Annex II

Addendum 7

Supplemental Requirements when Appropriate for the Submission of Methods for Analysis and Release Specifications in Applications for Tablets and Dragee Dosage Form Products for Registration in the Russian Federation

Where appropriate for the product submitted:

1. Description (appearance, color of tablets, appearance in fracture, size of tablets, diameter and height, strength)
2. Average mass of tablets, method, allowable deviations
3. Identification test
4. Impurity(ies) test(s) (Chromatographic Profile)
5. Insoluble Ash test (HCl)
6. Disintegration test (method)
   AND/OR
7. Dissolution test
   OR
   Release rate test
8. Uniformity of Dosage Units test/Content uniformity test
9. Assay
10. Microbiology purity test(s)

''Requirement #8 shall apply for tablets in which proportion of active ingredient in one tablet amounts to 50 mg or less.

Annex II

Addendum 8

Supplemental Requirements when Appropriate for the Submission of Methods for Analysis and Release Specifications in Applications for Solid Oral Capsule Dosage Form Products for Registration in the Russian Federation

Where appropriate for the product submitted:

1. Description of capsule and its contents (appearance, form, color)
2. Identification test
3. Average weight of capsule contents/ weight variation test (method and allowable deviations)
4. Disintegration test (method and norms)
   AND/OR
   Dissolution test
   OR
   Rate of Release test
5. Uniformity of Dosage Units test/Content uniformity
6. Solubility test
7. Assay
8. Microbiology purity test
9. Impurity(ies) test(s) (Chromatographic Profile)

Requirements 5 and 6 apply to capsules in which proportion of active ingredient per one capsule amounts to 50 mg. or less.

Annex II

Addendum 9

Supplemental Requirements when Appropriate for the Submission of Methods for Analysis and Release Specifications in Applications for Suppository Products for Registration in the Russian Federation

Where appropriate for the product submitted:

1. Description (appearance, color, form, diameter, homogeneity)
2. Average weight of dosage unit test
3. Identification test
4. Melting point or measuring full deformation time (lipophilic bases)
5. Dissolution time (hydrophilic bases)
6. Test for Uniformity of Dosage Units (Content Uniformity)
7. Assay
8. Microbiology purity test(s)
9. Impurity(ies) test(s) (Chromatographic Profile)

Requirement 5 shall be observed for suppositories where proportion of active ingredient in one suppository amounts to 50 mg. or less.

Annex II

Addendum 10

Supplemental Requirements when Appropriate for the Submission of Methods for Analysis and Release Specifications in Applications for Topical Solid Products for External Use for Registration in the Russian Federation

Where appropriate for the product submitted:

1. Description (appearance, color)
2. Identification test
3. Net Contents test
4. pH of aqueous extraction solution
5. Uniformity of Dosage Unit test
6. Particle size test (Size determination of drug particles)
7. Sterility test(for eye ointments)
8. Assay
9. Microbiological purity tests
10. Impurity(ies) test(s) (Chromatographic Profile)

Requirement 6 shall apply in accordance with the type of ointment.

Annex II

Addendum 11

Supplemental Requirements when Appropriate for the Submission of Methods for Analysis and Release Specifications in Applications for Tincture and Extract products for Registration in the Russian Federation

Where appropriate for the product submitted:

1. Alcohol test
2. Description (appearance, color)
3. Identification test
4. Heavy metals
5. Specific gravity/density.
6. Residue on drying
7. Net contents test
8. Assay
9. Moisture content test

NOTE: This Applies only to tincture and extract regulated as drug products.

Medicinal Plants and Teas are not covered under this MOU.

[FR Doc. 96–32188 Filed 12–18–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[BPD–849–FN]

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: Final notice.

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

EFFECTIVE DATE: The provisions of this notice are effective beginning on December 19, 1996 through December 19, 2002.

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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. 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. 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.

In making our finding as to whether the accreditation body demonstrates 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.

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 accreditation 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 that we grant deemed status for ASCs.

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 body, then ASCs must be accredited by that body to receive Medicare certification. accreditation by an 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 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 accreditation organizations provide reasonable assurance that entities accredited by them would meet Medicare conditions 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 (e.g., ASCs) under the provider entities that we may consider for deemed status. We are required to publish an initial 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 we are required to publish a notice of our findings within 210 days after we receive an organization's deeming application.

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. We view this letter as triggering the schedule set forth in the new law, and we published the initial notice within 60 days of the May 23, 1996 letter from AAAHC. 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.

C. Ambulatory Surgical Center Conditions for Coverage and Requirements

The regulations specifying the Medicare conditions for 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. Provisions of the Proposed Notice

The initial notice proposed to recognize the accreditation programs of JCAHO and AAAHC, two national accrediting organizations, but only to the extent that they accredited ASCs.

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 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 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.)

We met separately with representatives from each organization. In evaluating the accreditation standards and survey processes of JCAHO and AAAHC to determine if they demonstrated that their 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 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.

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. In seven areas, JCAHO has made the following revisions:

- *Exclusivity requirement*—JCAHO has included a statement on ASC surgical exclusivity as an integral part of its application package.
- *Use of Medicare approved laboratory and radiological facilities*—An accredited 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 a certification under part 493 (''Laboratory Requirements''). The 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.
- *Separate recovery and waiting areas*—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 accredited ASCs seeking Medicare certification based on their accreditation.
- *Emergency Equipment*—In its 1996 manual revision, JCAHO has amended its environmental care standard scoring guideline (EC.4.2) and enumerated the emergency equipment required by 42 CFR § 416.44(c).
- *Patient care responsibilities for all nursing services personnel*—JCAHO has included, in 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 based on their accreditation.
- *Administration of drugs, drug prescriptions, and the administration of blood products*—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.
- *Unannounced surveys and frequency of surveys*—JCAHO has agreed that it will conduct unannounced surveys of ASCs requesting to use their JCAHO accreditation for Medicare certification purposes.

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

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. In nine areas, AAAHC has made the following changes:

- *Exclusivity requirement*—AAAHC has supplemented its surgical services standard to include the Medicare exclusivity requirement for its accredited ASCs that want to apply AAAHC accreditation for Medicare certification purposes.
- *Separate recordkeeping and staffing requirement*—AAAHC 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).
- *Separate recovery and waiting areas*—AAAHC has included this requirement in its supplement to Chapter 8, ''Facilities and Environment,'' separate recovery and waiting areas for ASCs interested in Medicare certification based on AAAHC accreditation.
- *Life Safety Code of the National Fire Protection Association*—AAAHC supplementary standard to Chapter 8, ''Facilities and Environment,'' requires an ASC requesting Medicare certification, based on accreditation, 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.
- *Requirements relating to pharmaceutical services*—AAAHC states 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.

• *Requirement relating to laboratory services*—AAAHC did not have this requirement but has included it in the supplement to Chapter 16, ''Pathology and Medical Laboratory Services.'' Specifically, as 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.

• *Radiologic services*—AAAHC states in its supplement to Chapter 17, ''Diagnostic Imaging Services,'' that ASCs desiring Medicare certification based on their accreditation must have arrangements with a Medicare approved providers/suppliers of radiology services to meet the needs of patients.

• *Hospitalization*—AAAHC has included the Medicare requirement in its supplement to Chapter 10, ''Surgical Services,'' for ASCs seeking Medicare certification based on AAAHC accreditation to transfer to a hospital a patient requiring emergency medical care beyond the ASC's capabilities. If further requires that the hospital be a local, Medicare-participating hospital, or a local, nonparticipating hospital that meets the requirements for payment for emergency services under Federal regulations.

• *Unannounced surveys and resurvey frequency*—AAAHC handbook section, ''Accreditation Policies and Procedures,'' has stated that it will conduct unannounced surveys for ASCs seeking Medicare certification based on AAAHC accreditation.

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. Therefore AAAHC's 3-year resurvey cycle meets Medicare requirements.

C. Proposed Stipulations Relating to Accreditation by the Joint Commission on the Accreditation of Health Care 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 grant 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 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(d):

• We 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 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(d), JCAHO or AAAHC standards or accreditation policies would not demonstrate that the revised Medicare ASC conditions are met.

• We reserve the right to withdraw deemed status from all JCAHO or AAAHC accredited ASCs if a validation review or a public complaint 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 cease to demonstrate that they meet Medicare conditions.

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 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. The provisions of this notice are effective beginning on December 19, 1996 through December 19, 2002.

D. Analysis and Responses to Public Comments

We receive 86 comments to our July 23, 1996 notice. Of these, 63 were from ASCs or medical centers, 11 from M.D.s, 1 from a dentist, 10 from professional medical associations an 1 from a State government. Seventy-eight (78) commenters favored deeming for JCAHO and AAAHC, 6 approved deeming with reservations and 1 opposed it. A summary of these comments and our responses are discussed as follows:

• *Comment:* Seventy-eight (78) commenters, most of whom are ASCs, expressed strong support for our approval of the JCAHO's and AAAHC's applications for deemed status. Commenters stated that the two organizations are leaders in the development of outpatient oriented health care delivery and have developed standards of care and survey process that accrue the highest possible quality health care in the ambulatory setting.

• *Response:* We acknowledge the support shown and have developed an approval notice consistent with the provisions contained in our initial notice.

• *Comment:* One commenter suggested that since AAAHC's application for deeming was filed prior to the enactment of the new deeming legislation (Public Law 104–134), AAAHC's application should be considered filed the date Public Law 104–134 was enacted (April 26, 1996).

Response: As we stated in the initial notice, we do not believe the timeframe set forth in the new deeming legislation is applicable to deeming applications filed prior to its enactment. We viewed the letter that AAAHC wrote to us on May 23, 1996, requesting that we process its application under the new timeframes, as triggering the new timeframes. In order to comply with the requirements 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 the request, we placed our initial notice on public display July 19, 1996, and it appeared in the July 23, 1996 issue of the Federal Register. Likewise, in order to comply with the requirement that we publish an approval notice of our findings within 210 days after we received an approved notice by December 19, 1996.

Comment: One commenter stated that AAAHC's ASC ''accreditees'' are not ''members'' of AAAHC.

Response: We accept this comment and will refrain from referring to AAAHC accredited ASCs as members of AAAHC.

Comment: Five commenters stated that if a national accreditation organization has its deeming authority

withdrawn by HCFA, this change should not affect ASCs already granted deemed status based on the organization's accreditation. In the same vein, three other commenters expressed concern about possible consequences to an ASC if the ASC's accreditation organization lost its deeming authority. One commenter argued that HCFA would not revoke Medicare certification of an ASC certified by a State surveyor if HCFA changed the conditions for coverage, or if the State surveying agency changed its survey procedures. The commenter stated that HCFA should conduct a facility by facility review to determine which facilities continue to satisfy Medicare conditions.

Response: Our procedures have been well established in regulations and we must follow them in this notice. In accordance with 42 CFR 488.8 (f)(7), should we rescind an accreditation organization's deeming authority, we will publish a notice in the Federal Register detailing the reasons for such action. Accreditation organizations are required to notify all accredited ASCs within 10 days of our withdrawal of their deeming authority.

Under 42 CFR 488.8(f)(8) an affected ASC retains its deemed status for 60 days after notification and it can be extended an additional 60 days if we determine that the ASC submitted an application within the initial 60-days timeframe to another approved accreditation organization or to us so that compliance with Medicare conditions can be determined. An ASC's failure to do so will jeopardize its participation in the Medicare program.

Comment: One commenter requested that HCFA address the issue of an ASC applying to a deemed accreditation organization for Medicare certification based on its accreditation when the ASC is exempted by its State from licensure requirements. The commenter gave the example of an entity qualifying as a physician's office which is exempt from licensure under State law. In this case, the commenter concluded the accreditation organization would request that the ASC procedure either a license or evidence of exemption from licensure.

Response: Section 416.26(a)(2) requires that facilities seeking Medicare certification as ASCs based on their accreditation by either JCAHO or AAAHC comply with State licensure requirements where applicable. Therefore, in the example cited, the commenter is correct in stating that the accreditation organization would request a license or evidence of exemption if the State permits a physician's office to operate as an ASC.

Comment: One commenter questioned if deemed status will apply to physicians' offices that meet the standards set by AAAHC for ASCs but do not otherwise qualify as ASCs as defined by State laws.

Response: As previously stated, if State law requires a license for a facility to operate in that State as an ASC, such requirement must be met before an entity such as a physician's office accredited by the JCAHO or AAAHC under its ASC accreditation program can be granted deemed status for Medicare certification as an ASC.

Comment: Two commenters asked how deemed status affects ASCs that were Medicare certified through State survey and accredited by either JCAHO or AAAHC prior to HCFA's approval of deemed status for these accreditation organizations. One of the commenters also asked if there is a deadline by which a currently certified ASC should notify HCFA that it is accredited by a deemed organization.

Response: After this approval notice is published in the Federal Register, ASCs accredited by either JCAHO or AAAHC, and already Medicare certified, are considered deemed for Medicare certification. When this status change is executed 42 CFR 488.7(a) discharges the State agencies from ongoing responsibility for conducting periodic surveys in deemed ASCs unless the ASC is selected for a sample validation survey or there is a substantial allegation of noncompliance. If the ASC is selected for a sample validation survey, the ASC will be notified by the State agency before the survey is conducted. In accordance with 42 CFR 488.7, State surveyors will determine if the ASC is out of compliance with a condition of coverage. If the ASC is found to be out of compliance, the ASC will no longer be deemed to meet the Medicare conditions and will be subject to full review by the State agency. Likewise, if there is a substantial allegation of noncompliance and the State agency conducts a compliance survey and finds a condition for coverage out of compliance, the ASC will be subject to full review by the State agency.

Comment: Another commenter asked that we explain the procedure that new ASCs would follow to become Medicare certified after we grant deem status to JCAHO and AAAHC.

Response: First, Medicare certification based on accreditation is strictly voluntary. ASCs seeking Medicare certification, have the option of determining whether they would prefer certification based on (1) a State agency survey or (2) accreditation by one of the deemed organizations. If the ASC chooses the first option, it would apply directly to the State survey agency in its area with which we have a survey agreement. After the survey is completed the State agency would forward its recommendation for Medicare certification to the appropriate regional office for processing. Our regional office would notify both the ASC and the State agency of the ASC's eligibility to participate in the Medicare program.

If the ASC elects the second option, the accreditation organization would send a notice to our applicable regional office indicating the ASC's accreditation status and whether the ASC is deemed or not deemed for Medicare certification. The accrediting organization should also send a courtesy copy of such notification to the appropriate State agency. One receipt of such notification, the regional office will advise both the ASC and appropriate State agency of the ASC's Medicare certification status.

Comment: One commenter believed it should remain the sole entity within the State responsible for determining facilities' Medicare certification for outpatient surgery since it believed surgical procedures could eventually be attempted in settings inappropriate for surgery. The commenter stated that all such facilities should be licensed by the State department of public health.

Response: We have no reason to believe that granting deeming authority to either JCAHO or AAAHC will result in outpatient surgery being performed in inappropriate settings. Based on our review of each accreditation organization's standards and survey policies and procedures, we have determined that they both demonstrate the ASCs accredited by them would meet or exceed HCFA conditions. Furthermore, in this notice we reserve the right to revoke deemed status for all JCAHO-accredited or AAAHC-accredited ASCs should either organization revise its standards or accreditation policies and procedures in a manner which fails to demonstrate that its ASCs continue to meet Medicare conditions; or if a validation review or a public complaint review reveals widespread, systematic, and unresolved problems with either organization's accreditation process for ASCs; or if we determine that either organization has failed to sufficiently revise its standards to the extend necessary to demonstrate that revised Medicare conditions are met and enforced. Moreover, each State has the option to establish more stringent licensure requirements or

monitoring procedures to safeguard the quality of surgery performed in an ASC.

Comment: One commenter believes that both JCAHO's and AAAHC's anesthesia requirements are not equivalent to Medicare's anesthesia conditions since neither organization currently requires physician supervision of non-physician administration of anesthesia and since JCAHO's standards contain no provision as to the identity or supervision of the actual anesthesia provider.

Response: We believe that the commenter may be referring to these organizations' anesthesia standards as stated prior to each organization's most recent handbook editions. JCAHO's 1996 Comprehensive Accreditation Manual for Ambulatory Care Section 2 Leadership (LD), standard LD 1.9–2.6 and AAAHC's 1996–1997 Accreditation Handbook for Ambulatory Health Care (Chapter 9) supplement their previous requirements in order to meet Medicare's anesthesia conditions. We have examined both organizations' supplemental anesthesia standards and are satisfied that both organizations demonstrate they meet our requirements for physician supervision of non-physician administration of anesthesia and identification of the anesthesia provider under 42 CFR 416.42(b) Standard: Administration of Anesthesia.

Comment: One commenter advocated eliminating HCFA's requirement that physicians supervise certified registered nurse anesthetists. The commenter stated that HCFA seemed receptive to this recommendation when considering revisions of its hospital conditions of participation.

Response: We cannot accept this comment. The issue raised is not the subject of this notice, which is limited to the approval of ASC deeming authority for JCAHO and AAAHC.

Comment: One commenter expressed concern about the dominating presence of physicians on each of the governing bodies for JCAHO and AAAHC. The commenter believed that these organizations should have representatives on their governing bodies that reflect broad community interest.

Response: Revised section 1865(b)(1) of the Act requires us to determine whether accreditation by a national accreditation organization demonstrates that Medicare conditions are met. We have determined that accreditation by JCAHO and AAAHC demonstrate that Medicare conditions for ASCs are met. Because there are no statutory or regulatory requirements for broad community representation on the governing or advisory boards or committees of private accreditation organizations, we are not in a position to require either JCAHO or AAAHC to include any specific groups on its boards or committees. Our primary concern is the content and application of the accreditation standards and procedures.

Comment: One commenter stated that HCFA should be aware that the private creation of patient care standards is fraught with peril by virtue of the thrust of the federal antitrust laws. The comment read: ''Simply stated, it cannot be routinely expected that private standard-setting bodies will make legitimate patient safety considerations paramount when confronted with the threat of antitrust legislation, a threat which HCFA does not face.''

Response: HCFA, in its process of granting deemed authority, is not fostering the creation of private patient care standards. We have our own conditions for coverage and the organizations requesting deemed authority must have their standards meet these conditions. Therefore, since outside groups are not acting together to create private care standards, we do not anticipate antitrust implications.

Comment: One commenter proposes that we modify our regulations to allow AAAHC to perform ''unannounced inspections'' rather than ''unannounced surveys'' to assess an ASC's compliance with Medicare conditions. The commenter suggests that unannounced inspections for compliance be conducted in conjunction with regularly scheduled tri-annual full surveys. The commenter contends that ''the time and cost (disruption) associated with a full survey is quite high.'' The commenter argues that inspections would be less disruptive and require fewer staff resources.

Response: We believe the commenter has assumed that mandated use of unannounced surveys for ASCs seeking Medicare certification based on their AAAHC accreditation would necessitate two separate survey processes for such ASCs, i.e., an announced survey to accredit an ASC plus an unannounced survey to determine if the ASC meets our Medicare conditions. We have no intention of imposing such survey requirements on either AAAHC or ASCs. Instead, the required use of unannounced surveys simply means that AAAHC would conduct full triennial surveys on ASCS seeking deemed status without advising them in advance that such a survey is forthcoming on a specific date.

Comment: One commenter asked for a definition of an ''unannounced'' survey. Specifically, the commenter wanted to know if JCAHO would still send a notice of intent to survey prior to conducting the survey.

Response: As a matter of policy, we interpret unannounced surveys to mean the accreditation organization will not send a notice of intent to survey an ASC prior to conducting the survey for those ASCs that want their accreditation to count for Medicare certification. We understand that unannounced surveys may result in some minor survey problems; therefore, under section 2700 (''The Survey Process'') of our State Operations Manual, facilities may be given advanced notice (no more than two working days) if the following two criteria are met:

- The facility is inaccessible via conventional travel means and making special or extraordinary travel arrangements are necessary; and
- There is a high probability that the staff essential to the survey process will be absent or the facility will be closed unless the survey is announced.

Both accrediting organizations have agreed to the unannounced survey process for those ASCs that wish to be deemed to meet Medicare conditions for coverage based on their accreditation. Hence, the ASCs that are deemed to meet Medicare conditions for coverage based on accreditation will not be sent a notice of intent to survey, unless both of the above criteria are met.

Comment: One commenter said it is unclear from our initial notice whether we have made an attempt to assess the ability of JCAHO and AAAHC to monitor Life Safety Code application. The commenter was not aware of any ongoing capability to survey and assess the compliance with Life Safety Code requirements.

Response: In our initial notice, we discussed specific areas in which our Medicare conditions for ASCs exceeded accreditation standards for both JCAHO and AAAHC as they existed prior to discussions with both organizations and before their submittal of amendments or supplements to their standards, survey procedures are scoring guidelines were submitted to comply with Medicare ASC conditions. On examination, we found no disparity between our Life Safety Code condition and JCAHO's standard. However, as stated in our initial notice, examination revealed that AAHC had not previously mandated compliance with the provisions of the National Fire Protection Association Life Safety Code as we require for ASCs. Instead, AAAHC had heretofore required compliance with applicable local or State safety codes to ensure patient and facility safety in the event of fire. We advised in our initial notice

that AAAHC had developed a supplementary standard to Chapter 8, ''Facilities and Environment'', that requires an ASC requesting Medicare certification to comply with the provisions of the National Fire Protection Association Life Safety Code. Furthermore, AAAHC has incorporated the Life Safety Code by reference into the AAAHC standard. Therefore, we have no reason to believe these two organizations lack the ability to monitor Life Safety Code application.

Comment: One commenter asked how State agencies would monitor plans of corrections for deficiencies or violations cited by JCAHO or AAAHC as proposed on page 61 FR 38209 of our initial notice. The commenter also asked how State agencies would obtain such violations in a timely manner; how State surveys would be trained to survey against the deemed organization's standards; and how this monitoring activity would be funded.

Response: Thank you for indicating a discrepancy in our discussion on page 61 FR 38209 about monitoring an ASC's plan of correction. The discussion pertains to the use of an accreditation organization's scoring guidelines to assess an ASC's level of compliance with its standards. In that discussion, we incorrectly stated that the State agency would monitor an ASC's plan of correction if the ASC received from the organization a score of 3, 4, or 5, which corresponds to our determination of noncompliance. We should have instead stated that in such cases the accreditation organization, not the State agency, would monitor the ASC's correction plan.

Comment: One commenter expressed concern about the ability of JCAHO and AAAHC to investigate individual complaints about a specific provider it accredits.

Response: Our evaluation of the accreditation programs for both JCAHO and AAAHC did not detect any indications that either of these organizations would be incapable of investigating individual complaints about any ASC either organization accredits.

III. Paperwork Reduction Act

The public reporting and recordkeeping 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 HSQ–159–F 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 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. In fiscal year 1996, there were 2,219 ASCs. This was an increase of 114 Medicare/Medicaid certified ASCs. We conducted 180 initial, 115 recertification (both at a cost of $848,125) and one complaint survey. 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 during fiscal year 1996 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.

While the fiscal year 1997 appropriation for survey activities has been substantially increased (by seven percent) for the first time in four years, the increase is insufficient to meet the survey demand. The numbers of participating providers and suppliers continue to increase. As indicated above, there was a 25 percent increase in ASCs within 4 years (fiscal years 1993 through 1996). 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 approving deeming for 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 provision 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: December 6, 1996.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: December 13, 1996.

Donna E. Shalala,

Secretary.

[FR Doc. 96–32194 Filed 12–18–96; 8:45 am]

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Health Resources and Services Administration Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of February 1997:

Name: National Advisory Committee on Rural Health.

Dates and Time: February 3–5, 1997.

Place: The Westin (Formerly known as The Vista Hotel), 1400 M Street, N.W., Washington, D.C. 20005, Phone: (202) 429–1700, FAX: (202) 785–0786.

The meeting is open to the public.

Agenda: The plenary session on Monday, February 3, will convene at 8:30 a.m. The meeting will be devoted to developing the Committee's agenda for the coming year. There will be discussion of linkages between the activities of the Advisory Committee and rural research centers supported by the Office of Rural Health Policy. There will be a general review of the Advisory Committee's activities in light of departmental and congressional priorities for the coming year.

On Monday afternoon and Tuesday, February 4, the Committee will meet in Work Group sessions to deliberate and refine objectives relating to J–1 Visas and Antitrust issues initiated at the last meeting.

The meeting will convene at 8:30 a.m. on Wednesday, February 5. Adjournment is anticipated by 12:30 p.m.

Anyone requiring information regarding the subject Committee should contact Dena S. Puskin, Executive Secretary, National Advisory Committee on Rural Health, Health Resources and Services Administration, Room 9–05, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–0835, FAX (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Ms. Arlene Granderson or Lisa Shelton, Office of Rural Health Policy, Health Resources and Services Administration, Telephone (301) 443–0835.

Agenda Items are subject to change as priorities dictate.

Dated: December 16, 1996.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 96–32270 Filed 12–18–96; 8:45 am]

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