

PLACE: Teleconference call will originate at the Centers for Disease Control and Prevention, National Institutes for Occupational Safety and Health, Atlanta, Georgia. Please see **SUPPLEMENTARY INFORMATION** for details on accessing the teleconference.

STATUS: Meeting cancelled. Published in the **Federal Register**: April 17, 2002, Volume 67, Number 74, page 18911.

FOR FURTHER INFORMATION CONTACT: Dr. Lewis Wade, Executive Secretary, MSHRAC, NIOSH, CDC, HHHB HHH 715H, P12, Washington, DC 20201-0004, telephone 202/401-2192.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 20, 2002.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 02-13073 Filed 5-23-02; 8:45 am]

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

Name: Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH).

Times and Dates: 8:30 a.m.—5:30 p.m., June 27, 2002. 8 a.m.—5 p.m., June 28, 2002.

Place: The Churchill Hotel, 1914 Connecticut Avenue, NW., Washington, DC, telephone 202/797-2000.

Status: Open 8:30 a.m.—9:30 a.m., June 27, 2002. Closed 9:30 a.m.—5:30 p.m., June 27, 2002. Closed 8 a.m.—5 p.m., June 28, 2002.

Purpose: The Safety and Occupational Health Study Section will review, discuss, and evaluate grant application(s) received in response to the Institute's standard grants review and funding cycles pertaining to research issues in occupational safety and health, and allied areas. It is the intent of the NIOSH to support broad-based research endeavors in keeping with the Institute's program goals. This will lead to improved understanding and appreciation for the magnitude of the aggregate health burden associated with occupational injuries and

illnesses, as well as to support more focused research projects, which will lead to improvements in the delivery of occupational safety and health services and the prevention of work-related injury and illness. It is anticipated that research funded will promote these program goals.

Matters to be Discussed: The meeting will convene in open session from 8:30–9:30 a.m. on June 27, 2002, to address matters related to the conduct of Study Section business. The remainder of the meeting will proceed in closed session. The purpose of the closed sessions is for the SOHSS to consider safety and occupational health-related grant applications. These portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6) title 5 U.S.C., and the Determination of the Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention, pursuant to Pub. L. 92-463.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Charles N. Rafferty, Ph.D., NIOSH Scientific Review Administrator, 6701 Rockledge Drive, Room 4114, MSC 7816, Bethesda, Maryland 20892, telephone 301/435-3562, fax 301/480-2644.

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Dated: May 17, 2002.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 02-13072 Filed 5-23-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2141-PN]

RIN 0938-ZA35

Medicare and Medicaid Programs; Application by the American Osteopathic Association (AOA) for Approval of Deeming Authority for Ambulatory Surgical Centers (ASCs)

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice announces the receipt of an application from the American Osteopathic Association (AOA), for recognition as a national accreditation program for ambulatory surgical centers that wish to

participate in the Medicare or Medicaid programs. The Social Security Act requires that the Secretary publish a notice identifying the national accreditation body making the request, describing the nature of the request, and providing at least a 30-day public comment period.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on June 24, 2002.

ADDRESSES: In commenting, please refer to file code CMS-2141-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Mail written comments (one original and three copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2141-N, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses: Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Laura A. Weber, (410) 786-0227.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786-7197.

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration

date. Credit card orders can also be placed by calling the order desk at (202) 512-1800 or by faxing to (202) 512-2250. The cost for each copy is \$9. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through *GPO Access*, a service of the U.S. Government Printing Office. The website address is: <http://www.access.gpo.gov/nara/index.html>.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in an ambulatory surgical center (ASC) provided that the ASC meets certain requirements. Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) includes requirements that an ASC have an agreement in effect with the Secretary and that it meet health, safety, and other standards specified by the Secretary in regulations.

Requirements concerning supplier agreements are located in 42 CFR part 489 and those pertaining to the survey and certification of facilities are set forth in 42 CFR part 488.

In 42 CFR part 416, we specify the conditions that an ASC must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for facility services.

For an ASC to enter into an agreement, a State survey agency must first certify that the ASC complies with our conditions or requirements. Following that certification, the ASC is subject to routine monitoring by a State survey agency to ensure continuing compliance. As an alternative to surveys by State agencies, section 1865(b)(1) of the Act provides that, if the Secretary finds that, through accreditation by a national accreditation body, a provider entity demonstrates that all of our applicable conditions and requirements are met or exceeded, the Secretary may deem that the provider entity has met the applicable Medicare requirements.

Section 1865(b)(2) of the Act further requires that the Secretary's findings consider the applying accreditation organization's—

- Requirements for accreditation;
- Survey procedures;
- Ability to provide adequate resources for conducting required surveys;
- Ability to supply information for use in enforcement activities;

- Monitoring procedures for provider entities found out of compliance with the conditions or requirements; and
- Ability to provide the Secretary with necessary data for validation.

Section 1865(b)(3)(A) of the Act requires that the Secretary publish a notice within 60 days of receipt of a completed application; the notice must—

- Identify the national accreditation body making the request;
- Describe the nature of the request; and
- Provide at least a 30-day public comment period.

In addition, we must publish a finding of approval or denial of the application within 210 days from the receipt of the completed request.

The American Osteopathic Association (AOA) previously applied to us for deeming authority which we announced in the **Federal Register** on March 14, 2001 (66 FR 14906). However, the organization withdrew its application before a final decision was made. We received a revised complete application from AOA on April 18, 2002.

II. Determining Compliance—Surveys and Deeming

A national accrediting organization may request the Secretary to recognize its program. The Secretary then examines the national accreditation organization's requirements to determine if they meet or exceed Medicare standards. If the Secretary recognizes an accreditation organization in this manner, any provider accredited by the national accrediting body's program that we have approved for that service will be "deemed" to meet the Medicare conditions of coverage. To date, three such organizations have been recognized to have deeming authority for their ambulatory surgical programs: The Joint Commission on Accreditation of Health Organizations, the Accreditation Association for Ambulatory Health Care, and the American Association for Accreditation of Ambulatory Surgery Facilities, Inc.

The purpose of this notice is to notify the public of the request of the AOA for approval of its request that the Secretary find that its accreditation program for ASCs meets or exceeds Medicare conditions and requirements. This notice also solicits public comments on the ability of this organization to develop and apply standards that meet or exceed the Medicare conditions for coverage to ASCs. Our regulations concerning approval of accrediting organizations are set forth in 42 CFR § 488.4, 488.6, and 488.8.

III. 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 the Secretary under section 1833(i)(1)(a) of the Act.

Under section 1865(b)(2) of the Act and our regulations in 42 CFR 488.8 (Federal review of accreditation organizations) our review and evaluation of a national accreditation organization will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of an accreditation organization's requirements for an entity to our comparable requirements for that 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 processes 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 in 42 CFR 488.7(d).
 - + 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, and its financial viability.
 - + 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).

IV. Notice Upon Completion of Evaluation

Upon completion of our evaluation, including our review of comments received as a result of this notice, we will publish a notice in the **Federal Register** announcing the results of our evaluation.

V. Response to Public Comments

Because of the large number of comments 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 will respond to them in a forthcoming rulemaking document.

VI. 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 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 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).

The RFA requires agencies to analyze options for regulatory relief for 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 \$5 million to \$25 million or less in any 1 year (for details, see the Small Business Administration's publication that set forth size standards for health care industries at 65 FR 69432). For purposes of the RFA, States and individuals are not considered small entities.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any notice that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we consider a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

This notice merely recognizes AOA as a national accreditation organization

that has requested approval for deeming authority for ambulatory surgical centers that are participating in the Medicare program. Since these provider entities must be routinely monitored to determine compliance with Medicare requirements, we believe that this organization's accreditation program has the potential to reduce both the regulatory and administrative burdens associated with the Medicare program requirements.

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.

Therefore, we have determined, and the Secretary certifies, that this proposed notice would not result in a significant impact on small entities and would not have an effect on the operations of small rural hospitals. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

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 would have no consequential effect on State, local, or tribal governments. We believe the private sector costs of this notice would fall below this threshold as well.

In accordance with Executive Order 13132, this notice would not significantly affect the rights of States and would not significantly affect State authority. This notice describes only processes that must be undertaken to fulfill our obligation to enforce our regulations as required by the April 8, 1997 (62 FR 16985) regulation.

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

Authority: Section 1865(b)(3)(A) of the Social Security Act (42 U.S.C. 1395bb(b)(3)(A)).

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

Dated: May 17, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02-12929 Filed 5-23-02; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0159]

Agency Information Collection Activities; Proposed Collection; Comment Request; Focus Groups as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on focus groups as used by FDA. These focus groups gauge public opinion, and policymakers can use focus group findings to test and refine their ideas so they can conduct further research whose findings can be used to adopt new policies and to allocate or redirect significant resources to support these policies.

DATES: Submit written or electronic comments on the collection of information by July 23, 2002.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Mark L. Pincus, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1471.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests