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, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We have determined that this is not a major rule because it does not impose an economically significant impact on covered entities or the Medicare program.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Individuals and States are not included in the definition of a small entity. This notice will not result in a significant impact on small businesses because the notice simply announces three applications we have received from hospitals requesting waivers from entering into agreements with their designated OPOs.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

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 notice will not result in an impact of $110 million or more on the governments mentioned or 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. We have reviewed this notice under these requirements and have determined that it will not impose substantial direct requirement costs on State or local governments.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this notice will not have a significant economic impact on the operations of a substantial number of small rural hospitals.

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

Authority: Sec. 1138 of the Social Security Act (42 U.S.C. 1320b–8).

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

Dated: November 18, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02–29796 Filed 11–21–02; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2154–FN]

Medicare and Medicaid Programs; Application by the Joint Commission on Accreditation of Healthcare Organizations for Continued Deeming Authority for Ambulatory Surgical Centers

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This notice announces our decision to re-approve the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as a national accreditation program for Ambulatory Surgical Centers (ASCs) seeking to participate in the Medicare program. Following our evaluation of the organizational and programmatic capabilities of JCAHO, we have determined that JCAHO standards for ASCs meet or exceed the Medicare conditions for coverage. Therefore, ASCs accredited by JCAHO will receive deemed status under the Medicare program.

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

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786–0310.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in an ambulatory surgical center (ASC), provided that the ASC meets 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 designation as ASCs. Under this authority, the Secretary has set forth in regulations minimum requirements that an ASC must meet in order to participate in Medicare. The regulations concerning supplier agreements are at 42 CFR part 489 and those pertaining to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 416 specify the conditions that an ASC must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for facility services.

Generally, in order to enter into an agreement, an ASC must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 416 of our regulations. Then, the ASC is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(b)(1) of the Act provides that, if a provider entity demonstrates through accreditation that all applicable Medicare conditions are met or exceeded, the Centers for Medicare & Medicaid Services (CMS) shall ''deem'' those provider entities to have met the requirements. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation.

If an accreditation organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accreditation organization applying for approval of deeming authority under part 488, subpart A must provide us with reasonable assurance that the accreditation organization requires the

accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. 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 accreditation organizations to reapply for continued approval of deeming authority every 6 years or sooner as determined by CMS. The Joint Commission on Accreditation of Healthcare Organization's (JCAHO) current term of approval as a recognized accreditation program for ASCs expires December 19, 2002.

A. 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. The Act provides us with 210 calendar days after the date of receipt of an application to complete our survey activities and application review process. Within 60 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. At the end of the 210-day period we must publish an approval or denial of the application.

II. Proposed Notice

On June 28, 2002, we published a proposed notice at 67 FR 43612 announcing the JCAHO's request for reapproval as a deeming organization for ASCs. In this notice we detailed our evaluation criteria. Under section 1865(b)(2) of the Act and § 488.4, we conducted a review of the JCAHO application in accordance with the criteria specified by our regulation, which include, but are not limited to the following:

• An onsite administrative review of JCAHO'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 JCAHO's ASC accreditation standards to our current Medicare ASC conditions for coverage.

• A documentation review of JCAHO's survey processes to:

+ Determine the composition of the survey team, surveyor qualifications, and the ability of JCAHO to provide continuing surveyor training.
+ Compare JCAHO'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 JCAHO's procedures for monitoring providers or suppliers found to be out of compliance with JCAHO program requirements. The monitoring procedures are used only when the JCAHO identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at § 488.7(d).
+ Assess JCAHO's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.
+ Establish JCAHO's ability to provide us with electronic data in ASCII-comparable code and reports necessary for effective validation and assessment of JCAHO's survey process.
+ Determine the adequacy of staff and other resources.
+ Review JCAHO's ability to provide adequate funding for performing required surveys.
+ Confirm JCAHO's policies with respect to whether surveys are announced or unannounced.
+ Obtain JCAHO'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 JCAHO's requirements met or exceeded the Medicare conditions of coverage for ASCs. 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

We compared the standards contained in JCAHO's ''Comprehensive Accreditation Manual for Ambulatory Care'' (CAMAC) and its survey process in the ''Ambulatory Surgery Centers Request for Continued Deeming Handbook'' with the Medicare ASC conditions for coverage and CMS'' State and Regional Operations Manual. Our review and evaluation of JCAHO's deeming application, which were conducted as described in section III of this notice, yielded the following:

• In order to meet the requirements of § 488.4(a)(4)(ii), JCAHO provided the education and experience requirements surveyors must meet. JCAHO surveyors must have 5 years of recent experience in an appropriate health care setting and a minimum of a Master's degree in an appropriate discipline.

• JCAHO addressed our regulations at § 488.4(a)(4)(v) by providing JCAHO's policy that no one may conduct a survey if they have had a relationship with the facility in the last 3 years. All JCAHO employees are required to sign a conflict-of-interest statement upon hire.

• JCAHO provided a list of all full and partial ASC accreditation surveys scheduled to be performed by the organization in 2002 to satisfy our requirements at § 488.4(a)(10).

• In reference to the CMS final rule published in the **Federal Register** November 13, 2001 (66 FR 56762), the Joint Commission recognized that the exception permitting certified registered nurse anesthetists (CRNAs) to administer anesthesia without supervision of a physician when requested by the Governor of a State, in consultation with the State's Board of Medicine and Nursing was not addressed. JCAHO will reference the role of and supervisory requirements for CRNAs in the next revision of the CAMAC. The crosswalk of the JCAHO standards to the Medicare Conditions will also be amended. JCAHO will also notify current and prospective ASCs seeking deemed status of this revised CMS requirement in JCAHO's official communication vehicle, *Perspectives,* which is published monthly.

• JCAHO recognizes CMS' expectation that an ASC is by definition an ambulatory health care occupancy with or without regard to size of the facility as incorporated in § 416.44(b). JCAHO agrees to survey ASCs seeking deemed status with this requirement and will add language to the CAMAC. In addition, JCAHO will review the application for survey submitted by ASCs to JCAHO and, as appropriate, will make this requirement more prominent to avoid any misunderstandings.

• JCAHO addressed our regulations at § 416.44 by recognizing that assessing compliance with the life safety code (LSC) is a JCAHO responsibility. In the evaluation of the LSC, the JCAHO surveyor physically inspects and evaluates the ASC's physical plant (both above and below the ceiling) in relationship to the requirements of the LSC. As an adjunct survey assessment technique and tool, the JCAHO uses and evaluates the organization's Statement of Condition (SOC) and Plan for Improvement (PFI) during the on-site inspection; however, the SOC/PFI is not

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