

information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: September 11, 2001.

John P. Burke, III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2099-FN]

RIN 0938-ZA13

Medicare Program; Approval of Deeming Authority for Critical Access Hospitals by the American Osteopathic Association (AOA)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the American Osteopathic Association's (AOA) initial application as a national accrediting organization for critical access hospitals (CAHs) seeking to participate in the Medicare program. Following our evaluation of the organizational and programmatic capabilities of the AOA, we determined that AOA standards for CAHs meet or exceed the Medicare conditions of participation. Therefore, CAHs accredited by the AOA will be granted deemed status under the Medicare program.

EFFECTIVE DATE: This final notice is effective December 27, 2001, through December 27, 2007.

FOR FURTHER INFORMATION CONTACT: Irene H. Dustin (410) 786-0495.

SUPPLEMENTARY INFORMATION:

I. Background

Statutory Provisions and Regulations

Under the Medicare program, eligible beneficiaries may receive covered services in a critical access hospital (CAH), provided that the CAH meets certain requirements. Sections 1820(c)(2)(B) and 1861(mm) of the Social Security Act (the Act) establish distinct criteria for facilities seeking CAH designation. Under this authority,

the minimum requirements that a CAH must meet to participate in Medicare are set forth in regulations at 42 CFR part 485, subpart F (Conditions of Participation: Critical Access Hospitals (CAHs)) which determine the basis and scope of CAH covered services. Conditions for Medicare payment for critical access services are in § 413.70. Applicable regulations concerning provider agreements are at part 489 (Provider Agreements and Supplier Approval) and those pertaining to facility survey and certification are at part 488, subparts A and B.

Verifying Medicare Conditions of Participation

In general, we approve a CAH for participation in, or coverage under the Medicare program, if it is participating as a hospital at the time it applies for CAH designation, and is in compliance with parts 482 (Conditions of Participation for Hospitals), and 485, subpart F (Conditions of Participation: Critical Access Hospitals (CAHs)). Section 403 of the Balanced Budget Refinement Act of 1999 expanded these criteria to allow a limited number of additional facilities to become eligible for CAH designation under certain circumstances. Specifically, a rural health clinic previously downsized from an acute care hospital, or a closed hospital that requests to reopen as a CAH, need only meet the provisions of part 485, subpart F at the time they apply for CAH designation to be eligible to participate in Medicare.

For a hospital to enter into a provider agreement, a State survey agency must certify that the hospital is in compliance with the conditions or standards set forth in the statute and part 482 of our regulations. Then, the hospital is subject to ongoing review by a State survey agency to determine whether it continues meeting Medicare requirements. There is, however, an alternative to State compliance surveys. Certification by a nationally-recognized accreditation program can substitute for ongoing State review.

Section 1865(b)(1) of the Act provides that, if a provider is accredited by a national accreditation body under standards that meet or exceed the Medicare conditions of participation, the Secretary can "deem" the provider as meeting the Medicare requirements for those conditions. Accreditation is voluntary and not required for participation in Medicare; providers have the option to undergo State surveys or pursue accreditation. Prior to this application for deeming status by the AOA, there has been no national accreditation organization for CAHs.

II. Deeming Application Approval Process

Section 1865(b)(3)(A) of the Act provides a statutory timetable to ensure that our review of deeming applications is conducted in a timely manner. Regulations provide us with 210 calendar days to complete our survey activities and application review process. Within sixty days of receiving a completed application, we must publish a notice in the **Federal Register** that identifies the national accreditation body making the request, describes the nature of the request, and provides no less than a 30-day public comment period.

III. Proposed Notice

On April 16, 2001, we published a proposed notice in the **Federal Register** at 66 FR 19509 announcing the AOA's request for approval as a deeming organization for CAHs. In the notice, we detailed our evaluation criteria. Under section 1865(b)(2) of the Act and 42 CFR 488.4, we conducted a review of the AOA application in accordance with the criteria specified by our regulation, which includes, but is not limited to the following:

- An onsite administrative review of AOA's (1) corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors, (4) ability to investigate and respond appropriately to complaints against accredited facilities; and (5) survey review and decision-making process for accreditation.

- A comparison of AOA's CAH accreditation standards to our current Medicare conditions of participation standards.

- A documentation review of AOA's processes to:

- Determine the composition of the survey team, surveyor qualifications, and the ability of AOA to provide continuing surveyor training.

- Compare AOA's processes to that of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

- Evaluate AOA's procedures for monitoring providers or suppliers found out of compliance with AOA program requirements.

- Assess AOA's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

- Establish AOA's ability to provide us with electronic data in ASCII-comparable code and reports necessary for effective validation and assessment of AOA's survey process.

- Determine the adequacy of staff and other resources.
- Review AOA's ability to provide adequate funding for performing required surveys.
- Confirm AOA's policies on whether surveys are announced or unannounced.
- Obtain AOA's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(b)(3)(A) of the Act, the proposed notice also solicited public comments regarding whether AOA's requirements met or exceeded the Medicare conditions of participation for CAHs. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between AOA and Medicare's Conditions and Survey Requirements

We compared the standards contained in the AOA's published "2000-2001 Standards Manual of Accreditation Requirements for Critical Access Facilities" and its survey process in the "2000-2001 Healthcare Facilities Accreditation Survey Team Handbook" with the Medicare CAH conditions of participation and CMS's "State and Regional Operations Manual." Our review and evaluation of the AOA's deeming application, which were conducted as described in section III of this notice, yielded the following:

- The AOA provided an updated crosswalk (a table showing the match between their standards and our standards) of the following recommended revisions or clarifications to their requirements to ensure that the requirements meet or exceed CMS requirements.
- AOA adjusted language to consistently refer to Critical Access Hospitals as opposed to Critical Access Facilities.
- AOA modified their standards to require that a doctor of medicine or osteopathy provide medical supervision of the health care staff in addition to providing for the health care staff in order to meet requirements at § 485.631(b)(1)(i).
- AOA added a cross-reference in their crosswalk to the AOA Accreditation Requirements Manual to indicate the location of CMS regulation at § 485.610 regarding status and location.
- AOA added a standard to the crosswalk to include a description of personnel requirements for emergency

services provided by the CAH, consistent with § 485.618(d).

- AOA added language to their standards to clarify that a CAH must document in its records any extraordinary circumstances that would excuse the CAH from compliance with the requirement for biweekly physician assessments, as required by § 485.631(b)(2).

- AOA corrected their standard to read "services provided by the critical access hospital" rather than "services provided by the pharmacy," in order to meet the requirement in § 485.635(a)(3)(iii).

- AOA added language to their standards to address the CAH's periodic review of the overall utilization of its services, including at least the number of patients served and the volume of services, as specified in § 485.641(a)(1)(i).

- AOA addressed our regulations at § 485.650 for number of beds and length of stay in their Accreditation Requirements Manual. For clarification, AOA cross-referenced this regulation in their crosswalk.

- AOA standards previously indicated resurvey of a CAH every 3 years. AOA modified their standards to indicate in the resurvey requirements that a follow-up visit one year after the initial accreditation survey is required. After the one-year-follow-up, CAHs will be re-surveyed every three years.

- AOA modified its manual to require that CAHs meet the requirements of Chapter 12 (New Health Care Occupancy), or Chapter 13 (Existing Health Care Occupancy) of the 1985 edition of the Life Safety Code (LSC) of the National Fire Prevention Association (NFPA) in accordance with § 485.623(d). AOA added to their application a crosswalk between AOA's LSC standards and ours found at § 485.623(d). Further, AOA added language specifying that facilities must be inspected by AOA and that self-assessment by the CAH does not meet or exceed our requirements. AOA may use their own staff or may provide this service under arrangement with qualified entities.

B. Term of Approval

Based on the review and observations described in section III of this final notice, we have determined that the AOA's requirements for CAHs meet or exceed our requirements. Therefore, we recognize the AOA as a national accreditation organization for CAHs that request participation in the Medicare program, effective December 27, 2001 through December 27, 2007.

V. Collection of Information Requirements

This final notice 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, 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.

VI. Regulatory Impact Statement

We have examined the impact of this notice as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Pub. L. 98-354). 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 100 beds.

This final notice recognizes the AOA as a national accreditation organization for CAHs 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. 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 accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget. 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: Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplemental Medical Insurance Program)

Dated: September 10, 2001.
Thomas A. Scully,
Administrator, Centers for Medicare & Medicaid Services.
 [FR Doc. 01-24327 Filed 9-27-01; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: The Revised Reporting Requirements And Transmission Layouts On TANF Work Measures For FY 2002, TANF High Performance Bonuses (HPB).
OMB No.: New Collection.

Description: The purpose of this collection is to obtain data upon which to base the computation for measuring State performance in meeting the legislative goals of TANF as specified in section 403(a)(4) of the Social Security Act and 45 CFR part 270. Specifically, DHHS will use the data to award the portion of the bonus that rewards States for their success in moving TANF recipients from welfare to work. This information collection will replace Form ACF-200 in FY 2002 (Bonus Year 2002). States will not be required to submit this information unless they elect to compete on a work measure for the TANF High Performance Bonus awards.

Respondents: Respondents may include any of the 50 States, Guam, Puerto Rico, and the Virgin Islands.

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
The Revised Reporting Requirements And Transmission Layouts On TANF Work Measures For FY 2002, TANF High Performance Bonuses (HPB) ..	54	2	16	1,728
Estimated Total Annual Burden Hours:				1,728

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: September 24, 2001.
Bob Sargis,
Reports Clearance Officer.
 [FR Doc. 01-24324 Filed 9-27-01; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Low Income Home Energy Assistance Program (LIHEAP) Carryover and Reallotment Report.
OMB No.: 0970-0106
Description: The LIHEAP statute and regulations require LIHEAP grantees to report certain information to HHS concerning funds forwarded and funds subject to reallotment. The 1994 reauthorization of the LIHEAP statute, the Human Service Amendments of

1994 (Public Law 103-252), requires that the carryover and reallotment report for one fiscal year be submitted to HHS by the grantee before the Allotment for the next fiscal year may be awarded.

We are requesting changes in the collection of data by adding a form, the Carryover and Reallotment Report for FY 20 ____, for the collection of data previously requested by the Simplified Instructions for Timely Obligations of FY 20 __ LIHEAP Funds and Reporting Funds for Carryover and Reallotment. The addition of the form will clarify the information being requested and ensure the submission of all the required information. Use of the form will be voluntary. It is being added in response to numerous queries each year concerning how to provide information. It will not add any additional burden on grantees. Grantees would have the option to use another format.

Respondents:

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Carryover and reallotment	177	1	3	531
Estimated total Annual Burden Hours				531