Volume 69, Number 215, pages 64762–64769.

The notice is amended as follows: On page 64765, second column, Section IV.2, line 4, delete ''Maximum number of pages: 25 pages'' and replace with ''Maximum number of pages: 2 pages.''

Dated: November 19, 2004.

Alan A. Kotch,

Acting Deputy Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04–26184 Filed 11–24–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–5011–WN]

Medicare and Medicaid Programs; Notice of Withdrawal of the Solicitation of Proposals for the Private, for-Profit Demonstration Project for the Program of All-Inclusive Care for the Elderly (PACE)

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

ACTION: Withdrawal notice.

SUMMARY: This document withdraws the ''Notice for the Solicitation of Proposals for the Private, For-Profit Demonstration Project for the Program of All-Inclusive Care for the Elderly (PACE)'' published in the **Federal Register** on August 10, 2001. That notice solicited proposals from private, for-profit organizations for a fully captitated joint Medicare and Medicaid demonstration. The goal of the solicitation notice was to determine whether the risk-based long-term care model employed by the nonprofit PACE could be replicated successfully by for-profit organization.

EFFECTIVE DATE: March 28, 2005.

FOR FURTHER INFORMATION CONTACT: Michael Henesch, (410) 786–6685.

SUPPLEMENTARY INFORMATION:

I. Background

Section 4804(a)(2) of the Balance Budget Act of 1997 (BBA) requires us to conduct a study to compare the costs, quality, and access to services provided by for-profit entities to those of nonprofit Program of All-Inclusive Care for the Elderly providers (PACE). Section 4801(h)(2)(A) of the BBA states that the terms and conditions for the for-profit PACE must be the same as those for PACE providers that are nonprofit, private organizations except that only 10 waivers may be granted.

On August 10, 2001, we published a notice in the **Federal Register** (66 FR 42229). The notice solicited proposals from for-profit entities to demonstrate that they could successfully provide comprehensive coordinated care for the frail elderly under a prepaid fully capitated payment system. The solicitation notice specified that we would consider proposals only from for-profit organizations and the demonstration would operate for 3 years.

II. Provisions of the Notice

This notice withdraws the solicitation notice that we published in the **Federal Register** on August 10, 2001. As specified in the solicitation notice, we would consider proposals only from for-profit organizations and the demonstration would operate for 3 years. Before submitting a proposal, all interested applicants were to submit letters of intent. We indicated that proposals would be accepted until 10 sites were awarded. Following the selection of 10 sites, organizations that had submitted letters of intent, but had not yet submitted proposals, would be notified that the limit of approved sites had been reached.

Since the publication of the solicitation notice, we received only ten letters of intent. Of these 10 letters of intent, 8 were received in 2001 and early 2002, 1 was received in February 2003, and 1 was received in August 2003. Although we have provided information to numerous organizations including having discussions with the organizations that have submitted letters of intent, we have not received any proposals. We have also contacted the two most recent organizations that have submitted letters of intent to offer technical assistance and have ascertained that only one organization has considered submitting a proposal. In addition, we have been informed by the National PACE Association, that it has consulted with organizations that have not submitted letters of interest.

Although the demonstration is mandated by the BBA, since CMS has not received any proposals that it could fund under the authority of the BBA, we are withdrawing our solicitation.

The need to keep abreast of regulatory provisions of the nonprofit PACE requires us to attend all PACE meetings, since the for-profit PACE demonstration would mirror nonprofit PACE policy. In the nearly 3 years since the implementation of the solicitation notice, the effort to maintain this level of activity has been extensive. With the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), we believe that our resources can better be utilized in addressing other workloads, including various studies, and other efforts related to the start-up of new programs and benefits. Furthermore, we believe it is unlikely that we will receive a proposal for a for-profit PACE demonstration. Therefore, we are withdrawing the August 10, 2001, solicitation notice.

This notice is intended to withdraw the solicitation by March 28, 2005. This withdrawal notice provides an opportunity for organizations that remain interested to submit proposals until that time.

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

Authority: Section 1894(h) and 1934(h) of the Social Security Act (42 U.S.C. 1395)

(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: September 10, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 04–25980 Filed 11–24–04; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2202–FN]

Medicare and Medicaid Programs; Approval of Application for Deeming Authority for Ambulatory Surgical Centers by the American Association for Accreditation of Ambulatory Surgery Facilities, Inc.

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

ACTION: Final notice.

SUMMARY: This final notice announces the approval of an application from the American Association for Accreditation of Ambulatory Surgery Facilities, Inc., (AAAASF) for continued recognition as a national accrediting organization for ambulatory surgical centers (ASCs) that request participation in the Medicare or

Medicaid programs. Following an evaluation of the organizational and programmatic capabilities of AAAASF, we determined that AAAASF's standards for ASCs meet or exceed the Medicare conditions for coverage. Therefore, ASCs accredited by AAAASF under the CMS-approved program will be deemed to have met the conditions for coverage under the Medicare program.

EFFECTIVE DATE: This final notice is effective November 26, 2004 through November 26, 2009.

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

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Provisions and Regulations

Under the Medicare program, eligible beneficiaries may receive covered services in an ambulatory surgical center (ASC), provided that the ASC meets certain requirements. Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) authorizes the Secretary to establish distinct criteria for a facility seeking designation as an ASC. Under this authority, the Secretary has set forth in regulations minimum requirements that an ASC must meet to participate in Medicare. The regulations at 42 CFR part 416 (Ambulatory Surgical Services) specify the conditions under which Medicare makes payments for covered services provided by an ASC. Applicable regulations concerning provider agreements are at part 489 (Provider Agreements and Supplier Approval) and those pertaining to facility survey and certification are at part 488 (Survey Certification and Enforcement Procedures), subparts A (General Provisions) and B (Special Requirements).

B. Verifying Medicare Conditions for Coverage (CfC)

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

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

II. Deeming Application Approval Process

Section 1865(b)(3)(A) of the Act provides a statutory timetable to ensure that we conduct our review of deeming applications in a timely manner. The Act provides us with 210 calendar days after the date of receipt of a complete application to complete our survey activities and application review process. Within 60 days of receiving a completed application, we must publish a notice in the **Federal Register** that identifies the national accreditation body making the request, describes the nature of the request, and provides no less than a 30-day public comment period.

III. Provisions of the Proposed Notice

On July 23, 2004, we published a proposed notice (69 FR 44027) in the **Federal Register** that announced the American Association for Accreditation of Ambulatory Surgery Facilities, Inc.'s (AAAASF's) request for approval as a deeming organization for ASCs. In that notice, we detailed our evaluation criteria. Under section 1865(b)(2) of the Act and regulations at § 488.4, we conducted a review of AAAASF's application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite administrative review of AAAASF's (1) corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and (5) survey review and decision-making process for accreditation.
- A comparison of AAAASF's ASC accreditation standards to our current Medicare conditions for coverage.
- A documentation review of AAAASF's survey processes to:

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

In accordance with section 1865(b)(3)(A) of the Act, the proposed notice also solicited public comments regarding whether AAAASF's requirements met or exceeded the Medicare conditions for coverage for ASCs.

We did not receive public comments regarding AAAASF's renewal application as a national accrediting organization for ASCs.

IV. Provisions of the Final Notice

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

On March 18, 2004, we sent a letter to AAAASF stating that ''AAAASF's new and revised standards meet or exceed the Medicare CfCs for ASCs and therefore has approved the revisions forwarded to CMS on March 3, 2004.'' We sent this letter in response to AAAASF's September 2003 submission of new and revised standards. Although, we approved the new and revised standards on March 18, 2004, AAAASF indicated in a letter dated June 10, 2004 that ''it will not implement its new standards until October 1, 2004 and that the approved Medicare standards will be printed prior to August 1, 2004 and will be sent to all new applicants after that date.'' Since AAAASF's implementation of its new and revised standards occurred during the review of its renewal application, we are including in this final notice AAAASF's

comments and responses to our review of its crosswalk ''Comparison of New AAAASF Standards and CMS Standards.'' The purpose of this review was to ensure that AAAASF's standards met or exceeded the Medicare CfCs for ASCs. The review yielded the following:

- In order to meet the requirements of § 416.41, AAAASF added to its standard that the governing body is legally responsible for the safe and effective operation of the ASCs.
- We requested AAAASF to clarify its standard *AAAASF number 4.020.11.0,* regarding its criteria for patient discharge. In addition, we recommended that AAAASF strike its reference to Post Anesthesia Care Unit (PACU) and insert ASC. AAAASF responded and revised its standards by requiring the physician to examine the patient immediately before discharge from the ASC. Lastly, AAAASF adopted our recommendation and removed PACU from its standards and inserted ASC.
- In order to meet the requirements of § 416.42(c), we recommended that AAAASF revise its standard, *AAAASF standard 8.001.08.0,* by requiring the ASCs to provide not only the patient's legally responsible representative with post-operative instructions before discharge, but also the actual patient himself or herself with post-operative instructions before discharge. AAAASF adopted our recommendation by revising its standard, which now requires adequate written post-operative instructions (including procedures in emergency situations) to be given to the patient and, if applicable, the adult responsible for the patient's care before discharge.
- AAAASF standard *10.002.01.0* indicated that the facility must display ''a professional look.'' We requested that AAAASF provide a definition/clarification of ''a professional look'' to ensure that its standard was in accordance with § 416.44. As referenced in Comparison of New AAAASF Standards and CMS Standards, AAAASF defines a professional look as ''the facility being properly constructed, equipped, and maintained to protect the health and safety of patients.''
- In order to meet the requirements of § 416.44(a)(2), we recommended that AAAASF revise its standard *3.032.02.0,* by requiring the ASC to have a separate recovery and waiting area. AAAASF revised its standard by requiring ASCs' recovery rooms in its Medicare ASCs to be distinctly separate and segregated from the waiting area.
- We asked AAAASF to revise its standard *9.002.00.1,* to comply with § 416.44(c)(1), by requiring its operating rooms (ORs) to have an emergency call system present in the OR. AAAASF revised its standards accordingly.
- To comply with § 416.44(c)(4), AAAASF revised its standard *9.002.00.4,* by requiring its facilities to use standard cardiac defibrillators versus an automated external defibrillators.
- We asked AAAASF to revise its standard *9.002.00.9,* which did not state that emergency medication must be readily available in the OR. The AAAASF standard failed to meet the requirements set forth in § 416.44(c)(9). AAAASF adopted our recommendation.
- AAAASF standard *7.004.09.0* failed to meet our standard § 416.44(d), by not specifying who was responsible for the use of cardiopulmonary resuscitation equipment in the ASC. AAAASF revised its standard by requiring a physician, Certified Registered Nurse Anesthetist (CRNA) or registered nurse (RN) with Advanced Cardiac Life Support certification or who is otherwise qualified in resuscitation to be immediately available in the facility until all patients have been discharged from the ASC.
- AAAASF standard *11.000.05.4* failed to reference granting privileges in accordance with recommendations from qualified medical personnel, as referenced at § 416.45(a). AAAASF revised its standard accordingly.
- We requested that AAAASF revise its standard *11.000.01.2,* which failed to state that medical staff would be accountable to the governing body. AAAASF revised it standard in accordance with our regulations at § 416.45.
- AAAASF standard *4.001.01* did not require medical records to be complete and comprehensive in accordance with § 416.47. AAAASF revised its standard by requiring medical records to be accurate, legible, documented, complete, comprehensive, and filed in a timely manner to ensure adequate patient care.
- In order to meet the requirements of § 416.47(b)(4), we recommended that AAAASF insert the phrase ''except those exempted by the governing body'', in its standard *4.020.05.0.* AAAASF adopted our recommendation. The standard now is identical to § 416.74(b)(4).
- In order to meet the requirements of § 416.47(b)(5), we recommended that AAAASF revise its standard *4.003.01.3,* by requiring the medical record to include documentation of patient drug reactions. AAAASF adopted our recommendation.
- In accordance with § 416.47(b)(8), AAAASF revised its standard *8.000.04.0,* to require the physician to include the discharge diagnosis in the patient's medical record.
- In accordance with § 416.48(a), AAAASF revised its standard *8.001.06.0,* to require a physician or RN to administer drugs to patients.

In addition to conducting a review of AAAASF's standards, we reviewed the materials contained in ''AAAASF Medicare Resource Guide,'' ''AAAASF's Policy and Procedures Manual,'' and AAAASF's ''Introductory Letter and Informational Packet.'' We compared this information with our State and Regional Operations Manual. This review yielded the following:

- We asked AAAASF to clarify the name of its Medicare Program for ASCs, as the organization used the title ''Medicare Accreditation and Medicare Certification'' interchangeably throughout its application materials. AAAASF advised us that the name of its program is ''AAAASF Medicare Accreditation.'' This program accredits Class B and Class C ASCs.
- We requested AAAASF to provide a definition or criteria for Class B and Class C facilities. According to AAAASF, a Class B facility performs surgical procedures in the facility under local or topical anesthesia and/or under intravenous or parenteral sedation, regional anesthesia, analgesia or dissociative drugs (excluding Propofol) without the use of endotracheal or laryngeal mask intubation, or inhalation general anesthesia (including nitrous oxide). In addition, the Class B facility must meet every standard under AAAASF's Class A facility requirements. AAAASF defines Class C facilities as facilities meeting the requirements under Class A and Class B. In addition, Class C facilities perform surgical procedures with intravenous Propofol, spinal or epidural anesthesia, endotracheal or laryngeal mask intubation or inhalation anesthesia (including nitrous oxide), spinal or epidural, which is administered by an anesthesiologist or a certified registered nurse anesthetist (CRNA).
- We requested AAAASF to clarify its accreditation decisions, as its policies and procedures indicate that, ''Offices can be approved or not approved for accreditation or they can be placed on provisional status.'' AAAASF responded that Class B and Class C facilities are either granted or denied Medicare Accreditation. These facilities are required to fully comply with AAAASF's Medicare standards and are prohibited from receiving provisional status.
- We requested AAAASF to provide clarification regarding its accreditation

cycle and its self-evaluation process. AAAASF responded that its Medicare accreditation is effective for 3 years (assuming that the facility remains in compliance with all AAAASF requirements for continued Medicare accreditation, which includes completion of a second and third year self-evaluation). The second and third year self-evaluation survey is conducted by the Facility Director and/or Registered Nurse (OR manager) annually to ensure continued compliance with all AAAASF requirements. AAAASF processes the evaluation and the facility is notified of any deficiencies. If the facility has any deficiencies, it is required to correct them within 30 days. AAAASF performs an onsite Medicare inspection at every consecutive 3-year cycle.

- We asked AAAASF to state who is responsible for performing the Life Safety Code (LSC) survey for its Medicare ASCs. It responded that it has contracted with *Fire and Life Safety Concepts, L.L.C.* to conduct its unannounced LSC surveys. In addition, AAAASF clarified that it is not requiring its Medicare ASCs to obtain their own LSC inspections from a state fire marshal or hired qualified inspector to qualify for Medicare accreditation.
- AAAASF submitted documentation stating that ''The Life Safety Code inspection is only performed during re-inspection if we require compliance with a new version of the NFPA Life Safety Code.'' We requested AAAASF to revise this statement, because a LSC survey is always required during re-accreditation by a deemed accreditation organization. In addition, we requested AAAASF to require its facilities to comply with the 2000 edition of the LSC. AAAASF responded that it will require its Medicare ASCs to obtain LSC surveys at the time of initial application, application renewal, or in instances which warrant a complaint survey involving physical environment. AAAASF provided us with copies of documentation that it sent to its Medicare ASCs, dated August 25, 2003, advising its facilities that effective September 11, 2003, all AAAASF Medicare approved ASCs are required to meet the NFPA 2000 LSC.
- We requested AAAASF to develop a comprehensive performance evaluation program for its Medicare inspectors. AAAASF responded by implementing a Medicare Inspector Examination Process. At the conclusion of each Medicare Inspector Training Workshop, an examination will be administered to assess the inspectors' knowledge and application of AAAASF's Medicare standards. In addition, we requested that the AAAASF inspectors accompany a field preceptor for an onsite Medicare facility inspection as part of the inspector training process. The field preceptor would complete a competency evaluation to assess the inspector's knowledge of AAAASF's survey process. Lastly, AAAASF now requires all of its Medicare ASCs to complete a facility evaluation form. It is a questionnaire completed by the surveyed facility and is designed to evaluate the inspector's skills and knowledge as it relates to the application of AAAASF standards, the inspection process, and Medicare requirements. AAAASF states that these tools will facilitate the proper evaluation of its Medicare inspectors' ability to apply AAAASF standards and survey processes, and will allow AAAASF to identify training needs for its inspectors.
- We asked AAAASF to develop policies and procedures for monitoring complaints in its Medicare ASCs. AAAASF has a toll-free hotline that patients, patient family members, or guardians may use to advise AAAASF of any complaints they may have regarding its Medicare ASCs. Each Medicare ASC is required to post AAAASF complaint certificate in its facility. This certificate provides the contact information individuals need to advise AAAASF of any comments or questions regarding services provided at the facility. The AAAASF Investigative Committee reviews all complaints. AAAASF's complaint categories are ''patient death,'' ''patient safety,'' and ''clinical practices.'' AAAASF's complaint surveys are always unannounced. The AAAASF Medicare survey team is responsible for conducting the complaint surveys in accordance with AAAASF's Medicare standards and with specific direction from the Investigative Committee chair. The survey team must investigate complaints involving patient death no later than 20 days after notifying the AAAASF office of the death. This allows the facility 10 days to respond to the request for information and allows AAAASF a maximum of 10 days to schedule the mandatory unannounced inspection. However, when investigating complaints involving patient safety or clinical practices, the survey team must complete its survey within 30 days after receipt of the initial complaint. This allows the facility 10 days to respond to the request for information and allows AAAASF a maximum of 20 days to schedule the mandatory unannounced inspection. The Investigative Committee Chair is responsible for advising the complainant of the result of AAAASF's investigation. The investigated facility will receive an outcome letter and a written investigation report. When applicable, the outcome letter will identify possible follow-up action (for instance, probation, suspension, or revocation of Medicare accreditation, follow-up visit, plan of correction, or no further action). Lastly, the outcome letter advises the facility of its rights to request a hearing in response to AAAASF's recommendations.
- We asked AAAASF to present documentation regarding its retention of facility files. AAAASF responded by submitting its policies and procedures for Record Retention and Maintenance. The policies and procedures state that facility records are maintained in both hard copy and database format. The hard copy file includes initial accreditation application records, surgeon credentials, Medicare accreditation onsite evaluations/outcomes and correspondence. AAAASF indicated that it purges its records periodically, however, and maintains the last 3 years' records for the facility including current credentials, correspondence, and evaluations.
- We asked AAAASF to clarify its procedures for scheduling Medicare accreditation surveys. AAAASF responded by submitting its policy, ''Procedure for Securing a Medicare Inspector.''

B. Term of Approval

Based on the review and observations described in section III of this final notice, we determined that AAAASF's requirements for ASCs meet or exceed our requirements. Therefore, we recognize AAAASF as a national accreditation organization for ASCs that request participation in the Medicare program, effective November 26, 2004 through November 26, 2009.

V. Regulatory Impact Statement

We have examined the impact of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential

economic, environmental, public health and safety effects; distributive impacts; and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This final notice recognizes AAAASF as a national accreditation organization for ASCs that request participation in the Medicare and Medicaid programs. There are neither significant costs nor savings for the program and administrative budgets of Medicare. Therefore, this notice is not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and Government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. Individuals and States are not included in the definition of a small entity. For purposes of the RFA, States and individuals are not considered small entities. We are not preparing an analysis for the RFA because we have determined that this notice will not have a significant economic impact on a substantial number of small entities.

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

In an effort to better assure the health, safety, and services of beneficiaries in ASCs already certified as well as provide relief to State budgets in this time of tight fiscal restraints, we deem ASCs accredited by AAAASF as meeting its Medicare requirements. Thus, we continue our focus on assuring the health and safety of services by providers and suppliers already certified for participation in a cost-effective manner.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This notice will have no consequential effect on the governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this notice does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

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

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb)

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

Dated: October 22, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 04–25830 Filed 11–19–04; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1374–GNC]

RIN: 0938–ZA50

Medicare Program; Criteria and Standards For Evaluating Intermediary, Carrier, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Regional Carrier Performance During Fiscal Year 2005

AGENCY: Centers for Medicare and Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: General notice with comment period.

SUMMARY: This notice describes the criteria and standards to be used for evaluating the performance of fiscal intermediaries (FIs), carriers, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) regional carriers in the administration of the Medicare program beginning on the first day of the first month following publication of this notice in the **Federal Register**. The results of these evaluations are considered whenever we enter into, renew, or terminate an intermediary agreement, carrier contract, or DMEPOS regional carrier contract or take other contract actions, for example, assigning or reassigning providers or services to an intermediary or designating regional or national intermediaries. We are requesting public comment on these criteria and standards.

DATES: *Effective Date:* The criteria and standards are effective December 27, 2004.

Comment Date: Comments will be considered if we receive them at the appropriate address as provided below no later than 5 p.m. on December 27, 2004.

ADDRESSES: In commenting, please refer to file code CMS–1374–GNC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments to *http://www.cms.hhs.gov/regulations/ecomments* or to *http://www.regulations.gov* (attachments must be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1374–GNC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government