therefore, we recognize CHAP 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, 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 impacts 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 CHAP 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 the Medicare program. 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 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 not reviewed by OMB.

In accordance with Executive Order 13132, Federalism, we have determined that this notice will not significantly affect the State, 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. 00-4156 Filed 2-18-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-2057-FN]

RIN 0938-AJ66

Medicare and Medicaid Programs; Recognition of the American Osteopathic Association (AOA) for Continued Approval of Deeming Authority for Hospitals

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

ACTION: Final notice.

SUMMARY: This notice announces the reapproval of the American Osteopathic Association (AOA) as a national accreditation organization for hospitals that request participation in the Medicare program. We believe that continuing accreditation of hospitals by AOA demonstrates that all Medicare hospital conditions of participation are met or exceeded. Thus, we grant deemed status to those hospitals accredited by AOA.

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

FOR FURTHER INFORMATION CONTACT:
Janice Adams-King, (410) 786-8354.

SUPPLEMENTARY INFORMATION:

I. Background

Laws and Regulations

Under the Medicare program, eligible beneficiaries may receive covered services in a hospital provided certain requirements are met. The regulations specifying the Medicare conditions of participation for hospital care are located in 42 CFR part 482. These conditions implement section 1861(e) of the Social Security Act (the Act), which specifies services covered as hospital care and the conditions that a hospital program must meet in order to participate in the Medicare program.

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

Generally, in order to enter into a provider agreement, a hospital must first be certified by a State survey agency as complying with the conditions or standards set forth in the statute and part 482 of the regulations. Then, the hospital is subject to regular 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" hospitals 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 participation. Section 1865(b)(1) of the Act provides that, if a provider demonstrates through accreditation that all applicable conditions are met or exceed the Medicare conditions, we can "deem" the hospital as having met the requirements.

Our regulations concerning reapproval of accrediting organizations are set forth at §§ 488.4 and 488.8(d)(3). The regulations at § 488.8(d)(3) require reapplication at least every 6 years and permit us to determine the required materials as enumerated in § 488.4 and the deadline to reapply for continued approval of deeming authority.

II. Approval of Deeming Organizations

Section 1865(b)(2) of the Act further requires that our findings concerning review of national accrediting organizations consider, among other factors, the accreditation organization's requirements for accreditation, its survey procedures, its ability to provide

adequate resources for conducting required surveys and ability to supply information for use in enforcement activities, its monitoring procedures for provider entities found out of compliance with the conditions or requirements, and its ability to provide us with necessary data for validation.

Section 1865(b)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accreditation body making the request, describing the nature of the request, and providing at least a 30-day public comment period. Subsequently, we have 210 days from receipt of the request to publish approval or denial of the application.

The purpose of this notice is to notify the public of our decision to approve AOA's request for continuation of its deeming authority. This decision is based on our finding that the AOA's separate accreditation programs for hospital care meet or exceed the Medicare hospital conditions of participation.

III. Proposed Notice

On September 10, 1999, we published a proposed notice at 64 FR 49199 announcing AOA's request for reapproval as a deeming organization for hospitals. In the notice, we detailed the evaluation criteria. Under section 1865(b)(2) of the Act and our regulations at § 488.8(d)(3)(i), our review and evaluation of the AOA application were conducted in accordance with the following criteria:

- An on-site administrative review of the corporate policies, resources to accomplish the proposed surveys, program and surveyor evaluation and monitoring, its ability to investigate and respond appropriately to complaints against accredited facilities, and the survey review and decision-making process for accreditation.
- A determination of the equivalency of AOA's standards for a hospital to our comparable hospital conditions of participation.
- A review through documentation and on-site observation of AOA's survey processes to determine the following:
 - The comparability of AOA'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 AOA provides to surveyors.
 - AOA's procedures for monitoring providers or suppliers found to be out of compliance with program requirements. (These procedures are

used only when AOA identifies noncompliance.)

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

- AOA's policies and procedures for identifying potential fraud and abuse and its coordination with us or reporting to us.

- AOA'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.

- AOA's data management system and reports used to assess its surveys and accreditation decisions, and its ability to 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 top 10 deficiencies found, and the number of actionable cases of noncompliance and the method and time frame for resolution.

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

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

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

- AOA'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.

IV. Summary of Public Comments Received on the Proposed Notice and Our Responses

Comments: We received comments in favor of renewing AOA's deeming authority from five professional osteopathic organizations. One organization stated that "The AOA is accepted as a leader in the osteopathic profession by providing quality service to its hospitals, enabling them to comply with the guidelines as set forth

by Medicare and Medicaid.” Another organization stated, “Historically, the AOA accreditation program has assured the hospitals of a program meeting, if not more stringent than, the recognized national standards.” These comments are representative of the support provided by these five osteopathic organizations, which favor the renewal of AOA’s application for deeming authority for hospitals.

Response: We are pleased that all comments received on behalf of renewing AOA’s deeming authority for hospitals were very supportive.

V. Review and Evaluation

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

Differences between the AOA and Medicare Conditions and Survey Requirements

We compared the standards contained in the AOA “Accreditation Requirements for Healthcare Facilities” and the AOA’s survey process outlined in its “Survey Team Handbook” supplemented by flow charts of the survey process with the Medicare conditions of participation and the “State and Regional Operations Manual.” The AOA has made the following revisions or clarifications:

- Patients’ Rights

AOA developed and implemented the New Patients’ Rights Condition of Participation in accordance with 42 CFR 482.13.

- Survey Process

AOA redesigned its standards and survey process for Life Safety Code to ensure that its surveyors assess hospitals for compliance to its standards. The AOA also made minor revisions to its standards for the survey process, excluding Life Safety Code, to ensure that hospitals surveyed met their standards.

- Fraud and Abuse

AOA developed and implemented the Fraud and Abuse standards in accordance with our renewal requirements.

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

VI. Results of Evaluation

We completed a standard-by-standard comparison of AOA’s conditions or requirements for hospitals to determine whether they met or exceeded Medicare

requirements. We found that, after requested revisions were made, AOA’s requirements for hospitals did meet or exceed our requirements. In addition, we visited the corporate headquarters of AOA 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 AOA’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 AOA as a national accreditation organization for hospitals that request participation in the Medicare program, effective February 22, 2000, through March 31, 2005.

VII. 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 June 30, 2002.

VIII. 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 AOA as a national accreditation organization for hospitals 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 the Medicare program. 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 ensure the health, safety, and services of beneficiaries in hospitals already certified, and to provide relief to State budgets in this time of tight fiscal constraints, we deem hospitals accredited by the AOA as meeting our Medicare hospital conditions of participation.

In accordance with Executive Order 13122, Federalism, we have included various provisions throughout this regulation that demonstrate cooperation with the States. For example, while the provisions of this notice may reduce the number of surveys a State Agency performs for Medicare certification of hospitals, it may engender additional validation surveys to assess the performance of the AOA survey process and standards as the validation process expands with the growth of deemed status facilities. State officials will remain responsible for any survey and certification requirements that are allegedly not being enforced.

In accordance with the provisions of Executive Order 12866, this notice was not 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; and Program No. 93.778, Medical Assistance Program)

Dated: February 2, 2000.

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Statement of Mission, Organization, Functions and Delegation of Authority

Part G, of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services, as amended at 60 FR 56606, November 9, 1995, and most recently amended at 61 FR 67048, December 19, 1996, is amended to reflect the establishment of the Division of Information Systems and Technology (GFNAE) and the abolishment of the Information Technology Support Branch (GFNAC1) within the Tucson Area Indian Health Service (TAIHS). The changes are as follows:

Section GFN-00, Tucson Area Indian Health Service—Mission

The Tucson Area IHS provides a comprehensive health services delivery system for American Indians and Alaska Natives (AI/AN) with opportunity for maximum tribal involvement in developing and managing programs to meet their health needs. The goal of the Tucson Area IHS is to raise the health level of the AI/AN people to the highest possible level.

Section GFN-10, Functions. Office of the Director (GFNA)

(1) Plans, develops, and directs the Area program within the framework of the Indian Health Service (IHS) policy and in pursuit of the mission; (2) delivers and ensures the delivery of high quality health services, allowing for alternative methods and techniques of health services management and delivery with maximum Tribal participation; (3) coordinates and advocates for IHS activities and resources internally and externally with those of other Government and nongovernmental programs; (4) promotes optimum utilization of health care services through management and delivery of services to American Indians and Alaska Natives; (5) applies the principles of Indian Preference and Equal Employment Opportunity (EEO); (6) provides liaison, consultative and administrative service to officials of Tribes, inter-tribal and urban Indian

organizations related to the provision of health and health related services, and supports the implementation of Self-Governance and Self-Determination; (7) assures the provision of access to the Internet and World Wide Web; as well as, basic automated information and telecommunications systems to facilitate effective program and health care administration; (8) supports the development of individual and Tribal capacities to participate in Indian health programs through means and modalities that they deem appropriate to their health needs and circumstances; and (9) participates with Indian tribes and other Indian community groups in developing goals and objectives for the Tucson Area IHS.

Division of Administration and Management (GFNAB)

(1) Plans, directs, coordinates and evaluates Area administrative and management services; (2) promotes, evaluates and monitors Area internal control activities; (3) provides for a sound financial management program including budget, general accounting, and accounts control; (4) provides overall management of supply program, office services and personal and real property, insuring proper documentation and reporting of all relative transactions; (5) plans, coordinates, administers, directs and evaluates the Area Civil Service and Commissioned Corps personnel management program; (6) provides human resource management support to Area office and Service Unit managers including recruitment, placement, position management, position classification, training, labor relations and employee relations, employee services, and public relations; (7) assures the full application of the Indian Preference policy in all personnel practices; (8) provides direction for acquisition management including monitoring of tribal/urban Indian, commercial and small purchase contracts.

Financial Management Branch (GFNAB1)

(1) Interprets policies, guidelines, manual issuances, OMB Circulars, and other directives or instructions issued by IHS, PHS, DHHS, OMB, Treasury, GAO and Congress relating to the fiscal management of resources; (2) provides direction for the organization, coordination and execution of all budget and financial operations; (3) provides technical guidance to Service Unit administration staff; (4) provides technical assistance and guidance to tribal organizations; (5) monitors funds

control for the operation of the Service Unit, program offices, and P.L. 93-638 contracted facilities; and (6) advises executive staff on status of funds and recommends action to maintain utilization of resources and to obtain maximum health care services.

Acquisition Management Branch (GFNAB2)

(1) Plans, organizes, and manages the acquisition services for the Area and makes recommendations on acquisition policies and procedures; (2) provides guidance to field personnel on the interpretation of acquisition laws, regulations, procedures and policies; (3) plans, develops, and coordinates all Area tribal contracts and grant awards including negotiation, administration and close-outs; (4) executes and administers Buy Indian contracts; (5) executes and administers construction contracts; and (6) executes and administers purchase orders for small procurement.

Human Resources Management Branch (GFNAB3)

(1) Provides overall human resource management support to Area Office and Service Unit managers; (2) maintains position classification and wage administration programs for the Area; (3) provides a centralized employee development program that includes planning, administering, supervising, and evaluating; (4) directs employee relations/services programs for the entire Area; (5) maintains and processes all Area Integrated Management of Personnel Administration through Computer Technology (IMPACT), Terminal Data Control Systems; (6) provides overall recruitment and employment information; (7) provides technical assistance in personnel management to American Indian organizations; (8) manages the IHS Indian Health Care Improvement Act (P.L. 94-437) Scholarship Program and Management Development Program coordination; (9) ensures that Indian Preference statutes are adhered to and that all legal and regulatory requirements are properly applied; and (10) provides liaison with IHS Field Support Personnel.

Division of Public Health Services (GFNAC)

(1) Provides leadership and guidance to IHS direct, tribal, and urban public health programs on IHS goals, objectives, policies, standards, and priorities; (2) coordinates and evaluates professional standards and reporting requirements, e.g., Health Care Finance Administration (HCFA), Joint