This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), (21 U.S.C. 360e(d), 360j(h)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: June 21, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–18556 Filed 7–22–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[BPD–849–PN]

Medicare Program; Recognition of the Ambulatory Surgical Center Standards of the Joint Commission on the Accreditation of Healthcare Organizations and the Accreditation Association for Ambulatory Health Care

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

ACTION: Proposed notice.

SUMMARY: This notice proposes to grant deeming authority to two organizations, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and the Accreditation Association for Ambulatory Health Care (AAAHC), for their member ambulatory surgical centers (ASCs) that request Medicare certification. We believe that accreditation of ASCs by both organizations would demonstrate that all Medicare ASC conditions are met or exceeded, and, thus, we would grant deeming authority to each organization.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on August 22, 1996.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–849–PN, P.O. Box 7519, Baltimore, MD 21207–0519.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, D.C. 20201, or Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD–849–PN. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone (202) 690–7890).

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FOR FURTHER INFORMATION CONTACT: Bob Cereghino, (410) 786–4645.

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 regular 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 for coverage. (Under our regulations at 42 CFR 416.40 (''Condition for coverage—Compliance with State licensure law''), an ASC must still meet the State's licensure requirements, however.) Specifically, section 1865(b) of the Act provides that if we find that accreditation of a provider entity by a national accreditation 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 making our finding as to whether the accreditation body makes this demonstration, we consider factors such as the accrediting 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. If we find that the accreditation of an ASC by the national accreditation body demonstrates that the Medicare conditions imposed on ASCs are met, we would treat the accredited ASCs as meeting those conditions. ASCs as suppliers are included by definition of provider entity in section 1865(b)(4) of the Act. Thus, if we were to recognize an ASC

accrediting organization's program as demonstrating that all the Medicare ASC conditions are met, the ASCs it accredits would be considered, or ''deemed,'' to meet the same conditions for which the accreditation standards have been recognized. The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and the Accreditation Association for Ambulatory Health Care (AAAHC) are the first two organizations to which we have considered granting deemed status.

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 accrediting organizations that wish to be recognized as providing reasonable assurance that Medicare conditions are met (§ 488.4, ''Application and reapplication procedures for accreditation organizations''). A national 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 Downpayment Toward a Balanced Budget and for Other Purposes (Public Law 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 requirement that accrediting organizations provide reasonable assurance that entities accredited by them would meet Medicare conditions or requirements. It now, in revised section 1865(b)(1) of the Act, requires organizations to demonstrate that their accredited entities would meet or exceed all of the applicable Medicare conditions. The legislation now also defines, in section 1865(b)(4) of the Act, the provider entities that we may consider for deemed status to include ASCs as suppliers. We are now required to publish an initial notice in the Federal Register 60 days after the receipt of a written request for a finding that accreditation by a national accreditation body demonstrates that the Medicare conditions or requirements are met.

This particular notice, however, is unique in that an expanded proposed draft had been developed along the lines of our requirements in the statute and regulations that were in effect before the enactment of section 516 of Public Law 104–134. We had received and accepted applications from JCAHO and AAAHC, two national accrediting bodies, long before the enactment of section 516 of Public Law 104–134. Therefore, this initial notice, unlike future deeming notices, contains material beyond the scope of the new legislative deeming requirements.

In this notice, we identify the national accreditation bodies making the deeming request, describe the nature of the request, and allow at least a 30-day public comment period. We received applications from JCAHO and AAAHC before the April 26, 1996 enactment of Public Law 104–134. Therefore, the timeframes imposed by the new legislation are not applicable to the processing of these two organizations' applications. However, AAAHC wrote to us on May 23, 1996 requesting that we process its application under the new timeframes. In order to comply with the requirement in revised section 1865(b)(3)(A) of the Act that we publish an initial notice identifying the national accreditation body making the request not later than 60 days after the date of receipt of that request, we must publish the notice by July 22, 1996. Likewise, in order to comply with the requirement that we publish an approval notice of our findings within 210 days after we receive an organization's deeming application, we must publish the approval notice by December 19, 1996. Since both applications had been submitted and considered before the enactment of Public Law 104–134, despite these timeframes, we will make every effort to publish the approval notice by November 22, 1996, which is 210 days after the date of the enactment of the new legislation.

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

- The equivalency of an accreditation organization's requirements for an entity to our comparable requirements for the entity.
- 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 its 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 by the organization to be out of compliance with program requirements. These monitoring procedures are used only when the organization identifies noncompliance. 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 as we may require (including corrective action plans).

C. Ambulatory Surgical Center Conditions of Coverage and Requirements

The regulations specifying the Medicare conditions of coverage for ASCs are located in 42 CFR 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. Proposed Approval of the Ambulatory Surgical Center Accreditation Standards of the Joint Commission of the Accreditation of Healthcare Organizations and the Accreditation Association for Ambulatory Health Care

The purpose of this notice is to propose that we recognize the accreditation programs of JCAHO and AAAHC, two national accrediting organizations, but only to the extent that they accredit ASCs. Based on a thorough examination of the standards, accrediting programs, and survey processes of both organizations, we believe that both JCAHO and AAAHC demonstrate that ASCs accredited by them meet Medicare conditions, and we, therefore, invite comments on our proposal to grant ASC deeming

authority to these two national organizations.

Section 1865(b)(3)(A) of the Act, as amended by section 516 of Public Law 104–134, states that a Federal Register approval notice granting deeming to accreditation organizations will follow no later than 210 days after the date of receipt of a written request or documentation necessary to make a determination on the request for deeming authority. We received applications from JCAHO and AAAHC before the April 26, 1996 enactment of Public Law 104–134. Therefore, the timeframes imposed by the new legislation are not applicable to the processing of these two organizations' applications. However, AAAHC wrote to us on May 23, 1996 requesting that we process its application under the new timeframes. In order to comply with the requirement in revised section 1865(b)(3)(A) of the Act that we publish an initial notice identifying the national accreditation body making the request not later than 60 days after the date of receipt of that request, we must publish the notice by July 22, 1996. Likewise, in order to comply with the requirement that we publish an approval notice of our findings within 210 days after we receive an organization's deeming application, we must publish the approval notice by December 19, 1996. Since both applications had been submitted and considered before the enactment of Public Law 104–134, despite these timeframes, we will make every effort to publish the approval notice by November 22, 1996, which is 210 days after the date of the enactment of the new legislation. The approval notice will specify the effective date of the deeming authority and the term of approval, which will not exceed 6 years.

Based on our initial review of each organization's standards and survey procedures contained in their individual applications and after our comparison of both organizations' standards to the Medicare ASC conditions and survey procedures, we contacted both JCAHO and AAAHC to discuss the differences between Medicare conditions and their standards.

We met separately with representatives from both organizations. The representatives responded to our concerns by proposing to change their standards for their member ASCs seeking Medicare certification. We subsequently received, from each organization, revised scoring guidelines with amended standards for their member ASCs requesting Medicare certification.

In evaluating the accreditation standards and survey processes of JCAHO and AAAHC to determine if they demonstrated that their accredited facilities meet 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. We outline below the differences between the Medicare requirements and the standards of the JCAHO and AAAHC and why we have concluded that they demonstrated that our requirements are met by their respective accreditation processes.

Before doing so, however, it is important to address the methods accreditation organizations and Medicare use to determine compliance. Information gathered during on-site surveys is the basis of an organization's accreditation decision. A surveyor or team of surveyors evaluates the ASC's level of compliance with applicable standards. Surveyors assess compliance in a variety of ways, including interviews, observations, and documentation reviews.

We refer frequently to the scoring guidelines that accompany each organization's standards. The scoring guidelines express parameters or common situations that the organizations' surveyors use to make judgments and assign scores to key requirements. Although scoring guidelines are not standards, they set forth the intent of the standard and describe the organizations' expectations as to how a particular standard must be met. These guidelines are consistently used by both organizations' surveyors in determining the score that will be applied to assess compliance with each standard.

When a surveyor evaluates a standard as having partial, minimal, or noncompliance, that is, when the scoring guideline has not been met or has been only partially met, a written recommendation results.

For example, an organization may use a 5-point scale to indicate an ASC's level of compliance with a standard. An ASC score of 1 or 2 for a particular accreditation standard corresponds to our determination of substantial compliance. A score of 3, 4, or 5 corresponds to our determination of noncompliance, which requires the ASC to submit an acceptable plan of correction. The facility's improvement will be monitored through a focused survey and/or written progress report. A written progress report assigned to address these deficiencies is normally due within either 1, 4, or 6 months from the date the accreditation is final. The plan of correction is monitored by the State Agency.

A. Differences Between the Joint Commission of the Accreditation of Healthcare Organizations and Medicare Conditions and Survey Requirements

We compared the standards contained in the JCAHO 1994 (and subsequent 1996) Accreditation Manual for Ambulatory Health Care and its survey procedures to the Medicare ASC conditions and survey procedures. We note that JCAHO standards exceed our conditions for coverage in some areas such as patient rights, education of patients and family, and continuity of care. In the following seven areas, however, Medicare conditions exceeded JCAHO standards as they existed before our discussions with JCAHO. As explained below, however, JCAHO now demonstrates that it meets our conditions in these areas.

Standards

Medicare ASC exclusivity requirement—Under our regulations at § 416.2 (''Definitions''), a Medicare ASC operates exclusively for the purpose of furnishing surgical services to patients not requiring hospitalization. JCAHO has no comparable surgical exclusivity requirement; however, for its member ASCs seeking Medicare certification, JCAHO has included a statement on ASC surgical exclusivity as an integral part of its application package. This statement by the ASC attests that the facility meets our requirements as to exclusivity and JCAHO would verify this attestation. Thus, JCAHO has taken adequate steps to match our exclusivity requirement.

Medicare requirement of ASC use of Medicare approved laboratory and radiological facilities—Section 416.49 (''Condition for coverage—Laboratory and radiologic services'') requires the use of Medicare-approved laboratory and radiologic facilities for ASCs while JCAHO requires only that laboratory and radiologic services be ''appropriate.'' JCAHO, however, has stated in its April 8, 1994 correspondence that an ASC seeking to use its accreditation for Medicare certification will be required, as an integral part of its application, to attest that, if it is not certified to perform its own laboratory services, it will obtain the services from a laboratory with certification under part 493 (''Laboratory Requirements''). The applicant ASC must also attest that it has procedures for obtaining radiologic services from a Medicare-approved facility to meet the needs of its patients. The ASC agrees to undergo JCAHO verification of these attestations before a

Joint Commission determination that the ASC qualifies for deemed status recognition. With this standard also, JCAHO has raised its requirements to an equivalency with our conditions.

Medicare requirement of separate recovery and waiting areas—Our regulations at paragraph (a)(2) of § 416.44 (''Condition for coverage—Environment'') require that Medicare ASCs have separate recovery and waiting areas. JCAHO has no requirement comparable to this Medicare condition for coverage. JCAHO in its revised 1996 Accreditation Manual for Ambulatory Health Care under the environmental care standard scoring guideline (EC.4.2) has included the Medicare requirement of separate recovery and waiting areas and will require compliance from its member ASCs seeking Medicare certification.

Medicare requirement relating to emergency equipment—Paragraph (c) of § 416.44 (''Condition for coverage—Environment'') requires that Medicare ASCs have specific equipment available to operating rooms. This equipment must include at least the following: emergency call systems, oxygen, mechanical ventilatory assistance equipment, cardiac defibrillator, cardiac monitoring equipment, tracheostomy set, laryngoscopes, endotracheal tubes, suction equipment, and emergency medical equipment and supplies specified by the medical staff. In its 1996 manual revision, JCAHO has amended its environmental care standard scoring guideline (EC.4.2) and enumerated the emergency equipment required by § 416.44(c). JCAHO's member ASCs requesting Medicare certification will comply with this requirement.

Patient care responsibilities for all nursing services personnel—Our regulations at § 416.46 (''Condition for coverage—Nursing services'') require that ASC nursing services be directed and staffed to assure that the nursing needs of all patients are met. Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be furnished in accordance with recognized standards of practice. Further, a registered nurse must be available for emergency treatment whenever there is a patient in the ASC. There was no comparable JCAHO requirement that patient care responsibilities be delineated for all nursing personnel. However, JCAHO has included, among its 1996 leadership standard scoring guidelines (LD.2.1 through LD.2.6), patient care responsibilities for nursing service personnel and requires compliance with this Medicare requirement for ASCs requesting Medicare certification.

Administration of drugs, drug prescriptions, and the administration of blood products—Our regulations at § 416.48 (''Condition for coverage—Pharmaceutical services'') are specific in their requirements regarding the administration of drugs, written drug administration, and follow-ups on oral prescriptions. JCAHO had no explicit standards comparable to these Medicare requirements.

JCAHO has included in its ''Management of Information'' standard scoring guidelines (IM.7 through IM.7.2) and ''Care of Patients'' standard scoring guideline (TX.5.3) revised procedures for obtaining blood and blood components to satisfy Medicare requirements. For example, in IM.7 through IM.7.2, orders given orally for drugs and biologicals must be followed by a written order signed by the prescribing physician and in TX.5.3, only physicians or registered nurses may administer blood and blood products.

Procedural Issue

Medicare requirement of unannounced surveys and frequency of surveys—JCAHO surveys of ASCs are announced, in contrast to the Medicare practice of conducting unannounced surveys. We believe that the findings on an announced survey are not comparable to those an unannounced survey may find when the facility is in its normal routine. JCAHO has agreed that it will conduct unannounced surveys of ASCs requesting to use their JCAHO accreditation for Medicare certification purposes.

JCAHO resurveys its ASCs every 3 years. Our original requirement was to survey ASCs every year. In practice, our resurveys have been averaging almost 3 years. Therefore, we accept JCAHO's 3-year resurvey cycle as comparable to ours.

We propose to make approval of JCAHO's accreditation program contingent on its continued agreement to implement the above seven changes in its standards and survey requirements. We believe that these changes bring JCAHO's accreditation program to a level at least equivalent to ours. JCAHO has thus demonstrated to our satisfaction that all of our applicable conditions or requirements are met or exceeded.

B. Differences Between the Accreditation Association for Ambulatory Health Care and Medicare Conditions and Survey Requirements

We compared the standards contained in the 1994 through 1995 (and subsequent 1996 through 1997) AAAHC Accreditation Handbook for Ambulatory Health Care and its survey procedures to the Medicare ASC conditions and survey procedures. We note that AAAHC standards exceed our conditions for coverage in some areas such as patient rights, radiation oncology treatment services, and occupational health services. In the following nine areas, however, Medicare conditions exceeded AAAHC standards, as they existed before our discussions with AAAHC. As explained below, however, AAAHC now demonstrates that it meets our conditions in these areas.

Standards

Medicare exclusivity requirement—Our regulations at § 416.2 (''Definitions'') define an ASC as a distinct entity operating exclusively for the purpose of furnishing surgical services to patients not requiring hospitalization. AAAHC had no comparable requirement.

AAAHC has supplemented its surgical services standard to include the Medicare exclusivity requirement for its ASCs that want to apply their AAAHC accreditation for Medicare certification purposes.

Medicare separate recordkeeping and staffing requirement—An ASC must be a separately identifiable entity, physically, administratively, and financially independent and distinct from other operations. Thus, an ASC maintains separate staff and keeps exclusive records. AAAHC had no comparable requirement but has supplemented its Chapter 10, ''Surgical Services'' section, to include requirements on exclusivity (that is, separate space, the nonmixing of functions, and separate recordkeeping and staffing).

Medicare requirement of separate recovery and waiting areas—Paragraph (a)(2) of § 416.44 (''Condition for coverage—Environment'') requires that Medicare ASCs have separate recovery and waiting areas. AAAHC does not require accredited facilities to have separate recovery room and waiting areas. AAAHC has included this requirement in its supplement to Chapter 8, ''Facilities and Environment,'' for ASCs interested in Medicare certification.

Adherence to the Life Safety Code of the National Fire Protection

Association—Under our regulations at paragraph (b) of § 416.44 (''Condition for coverage—Environment''), ASCs are generally required to comply with the provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association. While AAAHC standards contain a number of provisions related to ensuring patient and facility safety in the event of fire, AAAHC had not previously mandated compliance with the provisions of the National Fire Protection Association Life Safety Code but required compliance with applicable local or State safety codes.

Nevertheless, in its supplementary standard to Chapter 8, ''Facilities and Environment,'' AAAHC requires an ASC requesting Medicare certification to comply with the provisions of the National Fire Protection Association Life Safety Code. More specifically, the Life Safety Code is incorporated by reference into the AAAHC standard.

Specific Medicare requirements relating to pharmaceutical services—Medicare has specific requirements regarding adverse patient reaction to drugs, the administration of blood products and written/oral orders for drugs and biologicals (§ 416.48, ''Condition for coverage—Pharmaceutical services''). AAAHC requirements did not address these concerns.

AAAHC has stated in its supplement to Chapter 15, ''Pharmaceutical Services,'' that adverse drug reactions will be reported to the responsible physician and will be documented in the written record. Blood and blood products will only be administered by physicians and registered nurses. Further, orders given orally for drugs and biologicals will be followed by a written order, signed by the prescribing physician. We believe AAAHC's adoption of these practices ensures compliance with our requirement.

Medicare requirement relating to laboratory services—Medicare requires that physicians and other suppliers performing laboratory services meet the requirements of part 493 of our regulations (''Laboratory Requirements'').

AAAHC did not have this requirement but has included it in the supplement to Chapter 16, ''Pathology and Medical Laboratory Services.'' Specifically, an ASC that performs laboratory services must meet the requirements of part 493 of our regulations; if an 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 of our regulations. AAAHC further adds that this revised standard will be applicable to all organizations surveyed by AAAHC regardless of Medicare ASC status.

Medicare requirement on radiologic services—Medicare ASCs are required to obtain radiologic services from Medicare-approved facilities as outlined in our regulations at § 416.49 (''Condition for coverage—Laboratory and radiologic services''). The ASC must have procedures for obtaining radiologic services from a Medicare-approved facility to meet the needs of patients. AAAHC states in its supplement to Chapter 17, ''Diagnostic Imaging Services,'' that ASCs desiring Medicare certification must have arrangements with providers/suppliers of radiology services meeting Medicare conditions. This action, we believe, ensures that AAAHC's member ASCs seeking Medicare certification will comply with this requirement.

Hospitalization—Medicare requires ASCs to have procedures for transfer to a hospital of patients requiring emergency medical care beyond the ASC's capabilities. Medicare requires the hospital to be a local, Medicare-participating hospital, or a local, nonparticipating hospital that meets the requirements for payment for emergency services under Federal regulations. AAAHC required procedures for transfer to a nearby hospital but did not specify that it must be a Medicare participating hospital or a nonparticipating hospital meeting Federal emergency payment requirements. AAAHC has included this Medicare requirement in its supplement to Chapter 10, ''Surgical Services,'' for ASCs seeking Medicare certification.

Procedural Issue

Medicare requirement of unannounced surveys and resurvey frequency—AAAHC surveys of ASCs are announced in contrast to the Medicare practice of conducting unannounced surveys. In its handbook section, ''Accreditation Policies and Procedures,'' AAAHC has altered its original position and has stated that it will conduct unannounced surveys for ASCs seeking Medicare certification. AAAHC resurveys ASCS every 3 years. Our original requirement was to survey ASCs every year. In practice, our resurveys have been averaging almost 3 years. We therefore believe AAAHC's 3-year resurvey cycle meets Medicare requirements.

We propose to make our approval of AAAHC's accreditation program contingent on its continued agreement to implement the above nine changes to its standards and requirements. We believe that these changes bring AAAHC's accreditation program to a level at least equivalent to ours. AAAHC has thus demonstrated to our satisfaction that it meets or exceeds all Medicare applicable conditions or requirements.

After we evaluate public comments on this initial notice, we will issue an approval notice in accordance with section 516 of Public Law 104–134 and our regulations at § 488.12 (''Effect of survey agency certification''). Once this approval notice is approved and published in the Federal Register, ASCs would inform their respective State Agencies of their accreditation status with either the JCAHO or AAAHC. The State Agencies in turn, would inform their respective HCFA Regional Offices. The Regional Offices collect this information and put the information into the HCFA Online Survey and Certification Automated system.

C. Proposed Stipulations Relating to Accreditation by the Joint Commission on the Accreditation of Healthcare Organizations and the Accreditation Association for Ambulatory Health Care

According to our regulations at § 488.8 (''Federal review of accreditation organizations''), to ensure continuing comparability, an accreditation organization granted deeming authority is subject to continuing Federal oversight, which includes comparability reviews and validation reviews. Section 488.8 lists reapplication procedures, which may be no later than every 6 years. We propose to recognize as meeting Medicare's ASC conditions those ASCs accredited under JCAHO's and AAAHC's accreditation programs with the following restrictions included in § 488.8(e):

- We would reserve the right to withdraw deemed status from all JCAHO-accredited or AAAHC-accredited ASCs should either organization revise its standards or accreditation policies and procedures in a manner in which it fails to demonstrate that its ASCs continue to meet Medicare conditions.
- We also would reserve the right to withdraw deemed status from all JCAHO-accredited or AAAHC-accredited ASCs if we should change ASC conditions in a manner in which, after a time allowance specified in § 488.8(e), JCAHO or AAAHC standards or accreditation policies would not demonstrate that the revised Medicare ASC conditions are met.
- We would reserve the right to withdraw deemed status from all JCAHO or AAAHC accredited ASCs if a validation review or a public complaint

review reveals widespread, systematic, and unresolvable problems with the JCAHO or AAAHC accreditation process with respect to these ASC programs. These problems would provide evidence that JCAHO or AAAHC ASCs cease to demonstrate that they meet Medicare conditions.

D. Conclusion

For the reasons stated above, we believe that the JCAHO and AAAHC accreditation standards and survey processes, subject to the stipulations described, demonstrate that Medicare conditions or requirements have been met or exceeded. We therefore propose to deem ASCs accredited by JCAHO and AAAHC to be in compliance with the Medicare conditions for ASCs in accordance with the authority provided in section 1865 of the Act.

III. Paperwork Reduction Act

The burden reflected in this notice is referenced in the currently approved regulation entitled ''Granting and Withdrawal of Deeming Authority to National Accreditation Organizations (HSQ–159–F).'' The paperwork burden referenced in this regulation has been submitted to the Office of Management and Budget for review and approval under HCFA form number ''HCFA-R–191.'' Persons can reference the supporting statement for this paperwork collection (HCFA-R–191) on the INTERNET at http://www.hcfa.gov until the Office of Management and Budget's approval has been obtained.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on Federal Register documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Impact Regulatory Statement

In fiscal year 1993, there were 1,657 certified ASCs participating in the Medicare/Medicaid programs. We conducted 141 initial, 549 recertification (both at a cost of $537,312), and 18 complaint surveys. In fiscal year 1994, there were 1,855 certified ASCs. This was an increase of 198 facilities. We conducted 213 initial, 492 recertification (both at a cost of $555,068), and 24 complaint surveys. In fiscal year 1995, there were 2,105 ASCs. This was an increase of 250 Medicare/Medicaid certified ASCs. We conducted 211 initial, 288 recertification (both at a cost of $714,069), and 24 complaint surveys. As the data above indicate, the number of ASCs and the cost for conducting ASC surveys are increasing; however, the number of surveys conducted is decreasing. We contacted several Regional Offices to determine the number of pending ASC initial surveys, which number approximately 200 to 300. These pending initial surveys are not uniformly dispersed among the Regional Offices, so there would be a significant impact on some Regional Offices.

For the current fiscal year, the appropriation for survey activities has not increased over the levels granted for fiscal years 1994 and 1995. Yet, the numbers of participating providers and suppliers continue to increase. As indicated above, there was a 22 percent increase in ASCs within 3 years (fiscal years 1993 through 1995). In an effort to guarantee the continued health, safety, and services of beneficiaries in facilities already certified, as well as provide relief in this time of tight fiscal restraints, we are proposing to deem ASCs accredited by the JCAHO and AAAHC as meeting 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. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 28, 1996.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: July 18, 1996.

Donna E. Shalala,

Secretary.

[FR Doc. 96–18709 Filed 7–22–96; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of an Environmental Assessment/Habitat Conservation Plan and Receipt of Application for Incidental Take Permit for Construction and Operation of Residential Development on the Seven Oaks Ranch Property, in Austin, Travis County, Texas

SUMMARY: Bee Cave Oaks Development, Inc. (applicant) has applied to the U.S. Fish and Wildlife Service (Service) for an incidental take permit pursuant to Section 10(a)(1)(b) of the Endangered Species Act (Act). The applicant has been assigned permit number PRT–812688. The requested permit, which is for a period of 30 years, would authorize the incidental take of the endangered golden-cheeked warbler (*Dendroica chrysoparia*), and impacts to the proposed endangered Barton Springs salamander (*Eurycea sosorum*) have been addressed in the associated Habitat Conservation Plan. The proposed take on the 304-acre northern parcel may occur as a result of the development of 160 residential lots on 260 acres. Approximately 44 acres will be preserved as a greenbelt. Twenty-six residential lots are planned on approximately 29 acres of the 43-acre southern parcel, with 14 acres being preserved as a greenbelt. All construction will occur on the 347-acre Seven Oaks Ranch Property located in Austin, Travis County, Texas.

The Service has prepared the Environmental Assessment/Habitat Conservation Plan (EA/HCP) for the incidental take applications. A determination of whether jeopardy to the species will likely result or a Finding of No Significant Impact (FONSI) will not be made before 30 days from the date of publication of this notice. This notice is provided pursuant to Section 10(c) of the Act and National Environmental Policy Act regulations (40 CFR 1506.6).

DATES: Written comments on the application should be received on or before August 22, 1996.

ADDRESSES: Persons wishing to review the application may obtain a copy by writing to the Regional Director, U.S. Fish and Wildlife Service, P.O. Box 1306, Albuquerque, New Mexico 87103. Persons wishing to review the EA/HCP may obtain a copy by contacting Mary Orms, Ecological Services Field Office, 10711 Burnet Road, Suite 200, Austin, Texas 78758 (512/490–0063). Documents will be available for public inspection by written request, by