

used in lieu of nor does it replace, the on-site evaluation of the ASC's physical plant. In addition, JCAHO strongly supports CMS in the proposed adoption of the 2000 edition of the LSC for all providers. The JCAHO is in the process of adopting the 2000 edition of the LSC for all programs and expects to have this process completed consistent with CMS' adoption of the code.

B. Term of Approval

Based on the review and observations described in section III of this final notice, we have determined that JCAHO's requirements for ASCs meet or exceed our requirements. Therefore, we recognize the JCAHO as a national accreditation organization for ASCs that request participation in the Medicare program, effective December 20, 2002 through December 20, 2008.

IV. Collection of Information Requirements

This final notice 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 organizations, codified in 42 CFR part 488, "Survey, Certification, and Enforcement Procedures," are currently approved by OMB under OMB approval number 0938-0690.

V. Regulatory Impact Statement

We have examined the impacts of this final notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) 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 JCAHO as a national accreditation organization for ASCs 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 an effort to better assure the health, safety, and services of beneficiaries in ASCs already certified as well as provide relief to State budgets in this time of tight fiscal restraints, we deem ASCs 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.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This final notice will not have an effect on the governments mentioned nor on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final notice will not have a substantial effect on State and local governments. 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: November 2, 2002.

Thomas Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02-29363 Filed 11-21-02; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2155-FN]

Medicare and Medicaid Program; Approval of Application for Deeming Authority for Ambulatory Surgical Centers by the Accreditation Association for Ambulatory Health Care

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

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the Accreditation Association for Ambulatory Health Care's (AAAHC) application as a national accrediting organization for ambulatory surgical centers (ASCs) seeking to participate in the Medicare program. Following an evaluation of the organizational and programmatic capabilities of AAAHC, we have determined that AAAHC's standards for ASCs meet or exceed the Medicare conditions for coverage. Therefore, ASCs accredited by AAAHC will be granted deemed status under the Medicare program.

EFFECTIVE DATE: This final notice is effective December 20, 2002, through December 20, 2008.

FOR FURTHER INFORMATION CONTACT: Milonda Mitchell (410) 786-3511.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Provisions and Regulations

Under the Medicare program, eligible beneficiaries may receive covered services in ambulatory surgical centers (ASCs), provided that the ASCs meet

certain requirements. Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) authorizes the Secretary of the Department of Health and Human Services (the Secretary) to establish distinct criteria for facilities seeking ASC designation. Under this authority, the Secretary has set forth in regulations minimum requirements that ASCs must meet to participate in Medicare. The regulations at title 42 CFR part 416 (Ambulatory Surgical Services) of the Code of Federal Regulations (CFR) determine the basis and scope of covered services provided by ASCs and Conditions for Medicare payment for ASCs. 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 (Survey, Certification, and Enforcement Procedures), subparts A (General Provisions) and B (Special Requirements).

B. Verifying Medicare Conditions for Coverage

For an ASC to enter into a provider agreement, a State survey agency must certify that the ambulatory surgical center is in compliance with the conditions or standards set forth in part 416 of CMS regulations. Then, the ASC is subject to ongoing review by a State survey agency to determine whether it continues to meet the Medicare requirements. However, there is an alternative to State compliance surveys. Certification by a CMS-approved accreditation program can substitute for ongoing State review.

Section 1865(b)(1) of the Act states that provider entities accredited by CMS-approved accrediting organizations are deemed to be in compliance with Medicare conditions for coverage. Accreditation by an accreditation organization is voluntary and is not required of ASCs for participation in Medicare.

C. Deeming Application Approval Process

Section 1865(b)(3)(A) of the Act provides a statutory timetable to ensure that CMS conducts its review of deeming applications in a timely manner. The Act provides CMS with 210 calendar days after the date of receipt of an application to complete its survey activities and application review process. Within 60 days of receiving a completed application, CMS 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.

II. Proposed Notice

On June 28, 2002, CMS published a proposed notice announcing AAAHC's request for approval as a deeming organization for ASCs (67 FR 43610). In the notice, CMS detailed its evaluation criteria. Under section 1865(b)(2) of the Act and § 488.4, CMS conducted a review of AAAHC's application in accordance with the criteria specified by CMS regulations, which include, but are not limited to the following:

- An onsite administrative review of AAAHC'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 AAAHC's ASC accreditation standards to CMS' current Medicare conditions for coverage.

- A documentation review of AAAHC's survey processes to:

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

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

- Evaluate AAAHC's procedures for monitoring providers or suppliers found to be out of compliance with AAAHC program requirements. The monitoring procedures are used only when the AAAHC identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at § 488.7(d).

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

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

- Determine the adequacy of staff and other resources.

- Review AAAHC's ability to provide adequate funding for performing required surveys.

- Confirm AAAHC's policies with respect to whether surveys are announced or unannounced.

- Obtain AAAHC's agreement to provide CMS with a copy of the most current accreditation survey together

with any other information related to the survey that CMS 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 AAAHC's requirements met or exceeded the Medicare conditions for coverage for ASCs.

CMS received public comments from the American Academy of Facial Plastic and Reconstructive Surgery and the Federated Ambulatory Surgery Association recommending the approval of AAAHC's application as a national accrediting organization for ASCs.

III. Provisions of the Final Notice

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

CMS compared the standards contained in AAAHC's "Accreditation Handbook for Ambulatory Health Care," its survey process in the "AAAHC Survey Report Form," and its "AAAHC Environmental Spot-Checklist," with the Medicare ASC conditions for coverage and CMS' State and Regional Operations Manual. CMS conducted its review and evaluation of AAAHC's deeming application as described in section III of this notice. It yielded the following:

- In order to meet the requirements of § 416.41 AAAHC added to its standard that all ASCs must have an effective procedure for transfer to a local hospital, of patients requiring emergency medical care beyond the capabilities of the ASC.

- AAAHC revised its Accreditation Handbook and Survey Report Form to meet the requirement set forth at § 416.44(c), by requiring ventilatory assistance equipment, including airways, manual breathing bags, and ventilators in all ASC operating rooms.

- AAAHC accepted CMS' recommendation to adopt the 2000 Life Safety Code. AAAHC will issue a transmittal of the new LSC requirements to its AAAHC Medicare deemed ASCs, AAAHC surveyors, and to its potential ASCs applicants requesting an AAAHC Medicare deemed status survey. Furthermore, AAAHC has agreed to revise its AAAHC Accreditation Handbook Standards Chapter 8 R-MS, Appendix H; AAAHC Survey Report Form Chapter 8 R-MS; and Physical Environment Checklist for Ambulatory Surgical Centers in February 2003 to reflect the implementation of the 2000 Life Safety Code.

- CMS requested that AAAHC clarify its standard regarding requiring only

existing facilities to conform with existing codes as demonstrated by a fire marshal report performed by a State authority and its standard requiring that an existing facility which lacks a fire marshal report be required to solicit a Life Safety Code Survey from the State fire marshal. AAAHC indicated that it will perform a Life Safety Code survey for all ASCs applying for or re-applying for an AAAHC Medicare deemed status survey. A surveyor credentialed to perform such an inspection performs the AAAHC Life Safety Code survey.

- AAAHC provided clarification to its reference regarding the usage of batteries as an emergency power source by stating that its current requirement is based on the 1985 NFPA Life Safety Code. However, once CMS adopts the 2000 edition of the Life Safety Code, AAAHC agrees that the use of batteries will no longer be an acceptable source of emergency power in an ASC, unless specifically permitted by a CMS exception to the new NFPA standards. In addition, this clarification will be incorporated into the revisions of AAAHC's Physical Environment Spot-Check List for Ambulatory Surgical Centers, Appendix H; AAAHC Survey Report Form, Chapter 8; and the Facilities and Environment Section 18 B of the AAAHC Handbook when published in early 2003. Prior to these revisions, AAAHC will issue a transmittal to all ASCs currently deemed by AAAHC, AAAHC Medicare deemed status surveyors, and to ASCs applying for a AAAHC Medicare deemed status survey stating that in accordance with the 2000 edition of the Life Safety Code all new ambulatory health care facilities with "critical access areas" (including operating rooms and/or post-anesthesia recovery rooms) will be required to provide a "type I" essential electrical system (ESS).

- CMS requested AAAHC to clarify its descriptions of its accreditation decisions for ASCs deemed to participate in the Medicare program. AAAHC responded that its Accreditation Committee awards an ASC accreditation for a three-year term when it has no reservations about the accuracy of the survey findings or the ASC's commitment to continue providing high quality care and services, and when it concludes that the ASC is in compliance with all of Medicare's conditions for coverage all of AAAHC's standards. A one-year term of accreditation is awarded by AAAHC's Accreditation Committee when it concludes that the ASC meets the Medicare conditions for coverage, but that a portion of the ASC's operations

require more time to achieve and sustain compliance with all AAAHC standards. Therefore, the organization would have a special on-site review within 10 months from the first survey date to avoid a lapse in accreditation. Such a special on-site review would be conducted by one or more surveyors and would not be limited to the recommendations in the previous survey report. Finally, AAAHC's Accreditation Committee awards an ASC a six-month term of accreditation when it concludes that the organization meets the Medicare conditions for coverage and is in compliance with the AAAHC standards, but is ineligible for a three-year term of accreditation because the ASC has not been operational for 6 months. However, a six-month term of accreditation may also be awarded to an ASC that has been in business for longer than 6 months, is seeking both AAAHC accreditation and Medicare deemed status for the first time, and AAAHC's Accreditation Committee has determined that it meets the Medicare conditions for coverage and is in compliance with the AAAHC standards. All ASCs with a six-month term of accreditation would have a special on-site review within 5 months from the previous survey date with a focus on the issue of sustained performance since the initial survey. Such a special on-site review would be conducted by one or more surveyors and would not be limited to the recommendations in the previous survey report. CMS deems an ASC accredited by AAAHC for any of these terms to have met or exceeded Medicare standards for the duration of that term.

B. Term of Approval

Based on the review and observations described in section III of this final notice, CMS has determined that AAAHC's requirements for ASCs meet or exceed CMS requirements. Therefore, CMS recognizes AAAHC as a national accreditation organization for ASCs that request participation in the Medicare program, effective December 20, 2002 through December 20, 2008.

IV. 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, codified in

42 CFR part 488, "Survey, Certification, and Enforcement Procedures," are currently approved by OMB under OMB approval number 0938-0690.

V. Regulatory Impact Statement

We have examined the impact of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 98-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) 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, CMS considers 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 AAAHC as a national accreditation organization for ASCs 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. CMS has 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, CMS has not prepared 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 ASCs already certified as well as provide relief to State budgets in this

time of tight fiscal restraints, CMS deems ASCs accredited by AAAHC as meeting its Medicare requirements. Thus, CMS continues its focus on assuring the health and safety of services by providers and suppliers already certified for participation in a cost-effective manner.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This final notice will not have an effect on the governments mentioned nor on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final notice will not have a substantial effect on State and local governments. In accordance with Executive Order 13132, CMS has determined that this notice will not significantly affect the rights of States, local, or tribal governments.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

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: November 2, 2002.

Thomas Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02-29364 Filed 11-21-02; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1220-N]

RIN 0938-AL97

Medicare Program; Fee Schedule for Payment of Ambulance Services—Update for CY 2003

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

ACTION: Notice.

SUMMARY: This notice updates the Ambulance Inflation Factor (AIF) for ambulance services for calendar year (CY) 2003. The AIF is used in determining the payment limit for ambulance services required by section 1834(l) of the Social Security Act (the Act).

DATES: The AIF for 2003 is effective for ambulance services furnished during the period January 1, 2003, through December 31, 2003.

FOR FURTHER INFORMATION CONTACT: Anne E. Tayloe, (410) 786-4546.

SUPPLEMENTARY INFORMATION:

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I. Background

Requirements of the Statute for Updating the Ambulance Inflation Factor (AIF) for Ambulance Services for CY 2003

On February 27, 2002, we published a final rule entitled "Medicare Program; Fee Schedule for Payment of Ambulance Services and Revisions to the Physician Certification Requirements for Coverage of Nonemergency Ambulance Services; Final Rule" (HCFA-1002-FC) in the **Federal Register** (67 FR 9100), that established a fee schedule for ambulance services required by section 1834(l) of the Social Security Act (the Act). This final rule provided that the ambulance fee schedule would be updated by the AIF annually, based on the percentage increase in the consumer price index (CPI) for all urban

consumers (U.S. city average) for the 12-month period ending with June of the previous year (§ 414.610(f)). It also provided that notice of the AIF would be published in the **Federal Register** without opportunity for prior comment (§ 414.620). We will follow applicable rulemaking procedures in publishing revisions to the fee schedule for ambulance services that result from any factors other than the inflation factor. In this notice, we set forth the ambulance inflation factor for CY 2003.

II. Provisions of the Notice

Section 1834(l)(3)(B) of the Act provides the basis for updating payment amounts for ambulance services. Specifically, this section provides for an update in payments for CY 2003 that is equal to the percentage increase in the CPI for all urban consumers (CPI-U), for the 12-month period ending with June of the previous year (that is, June 2002). For CY 2003 that percentage is 1.1 percent.

During the transition period, the AIF is applied to both the fee schedule portion of the blended payment amount and to the reasonable charge/cost portion of the blended payment amount separately for each ambulance provider/supplier. Then, these two amounts are added together to determine the total payment amount for each provider/supplier.

III. Waiver of Proposed Rulemaking

We ordinarily publish a proposed notice in the **Federal Register** and provide a period for public comment before we make final the provisions of the notice. We can waive this procedure, however, if we find good cause that notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and we incorporate a statement of finding and its reasons in the notice issued. We find it unnecessary to undertake notice and comment rulemaking in this instance because the law specifies the method of computation of annual updates, and we have no discretion in this matter. Further, this notice does not change substantive policy, but merely applies the statutorily-specified update method. Therefore, under 5 U.S.C. 553(b)(B), for good cause, we waive notice and comment procedures.

IV. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102(b) of