

and the general public, through publications, newsletters, bibliographies, press releases, public service announcements, and other electronic and printed materials; (11) maintains a specialized collection of violence resources that includes subject files and reprints of CDC-authored publications and "MMWR" articles; (12) works closely with relevant offices or groups, including the NCIPC Office of Communication Resources and the CDC Office of Communication, to secure appropriate clearance of materials; (13) implements national violence prevention public information programs and assists in developing strategic communications activities and services at the national level to inform and educate the American public about violence, especially people who are at greatest risk.

Dated: March 5, 2001.

Jeffrey P. Koplan,

Director.

[FR Doc. 01-6281 Filed 3-13-01; 8:45 am]

BILLING CODE 4160-18-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-372]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, DHHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Annual Report on Home and Community Based Services Waivers and Supporting Regulations in 42 CFR 440.181 and 441.300-305;

Form No.: HCFA-372 (OMB# 0938-0272);

Use: States request waivers in order for beneficiaries to have the option of receiving hospital services in their homes. States with an approved waiver under section 1915(c) of the Act are required to submit the HCFA-372 or HCFA-372(S) annually in order for HCFA to: (1) Verify that State assurances regarding waiver cost-neutrality are met, and (2) determine the waiver's impact on the type, amount and cost of services provided under the State plan and health and welfare of recipients;

Frequency: Annually; *Affected Public:* State, local or tribal government;

Number of Respondents: 50;

Total Annual Responses: 243;

Total Annual Hours: 18,225.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Attn: HCFA 372, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: February 27, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 01-6251 Filed 3-13-01; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-2079-PN]

Medicare and Medicaid Programs; Recognition of the American Osteopathic Association for Ambulatory Surgical Centers Program

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

ACTION: Proposed Notice.

SUMMARY: In this notice we announce 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 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 April 13, 2001.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address:

Health Care Financing Administration,
Department of Health and Human Services,
Attention: HCFA-2079-PN, P.O. Box 8013,
Baltimore, MD 21244-8013.

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 443-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201, or Room C5-16-03,
7500 Security Boulevard, Baltimore,
MD 21244-8013.

Comments mailed to the above addresses may be delayed and received too late for us to consider them.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-2079-PN. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443-G of the Department's office at 200 Independence Avenue, SW., Washington, DC, on Monday

through Friday of each week from 8:30 to 5 p.m. (phone: (202) 690-7890).

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

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in an ambulatory surgical center (ASC) provided certain requirements are met. Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) includes the requirements that an ASC have an agreement in effect with the Secretary and meet health, safety, and other standards specified by the Secretary in regulations. Regulations concerning supplier agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. Our regulations at 42 CFR 416 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.

Generally, in order to enter into an agreement, an ASC must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 416 of our regulations. Then, the ASC is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(b)(1) of the Act provides that if the Secretary finds that accreditation of a provider entity by a national accreditation body demonstrates that all of the applicable conditions and requirements are met or exceeded, the Secretary shall deem those provider entities as meeting 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, its survey procedures, its ability to provide adequate resources for conducting required surveys and ability to supply information for use in enforcement activities, its monitoring procedures for provider entities found out of compliance with the conditions or requirements, and its ability to provide the Secretary with necessary data for validation. Section 1865(b)(3)(A) of the Act requires that the Secretary publish within 60 days of receipt of a completed application, 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. In addition, the Secretary has 210 days from the receipt of the request to publish a finding of approval or denial of the application.

II. Determining Compliance—Surveys and Deeming

Providers of health care services participate in Medicare and Medicaid programs pursuant to provider agreements with HCFA (for Medicare) and State Medicaid agencies (for Medicaid). Generally, in order to enter into a provider agreement, an entity must first be certified by a State survey agency as complying with the conditions or standards set forth in Federal law and regulations. Providers are subject to regular surveys by State survey agencies to determine whether the provider continues to meet these requirements.

A provider deemed through accreditation is one that has voluntarily applied for and been accredited by a national accreditation program that HCFA has determined applies and enforces standards that meet or exceed the applicable Medicare conditions or requirements. Section 1865(b) of the Act essentially permits these deemed providers of services to be exempt from routine surveys by State survey agencies to determine compliance with Medicare requirements. If the Secretary finds that the accreditation of the provider by the national accreditation body demonstrates that all the Medicare conditions and standards are met or exceeded, then the Secretary would "deem" the requirements to be met by the provider entity.

A national accrediting organization may request the Secretary to recognize its program. The Secretary then examines the national accreditation organization's accreditation requirements to determine if they meet or exceed the Medicare conditions as HCFA would have applied them. If the Secretary recognizes an accreditation organization in this manner, any provider accredited by the national accrediting body's HCFA approved program 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 American

Osteopathic Association (AOA) for approval of its request that the Secretary find its accreditation program for ambulatory surgical centers meet or exceed the Medicare conditions. This notice also solicits public comments on the ability of this organization to develop and apply standards to ASCs which meet or exceed the Medicare conditions for coverage. Our regulations concerning approval of accrediting organizations are at 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 ambulatory surgical centers 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 at § 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 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 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 at § 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 evaluation of comments received as a result of this notice, we will publish a notice in the **Federal Register** announcing the result of our evaluation.

V. Responses 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.

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

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

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

Dated: February 2, 2001.

Michael McMullan,

Acting Deputy Administrator, Health Care Financing Administration.

[FR Doc. 01-6311 Filed 3-13-01; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health, National Institute on Child Health and Human Development; Opportunity for Cooperative Research and Development Agreement

SUMMARY: The National Institute of Child Health and Human Development (NICHD) is seeking research statements from parties interested in entering into a Cooperative Research and

Development Agreement (CRADA). The purpose of the CRADA is to develop diagnostic and therapeutic uses of the newly identified human MATER (Maternal Effect Gene) gene and protein that are critical for normal oocyte function and fertility. The project is part of the ongoing activities of the Developmental Endocrinology Branch (DEB), Division of Intramural Research, NICHD. The term of the CRADA will be up to five (5) years.

DATES: Interested parties should notify this office in writing of their intent to file a formal proposal no later than April 13, 2001. Formal proposals must be submitted to this office no later than May 14, 2001.

ADDRESSES: Research Statements should be submitted to Kate Sinclair Dunn, Technology Development Specialist, Technology Development and Commercialization Branch, National Cancer Institute, National Institutes of Health, Executive Plaza South, Room 450, 6120 Executive Blvd., MSC 7182, Bethesda, MD 20892-7182, Phone: 301-496-0477, Fax: 301-402-2117, e-mail sinclair@otd.nci.nih.gov. Scientific questions should be addressed to Lawrence M. Nelson, M.D., Head, Gynecological Endocrinology Unit Developmental Endocrinology Branch, NICHD, NIH, Building 10, Room 10N262, Bethesda, MD 20892-1862; Phone (direct): 301-402-6608, Office: 301-496-4686; Fax: 301-402-0574, e-mail: Lawrence.Nelson@nih.gov. Inquiries directed to obtaining patent license(s) related to participation in the CRADA opportunity should be addressed to Dennis Penn, Pharm.D., MPH, Senior Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Blvd., Suite 325, Rockville, MD 20852-3804, Phone: 301-496-7735, Fax: 301-402-0220, e-mail: penn@od.nih.gov.

SUPPLEMENTARY INFORMATION: A CRADA is the anticipated joint agreement to be entered into by NICHD and a collaborator pursuant to the Federal Technology Transfer Act of 1986 (15 U.S.C. 3710 a), as amended. A CRADA is an agreement designed to enable certain collaborations between Government laboratories and non-Government laboratories. It is not a grant, and is not a contract for the procurement of goods/services. THE NICHD IS PROHIBITED FROM TRANSFERRING FUNDS TO A CRADA COLLABORATOR. Under a CRADA, the NICHD can offer the selected collaborator access to facilities, staff, materials, and expertise. The collaborator may contribute facilities,

staff, materials, expertise, and funding to the collaboration. A CRADA collaborator may elect an option to an exclusive or non-exclusive license to Government intellectual patent rights arising under the CRADA, and may qualify as a co-inventor of new technology developed under the CRADA. As between two or more sufficient, overlapping research proposals (where the overlap cannot be cured), the NICHD, as specified in 15 U.S.C. 3710a(c)(4), will give special consideration to small businesses, and will give preference to business units located in the U.S. that agree to manufacture CRADA products in the U.S.

The CRADA will employ a MATER null mouse line to examine the role of MATER in maintaining oocyte quality so as to support healthy early embryonic development. The project goal is to determine if abnormalities in the amount or quality of oocyte MATER content play a role in some cases of human infertility that is generally ascribed to "poor egg quality" or a failure of early embryonic development. A strategy should be developed to measure MATER's biologic activity, to determine the MATER content of human oocytes, and to detect MATER gene mutations. Preimplantation mouse oocytes and embryos may be used for protein analysis and profiling. Basic science expertise as applied to oocyte function in animal models and in the clinical setting will be required.

The described methods are the subject of a U.S. provisional patent application filed October 18, 2000 by the Public Health Service on behalf of the Federal Government. Furthermore, the initial report and characterization of the invention is described in: Tong et al., *Mamm. Genome* 11:281-287, 2000. Commercialization of new CRADA technology may require obtaining an appropriate PHS license.

The collaborator in this endeavor is expected to commit scientific personnel commensurate with the level of research activities defined by the CRADA Research Plan. It is anticipated that PHS laboratories and/or those of the collaborator will be utilized, as appropriate, for the research activities as defined by the Research Plan. NICHD anticipates, in addition, that the Collaborator, as appropriate, will provide funding for the project.

Party Contributions: The NICHD anticipates that its role may include, but not be limited to, the following:

(1) Plan research studies, interpret research results, and, as appropriate, jointly publish the conclusions with the collaborator;