

noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center Web site at [www.ffiec.gov/nic/](http://www.ffiec.gov/nic/).

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 25, 2002.

**A. Federal Reserve Bank of Atlanta** (Sue Costello, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 3030-B4470:

1. *Pinnacle S-Corp, Inc.*, Elberton, Georgia; to become a bank holding company by acquiring 100 percent of the voting shares of Pinnacle Financial Corporation, Elberton, Georgia, and thereby indirectly acquire voting shares of Pinnacle Bank, Elberton, Georgia.

Board of Governors of the Federal Reserve System, October 28, 2002.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 02-27859 Filed 10-31-02; 8:45 am]

BILLING CODE 6210-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Prospective Grant of Exclusive License: Pharmaceutical Methods of Delivering Folic Acid in a Hormonal Replacement or Contraceptive Composition

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** This is a notice in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i) that the Centers for Disease Control and Prevention (CDC), Technology Transfer Office, Department of Health and Human Services (DHHS), is contemplating the grant of a worldwide, limited field of use, exclusive license to practice the inventions embodied in the patent and patent applications referred to below to Johnson & Johnson Pharmaceutical Research & Development, L.L.C., having a place of business in Raritan, New Jersey. The patent rights in these inventions relate to the administration of folic acid in a contraceptive or hormonal replacement composition and have been assigned to Ortho-McNeil Pharmaceutical, Inc. (Raritan, New Jersey) and the government of the

United States of America. The patent and patent applications to be licensed are:

*Title:* Pharmaceutical Methods of Delivering Folic Acid in a Hormonal Replacement or Contraceptive Composition,  
U.S. Patent Application Serial No. 09/292,027.

*Filing Date:* 04/16/1999.

*Domestic Status:* Patent No.: 6,190,693.

*Issue Date:* 02/20/2001.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 60 days from the date of this published Notice, CDC receives written evidence and argument that the grant of this license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Folic acid is a vitamin. It plays a crucial role in DNA synthesis, and in hematopoiesis (although the details of this role remain undefined). Folic acid is involved, for example, in single carbon transfers (such as those required for purine and pyrimidine metabolism), and in the re-methylation of homocysteine to methionine. Numerous disorders can result from insufficient intake of folic acid. Enhanced effects of risk factors for cervical dysplasia (*e.g.* HPV infection) have been linked to decreased folic acid levels. Sub-optimal body stores of folic acid, as measured by red cell folic acid concentrations, may amplify oncogenic risk. Administering folic acid can reduce the onset of disorders such as cardiovascular disease and cervical dysplasia. This invention provides a pharmaceutical composition comprising (a) an oral contraceptive for preventing pregnancy in a subject, and (b) folic acid in an amount sufficient to treat or prevent a disorder which (c) afflicts subjects for whom the oral contraceptive is indicated at a higher-than-normal incidence, and (d) is treatable or preventable by folic acid administration.

**ADDRESSES:** Requests for a copy of this patent, inquiries, comments, and other materials relating to the contemplated license should be directed to Andrew Watkins, Director, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, Mailstop K-79, Atlanta, GA 30341, telephone: (770) 488-8610; facsimile: (770) 488-8615. Applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are

received by CDC within sixty days of this notice will be considered. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552. A signed Confidential Disclosure Agreement will be required to receive a copy of any pending patent application.

Dated: October 26, 2002.

**James D. Seligman,**

*Associate Director for Program Services, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 02-27788 Filed 10-31-02; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-2141-FN]

#### Medicare and Medicaid Programs; Approval of the American Osteopathic Association for Deeming Authority for Ambulatory Surgical Centers

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

**ACTION:** Final notice.

**SUMMARY:** This final notice announces the approval of the American Osteopathic Association (AOA) for recognition as a national accreditation program for ambulatory surgical centers (ASCs) that request certification to participate in the Medicare or Medicaid programs. We have found that accreditation of ASCs by this organization will demonstrate that all Medicare ASC Conditions for Coverage are met or exceeded, and, thus, ASCs accredited by AOA will be granted deemed status to participate in the Medicare program.

**EFFECTIVE DATE:** This final notice is effective January 30, 2003.

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

**SUPPLEMENTARY INFORMATION:** *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

### *Determining Compliance of Ambulatory Surgical Centers—Surveys and Deeming*

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 will deem that the provider entity has met the applicable Medicare requirements.

In making our finding as to whether the accreditation organization demonstrates that all Medicare conditions or requirements are met or exceeded, we consider factors such as the organization's accreditation requirements, its survey procedures, its ability to provide adequate resources for conducting required surveys and supplying information for us in

enforcement activities, its monitoring procedures for providers entities found to be out of compliance with conditions or requirements, and its ability to provide us with necessary data for validation.

It has been brought to our attention that some ASCs are under the mistaken impression that, once we have granted deeming authority to an accreditation organization, then ASCs must be accredited by such an organization to receive Medicare certification. Accreditation by an accreditation organization is voluntary, and we do not require that accreditation for Medicare certification.

The American Osteopathic Association (AOA) was the fourth accreditation organization to apply for deeming authority for ASCs. The three other accreditation organizations already granted deeming authority are the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), the Accreditation Association of Ambulatory Health Care (AAAHC), and The American Association for the Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF).

The AOA is defined as a national accrediting body in section 1865(b)(1) of the Act, and was granted deeming authority by us for hospitals (65 FR 8727, published February 22, 2000). This was taken into consideration in the evaluation of this application for ASC deeming authority.

The 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 and published notice of that receipt on May 24, 2002 (67 FR 36611).

## II. Determining Compliance—Surveys and Deeming

A national accrediting organization may request the Secretary to recognize its program as employing standards that meet or exceed Medicare's standards. 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 for Coverage.

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.

## III. Provisions of the Proposed Notice

The proposed notice, published on May 24, 2002 (67 FR 36611), announced the application of AOA for deemed status for its accreditation program for ASCs. Under section 1865(b)(2) of the Act and our regulations in § 488.8 (Federal review of accreditation organizations), our review and evaluation of a national accreditation organization was 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 those 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 § 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. Analysis of and Responses to Public Comments

We did not receive any comments to the proposed notice published in the **Federal Register** (67 FR 36611) on May 24, 2002.

#### V. Provisions of the Final Notice

##### A. Deeming Approval Review and Evaluation

We evaluated the AOA's standards and survey process to determine if facilities accredited by AOA met Medicare Conditions for Coverage. We did a standard-by-standard comparison of the applicable conditions or requirements to determine which of them met or exceeded Medicare requirements.

We compared the standards contained in the AOA's "Ambulatory Surgical Center (ASC) Manual" and its survey process in the "Ambulatory Surgical Center Surveyor Handbook" with the Medicare ASC Conditions for Coverage and our State and Regional Operations Manual. Our review and evaluation of AOA's deeming application, which were conducted as described in this notice, yielded the following clarifications:

- AOA provided an updated listing of its accredited ASC facilities.
  - AOA adjusted language to refer consistently to the entities as ASCs as opposed to hospitals in its documents.
  - AOA modified its standards to meet fully the requirements of the Medicare Conditions for Coverage.
  - AOA modified its survey policy to ensure that ASC surveys are unannounced.
  - AOA modified its requirements to indicate that any ASC seeking to participate in Medicare by virtue of an AOA accreditation must meet the "Accreditation with Medicare Certification," which requires that all State licensure requirements are satisfied in addition to meeting all AOA standards.
  - AOA adjusted its standards to require written confirmation of primary source verifications with regard to medical staff credentialing.
  - AOA adjusted its standard to conform with all applicable requirements of each State Nurse Practice Act to specify what duties a registered nurse may be allowed to perform in the area of pharmaceutical services.
  - AOA agrees to notify us of all accreditation decisions made.
- Review of AOA's application raised issues concerning the comparability of

the AOA's ASC accreditation standards with the Medicare Conditions for Coverage for ASCs. We requested that the AOA demonstrate compliance with the Medicare ASC Conditions for Coverage and submit supplemental information to clarify its policies and procedures. Upon our final review of this information, we have determined that the AOA's ASC accreditation program meets the Medicare Conditions for Coverage for ASCs.

##### B. Term of Approval

Based on the review and observations described in this final notice, we have determined that AOA's requirements for ASCs meet or exceed our requirements. We reserve the right to observe an AOA ASC survey to determine the compliance of AOA surveyors to the policies and procedures, as there were none scheduled during the review of this application. In addition, the AOA must seek approval of all standards pertaining to the Life Safety Code (LSC) when we move to the LSC 2000 Edition, which we intend to implement in Spring 2003. We therefore recognize the AOA as a national accreditation organization for ASCs that request participation in the Medicare program, effective for a 6-year period beginning January 30, 2003.

#### VI. Collection of Information Requirements

This final notice does not impose any information collection and record keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA. The requirements associated with granting and withdrawal of deeming authority to national accreditation organizations, codified in 42 CFR part 488, "Survey, Certification, and Enforcement Procedures," are currently approved by OMB under OMB approval number 0938-0690.

#### VII. 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 \$6 million to \$29 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).

Approximately 73 percent of ASCs are considered small businesses with total revenues of \$8.5 million or less according to the Small Business Administration's data. 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 604 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 ASCs 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 final notice will not result in a significant impact on small entities and will 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 will have no consequential effect on State, local, or tribal governments. We believe the private sector costs of this notice will fall below this threshold as well.

In accordance with Executive Order 13132, this notice will not significantly affect the rights of States and will not significantly affect State authority.

In accordance with the provisions of Executive Order 12866, this notice was 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: October 7, 2002.

**Thomas A. Scully,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 02–27782 Filed 10–31–02; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Proposed Information Collection Activity; Comment Request

##### Proposed Projects

*Title:* DHHS/ACF Rural Welfare-to-Work Strategies Demonstration Evaluation Project 18-Month Survey.

*OMB No.:* New Collection.

*Description:* the Rural Welfare-to-Work Strategies Demonstration Evaluation Project, which was developed and funded by the Administration for Children and Families (ACF) of the U.S. Department of Health and Human Services (HHS), is a national evaluation to determine the benefits and cost-effectiveness of

methods designed to aid current or former Temporary Assistance for Needy Families (TANF) recipients or other low-income families as they transition from welfare to the employment arena. This evaluation chiefly attempts to address four research questions:

- What are the issues and challenges associated with operating the new welfare-to-work services and policy approaches being studied?
- How effective are the welfare-to-work programs under the project in increasing employment and earnings and in improving other measures?
- What are the net costs of the welfare-to-work programs, and do the programs' benefits outweigh the costs?
- What approaches should policymakers and program managers consider in designing strategies to improve the efficacy of welfare-to-work strategies for families in rural areas?

The evaluation employs a multi-pronged approach to answer the research questions. These approaches include: (1) An impact study, which will examine the differences between control and intervention groups with respect to factors such as employment rates, earnings, and welfare receipt; (2) a cost-benefit analysis, which will calculate estimates of net program cost-effectiveness; and (3) an in-depth process study, which will identify implementation issues and challenges, examine program costs, and provide details on how programs achieve observed results. The data collected during the conduct of this study will be used for the following purposes:

- To study rural welfare-to-work programs' effects on factors such as employment, earnings, educational attainment, family composition;
- To collect data on a wider range of outcome measures—such as job acquisition, retention, and advancement, job quality, educational attainment, and employment barriers—than is available through welfare or

unemployment insurance records, in order to understand how individuals are being affected by the demonstration programs;

- To support research on the implementation of welfare-to-work programs across sites;
- To obtain program participation and service use information important to the evaluation's cost-benefit component; and
- To obtain contact information for a future follow-up survey that will be important to achieving high response rates for that survey.

*Respondents:* The respondents of the 18-month follow-up survey are current and former TANF recipients, or individuals in families at risk of needing TANF benefits (working poor, hard-to-employ) from the three states participating in the evaluation (Illinois, Nebraska, and Tennessee). The survey will be administered to both intervention and control groups in each participating site. The estimated sample size for the survey is 3,400 individuals, including projected samples of 2,200 in Tennessee, and 600 each in Illinois and Nebraska. The survey will be conducted primarily by telephone, with field interviews conducted with those individuals who cannot be interviewed by telephone.

Respondents of the process study data collection efforts (interviews, case studies, and focus groups) include State and local-level agency staff from welfare agencies and other organizations. These individuals include program directors and site managers, program line staff, workforce development staff, TANF agency staff, and community partners and employers. Approximately 105 staff members per site are expected to participate in semi-structured interviews, 21 in case conferences, and 108 in focus groups, across the three demonstration sites.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
18-Month Follow-up Survey .....	963	1	45 minutes or .75 hours .....	723
Process Study Data Collection Staff Interviews .....	105	1	75 minutes or 1.15 hours .....	120.8
Process Study Data Collection Staff Case Conferences .....	21	1	30 minutes or .5 hours .....	10.5
Process Study Data Collection Staff Focus Groups .....	108	1	90 minutes or 1.5 hours .....	162

*Estimated Total Annual Burden Hours:* 1016.3.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and

Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and

comments may be forwarded by writing to the Administration for Children and Families, Office of Administration Office of Information Services, 370 L'Enfant Promenade, SW., Washington,