

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Health Care Financing Administration

[HCFA-2008-FN]

RIN 0938-AI90

### Medicare Program; Recognition of the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. for Ambulatory Surgical Centers Program

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

**ACTION:** Final notice.

**SUMMARY:** This notice announces the approval of the American Association for the Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) as an accreditation organization acknowledged by the Medicare program. We have found that AAAASF's standards for ambulatory surgical centers (ASCs) meet or exceed those established by the Medicare program. ASCs accredited by AAAASF will receive deemed status under the Medicare program.

**EFFECTIVE DATE:** This final notice is effective December 2, 1998, through December 2, 2004.

**FOR FURTHER INFORMATION CONTACT:** Joan Berry, (410) 786-7233.

#### SUPPLEMENTARY INFORMATION:

#### I. Background

##### A. Determining Compliance of Ambulatory Surgical Centers—Surveys and Deeming

In order to participate in the Medicare program, ambulatory surgical centers (ASCs) must meet conditions for coverage specified in regulations that implement Title XVIII of the Social Security Act (the Act). ASCs enter into a Medicare participation agreement but generally only after they are certified by a State survey agency as complying with the ASC conditions for coverage set forth in the Act and regulations. ASCs are subject to routine surveys by State agencies to determine whether they continue to meet these requirements; an ASC that does not meet these requirements is considered out of compliance and risks having its participation in the Medicare program terminated.

Section 1865 of the Act includes a provision that permits ASCs to be exempt from routine surveys by the State survey agencies to determine compliance with the Medicare conditions of coverage. Specifically, section 1865(b) of the Act provides that

if we find that accreditation of a provider entity by a national accrediting body demonstrates that all Medicare conditions or requirements are met or exceeded, we would (for certain providers, including ASCs) "deem" these entities as meeting the applicable Medicare conditions. In order to enter the Medicare program under this deeming authority, the entities must meet the regulatory requirements at 42 CFR 489.13 ("Effective date of agreement or approval"). Under our regulations at § 416.40 ("Condition for coverage—Compliance with State licensure law"), an ASC must still meet the State's licensure requirements. However, certification by Medicare is still required to receive payment regardless of whether the certification is by us or the accrediting body.

In making our finding as to whether the standards of an accreditation body demonstrate comparability with all Medicare conditions or requirements, we consider factors such as the body's accreditation requirements, its survey procedures, its ability to provide adequate resources for conducting required surveys and supplying information for use in enforcement activities, its monitoring procedures for provider entities found to be out of compliance with the conditions or requirements, and its ability to provide us with necessary data for validation.

As suppliers, ASCs are included by definition of provider entity in section 1865(b)(4) of the Act. Thus, if we were to recognize an ASC accreditation organization's program as demonstrating that all the Medicare ASC conditions of coverage are met, the ASCs accredited under the approved Medicare program would be considered or "deemed" to meet the same conditions for which the accreditation standards have been recognized. The American Association for the Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) is the third accreditation organization that we have approved for ASCs. The other two accreditation organizations are the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and the Accreditation Association for Ambulatory Health Care (AAAHC).

It has been brought to our attention that some ASCs are under the mistaken impression that once deemed authority is granted by HCFA to an accreditation organization, then ASCs must be accredited by such a body to receive Medicare certification. Accreditation by an accreditation organization is voluntary and not required by HCFA for Medicare certification.

#### B. Deeming Authority Process

On November 23, 1993, we published a final rule (58 FR 61816) that set forth the procedure that we would use to review and approve national accreditation organizations that wish to be recognized as providing reasonable assurance that Medicare conditions of coverage are met (§ 488.4, "Application and reapplication procedures for accreditation organizations"). A national accreditation organization (Accreditation organization) applying for approval of deeming authority must furnish to us information and materials listed in our regulations at § 488.4. Our regulations at § 488.8 ("Federal review of accreditation organizations") detail the Federal review and approval process of applications for deeming authority. On April 26, 1996, however, new legislation entitled "Making Appropriations for Fiscal Year 1996 to Make a Further Down Payment Toward a Balanced Budget and for Other Purposes (Pub. L. 104-134)" was enacted.

Section 516 of Public Law 104-134 amended section 1865 of the Act in a number of ways. The legislation removed the requirements that accreditation organizations provide reasonable assurance that entities accredited by them would meet Medicare conditions coverage or requirements. In revised section 1865(b)(1) of the Act, organizations are now required to demonstrate that their accredited entities would meet or exceed all of the applicable Medicare conditions. Section 1865(b)(4) includes suppliers (for example, ASCs) under the provider entities that we may consider for deemed status. We are required to publish a proposed notice in the **Federal Register** 60 days after the receipt of a written request for deemed status by a national accreditation body. After review of the national accreditation body's application, the statute requires that we publish a notice of our approval or disapproval within 210 days after we receive a complete package of information and the organization's deeming application.

We received an application from AAAASF on November 18, 1997 and in accordance with the statute, this final notice should have been published by June 16, 1998. However, HCFA was waiting for AAAASF to submit required materials on a quality improvement project for their training program before approving its deeming authority. AAAASF chose to delay the publication date, rather than be denied deemed status and have to reapply for deemed authority. Regulations at § 488.8(c)

specify that the deeming authority for AAAASF will take effect 90 days from the publication of this final notice. Thus, AAAASF cannot award deemed accreditation to a supplier and request HCFA certification before the end of that 90-day period.

### *C. Ambulatory Surgical Center Conditions for Coverage and Requirements*

The regulations specifying the Medicare conditions for coverage for ASCs are located in part 416. These conditions implement section 1832(a)(2)(F)(i) of the Act, which provides for Medicare Part B coverage of facility services furnished in connection with surgical procedures specified by us under section 1833(i)(1) of the Act.

## **II. Provisions of the Proposed Notice**

The proposed notice announced the application of AAAASF for deemed status for its accreditation program only to the extent that it accredits ASCs.

Under section 1865(b)(2) of the Act and our regulations at § 488.8 ("Federal review of accreditation organizations"), our review and evaluation of this national accreditation organization was conducted in accordance with, but was not necessarily limited to, the following factors:

- The equivalency of an accreditation organization's requirements for an entity to be certified compared to our requirements for certification.

- The organization's survey process to determine the following:

- \* The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

- \* The comparability of the organization's process to that of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

- \* The organization's procedures for monitoring providers or suppliers found to be out of compliance with program requirements. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at § 488.7(b)(2).

- \* The ability of the organization to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

- \* The ability of the organization to provide us with electronic data in ASCII comparable code and reports necessary for effective validation and assessment of the organization's survey process.

- \* The adequacy of staff and other resources.

- \* The organization's ability to provide adequate funding for performing required surveys.

- \* The organization's policies with respect to whether surveys are announced or unannounced.

- The accreditation organization's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey that we may require (including corrective action plans).

We met with representatives of AAAASF to evaluate its accreditation standards and survey process to determine if the organization demonstrated that its accredited facilities met Medicare conditions. We did a standard by standard comparison of the applicable conditions or requirements to determine which of them met or exceeded Medicare requirements. The representatives responded to our concerns by proposing to change the organization standards for its member ASCs needing Medicare certification. We subsequently received revised survey guidelines and amended standards for their member ASCs requesting Medicare certification.

### *A. Differences Between the American Association for the Accreditation of Ambulatory Surgery Facilities, Inc. and Medicare Conditions and Survey Requirements*

We compared the standards contained in the AAAASF's 1994 Standards Manual for accreditation of ambulatory surgery facilities and its survey process in the 1994 Inspectors Manual to the Medicare ASC conditions and survey procedures. In 18 areas the AAAASF has made the following revisions:

- *Exclusivity Requirement*—AAAASF has included a statement on ASC surgical exclusivity as an integral part of its application package.

- *Unannounced Surveys*—AAAASF has added language to the on-site inspection information to include a declaration that all surveys will be unannounced. In order to accommodate the need to assure that key staff are on hand for surveys without notification of the facility, AAAASF has agreed to request that the facility send staffing schedules on a regular basis once their application is complete.

- *Frequency of Surveys*—AAAASF resurveys an ASC every 3 years. Our original requirement was to survey ASCs every year. In practice, our resurveys have been averaging almost 3 years. Both the JCAHO and AAAHC have 3-year resurvey cycles. Therefore, we accept AAAASF's 3-year resurvey cycle.

- *State and Local Laws*—AAAASF has agreed to assure that out-of-state inspectors receive adequate information on certification, licensure, and scope of practice requirements of that State.

- *Reasonable Assurance*—AAAASF has agreed to modify its process to build in a review of the past history of facilities that already have Medicare certification through the State.

- *Fraud and Abuse*—AAAASF has agreed to require that its inspectors report any suspected instances of fraud and abuse to the appropriate HCFA Regional Office.

- *Hearing Schedules and Appeals*—AAAASF has specified the dates and locations for its Accreditation Committee hearings over the next 4 years.

- *Hospitalization*—AAAASF has inserted the word "local" to indicate those hospitals eligible to receive immediate transfers for patients requiring emergency medical care beyond the capabilities of the ASC.

- *Anesthetic Risk and Evaluation*—AAAASF has added language to indicate that a physician must examine each patient immediately before surgery to evaluate the risk of anesthesia and the procedure to be performed.

- *Recovery Room and Waiting Area*—AAAASF has specified that an ASC must have a separate recovery room and waiting area.

- *Emergency Personnel*—AAAASF has added the requirement that personnel trained in the use of emergency equipment and cardiopulmonary resuscitation must be available whenever a patient is in the facility.

- *Other Practitioners*—AAAASF has added the requirement that if certified operating room technicians are employed that their certification or licensure must be current. Furthermore, if uncertified or unlicensed operating room technicians are used, it must be permissible under State law and the technician must be personally trained by the employing surgeon.

- *Organization and staffing*—AAAASF has added the requirement that a registered nurse must be available for emergency treatment whenever a patient is in the facility.

- *Oral Orders*—AAAASF has added a standard that requires that oral orders for drugs and biologicals must be followed by a written order and signed by the prescribing physician.

- *Laboratory and Radiologic Services*—AAAASF has added the requirement that radiologic services be obtained from a Medicare-approved facility and that ASC laboratories must meet requirements of part 493.

Furthermore, if the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with part 493. Any referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of part 493.

- *Life Safety Code: Surgical Procedures*—AAAASF agreed to require facilities to meet State and local requirements, or the National Fire Prevention Association (NFPA) Standards for Health Care Facilities (NFPA 99), and Life Safety Code (NFPA 101) Chapters 12 and 13 (and appropriate references), whichever is more stringent. Language was added to specify that their regular inspections for installation and maintenance of surgical equipment will be at least annually. In conformity with the NFPA requirements, AAAASF has made standby generator as the mandatory source of emergency power and reduced the time for such generators to reach full power from 30 to 10 seconds.

- *Life Safety Code: Environment*—AAAASF has specified that fire drills must be held once a month for each shift and has made smoke detectors mandatory for all office-based ASCs.

- *Life Safety Code: Standards Addendum*—AAAASF has specified that facilities must be inspected at least annually by the local or State fire control agency if this service is available. If not, AAAASF agrees to contract with a State agency or qualified subcontractor to perform the inspections.

- *Inspector Training Program*—AAAASF has submitted a revised training program that provides for consistent, national training of all inspectors in their processes and integrates instruction in the Medicare requirements based on either the trainer's participation in Medicare training or using Medicare survey experts as instructors.

We have agreed to accept language that requires compliance with the 1985 edition of the Life Safety Code with an encouragement by AAAASF that facilities comply with the 1997 Code. These standards will apply to all facilities regardless of size.

#### *B. Analysis and Responses to Public Comments and Provisions of the Final Notice*

We received no comments on our proposed notice. The provisions of the proposed notice are being made final in this notice.

### **III. Paperwork Reduction Act**

The public reporting and record keeping burden reflected in this notice is referenced in the currently approved regulation entitled "Granting and Withdrawal of Deeming Authority to National Accreditation Organizations (58 FR 61816)." The paperwork burden referenced in the above mentioned regulation is currently approved by the Office of Management and Budget (OMB), under OMB approval number 0938-0690, with an expiration date of 8/31/99.

### **IV. Regulatory Impact Statement**

In fiscal year 1995, there were 2,105 certified ASCs participating in the Medicare/Medicaid programs. We conducted 211 initial surveys, 288 recertification surveys (both at a cost of \$714,069), and 24 complaint surveys. In fiscal year 1996, there were 2,219 certified ASCs. This was an increase of 114 facilities. We conducted 180 initial surveys, 115 recertification surveys (both at a cost of \$848,125), and one complaint survey. In fiscal year 1997, there were 2,433 certified ASCs. This was an increase of 214 facilities. We conducted 236 initial surveys, 252 recertification surveys (both at a cost of \$1,403,000), and seven complaint surveys. As the data above indicate, the number of ASCs and the cost for conducting ASC surveys by State Agencies are increasing.

As indicated above, there was a 16 percent increase in ASCs within 3 years (fiscal years 1995 through 1997). The fiscal year 1998 appropriation for ASC survey activities to HCFA was decreased as the priority of both initial surveys and resurveys remained in the bottom 10 percent of surveys performed, but without any adjustment for inflation. This does not allow sufficient resources for some regions to meet the survey demand. In an effort to guarantee the continued health, safety, and services of beneficiaries in facilities already certified as well as provide relief to State budgets in this time of tight fiscal restraints, we are approving deeming for ASCs accredited by AAAASF 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 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—Supplementary Medical Insurance Program)

Dated: October 19, 1998.

**Nancy-Ann DeParle,**

*Administrator, Health Care Financing Administration.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, The History of Medicine Panel.

*Date:* December 4, 1998.

*Time:* 8:30 am to 12:00 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Gilbert Meier, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5112, MSC 7852, Bethesda, MD 20892, (301) 435-1169.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Ethics/Genome Study Section.

*Date:* December 7-8, 1998.

*Time:* 9:00 am to 12:00 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Georgetown Holiday Inn, 2101 Wisconsin Ave., N.W., Washington, DC 20007.

*Contact Person:* Cheryl M. Corsaro, Scientific Review Administrator, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 6172, MSC 7890, Bethesda, MD 20892, (301) 435-1045.