

Internet (http://www.cms.hhs.gov/FACA/04_APME.asp) for additional information and updates on committee activities. Press inquiries are handled through the CMS Press Office at (202) 690-6145.

SUPPLEMENTARY INFORMATION:

Section 9(a)(2) of the Federal Advisory Committee Act authorizes the Secretary of Health and Human Services (the Secretary) to establish an advisory panel if the Secretary determines that the panel is "in the public interest in connection with the performance of duties imposed * * * by law." Such duties are imposed by section 1804 of the Social Security Act (the Act), requiring the Secretary to provide informational materials to Medicare beneficiaries about the Medicare program, and section 1851(d) of the Act, requiring the Secretary to provide for "activities * * * to broadly disseminate information to [M]edicare beneficiaries * * * on the coverage options provided under [Medicare Advantage] in order to promote an active, informed selection among such options."

The Panel is also authorized by section 1114(f) of the Act (42 U.S.C. 1311(f)) and section 222 of the Public Health Service Act (42 U.S.C. 217a). The Secretary signed the charter establishing this Panel on January 21, 1999 (64 FR 7899, February 17, 1999) and approved the renewal of the charter on January 21, 2009. The Panel advises and makes recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program.

The goals of the Panel are as follows:

- To provide recommendations on the development and implementation of a national Medicare education program that describes benefit options under Medicare.
- To enhance the Federal government's effectiveness in informing the Medicare consumer.
- To make recommendations on how to expand outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of a national Medicare education program.
- To assemble an information base of best practices for helping consumers evaluate benefit options and build a community infrastructure for information, counseling, and assistance.

The current members of the Panel are: Gwendolyn T. Bronson, SHINE/SHIP Counselor, Massachusetts SHINE Program; Dr. Yanira Cruz, President and

Chief Executive Officer, National Hispanic Council on Aging; Stephen L. Fera, Vice President, Social Mission Programs, Independence Blue Cross; Clayton Fong, President and Chief Executive Officer, National Asian Pacific Center on Aging; Nan Kirsten-Forté, Executive Vice President, Consumer Services, WebMD; Cathy Graeff, R.Ph., M.B.A., National, Senior Vice President, Communications and Industry Relations, National Council for Prescription Drug Programs; Dr. Carmen R. Green, Director, Pain Research Division, Associate Professor, Anesthesiology, University of Michigan Health System; Dr. Jessie C. Gruman, President and Chief Executive Officer, Center for the Advancement of Health; Cindy Hounsell, J.D., President, Women's Institute for a Secure Retirement; Kathy Hughes, Vice Chairwoman, Oneida Nation; Gail Hunt, President and Chief Executive Officer, National Alliance for Caregiving; Dr. Andrew M. Kramer, Professor of Medicine, University of Colorado, Denver; Dr. Frank B. McArdle, Manager, Hewitt Research Office, Hewitt Associates; Sandy Markwood, Chief Executive Officer, National Area Agencies on Aging; Robert L. Mollica, Consumer; David Roberts, M.P.A., Vice President, Government Relations, Healthcare Information and Management Systems Society; Julie Bodén Schmidt, Associate Vice President, Training and Technical Assistance Department, National Association of Community Health Centers; Rebecca Snead, Executive Vice President and Chief Executive Officer, National Alliance of State Pharmacy Associations.

The agenda for the April 22, 2009 meeting will include the following:

- Recap of the previous (January 13, 2009) meeting.
- Subgroup Committee Work Summary.
- Medicare Outreach and Education Strategies.
- Public Comment.
- Listening Session with CMS Leadership.
- Next Steps.

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to Lynne Johnson at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available. Individuals not wishing to make a presentation may submit written comments to Ms. Johnson at the address listed in the **ADDRESSES** section of this

notice by the date listed in the **DATES** section of this notice.

Individuals requiring sign language interpretation or other special accommodations should contact Ms. Johnson at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

Authority: Sec. 222 of the Public Health Service Act (42 U.S.C. 217a) and sec. 10(a) of Public Law 92-463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR 102-3).

(Catalog of Federal Domestic Assistance Program No. 93.733, Medicare—Hospital Insurance Program; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 18, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E9-6773 Filed 3-26-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2282-N]

Medicare, Medicaid, and CLIA Programs; Approval of the American Osteopathic Association as a CLIA Accreditation Organization

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

ACTION: Notice.

SUMMARY: This notice announces CMS' grant of deeming authority to the American Osteopathic Association (AOA) under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. We have determined that the requirements of the AOA accreditation process are equal to or more stringent than the CLIA condition level requirements, and that the AOA has met the requirements of CMS. Consequently, laboratories that are voluntarily accredited by the AOA and continue to meet the AOA requirements will be deemed to meet the CLIA condition level requirements for laboratories and therefore are not subject to routine inspection by State survey agencies to determine their compliance with Federal requirements. They are, however, subject to Federal validation and complaint investigation surveys conducted by CMS or its designee.

DATES: *Effective Date:* This notice is effective from March 27, 2009 to March 27, 2015.

FOR FURTHER INFORMATION CONTACT:
Kathleen Todd, (410) 786-3385.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On October 31, 1988, Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578. CLIA replaced in its entirety section 353(e)(2) of the Public Health Service Act, as enacted by the Clinical Laboratory Improvement Act of 1967. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under the CLIA program, CMS may grant deeming authority to an accreditation organization that accredits clinical laboratories if the organization meets certain requirements. An organization's requirements for accredited laboratories must be equal to, or more stringent than, the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). The regulations in subpart E (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specify the requirements an accreditation organization must meet to be an approved accreditation organization. We approve an accreditation organization for a period not to exceed 6 years.

The approved accreditation organization must:

- Use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories at the frequency determined by CMS.
- Apply standards and criteria that are equal to, or more stringent than, those condition level requirements established by CMS.
- Assure that laboratories accredited by the accreditation organization continually meet these standards and criteria.
- Provide CMS with the name of any laboratory that has had its accreditation denied, suspended, withdrawn, limited, or revoked within 30 days of the action taken.
- Notify CMS at least 30 days before implementing any proposed changes in its standards.
- If we withdraw our approval, notify the accredited laboratories of the withdrawal within 10 days of the withdrawal.

CLIA requires that we perform an annual evaluation of approved accreditation organizations by inspecting a representative sample of laboratories accredited by the organization, as well as by any other

means that we determine to be appropriate.

The AOA was initially granted deeming authority under the CLIA program on July 21, 1995 (HSQ-229-N).

II. Notice of Approval of the American Osteopathic Association as an Accreditation Organization

In this notice, we approve AOA as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements. We have examined the AOA application and all subsequent submissions to determine equivalency with our requirements under subpart E of part 493 that an accreditation organization must meet to be approved under CLIA. We have determined that the AOA complies with the applicable CLIA requirements and grant the AOA deeming authority as an accreditation organization under subpart E, for the period stated in the "Effective Date" section of this notice for all specialty and subspecialty areas under CLIA.

As a result of this determination, any laboratory that is accredited by the AOA during the effective time period for an approved specialty or subspecialty is deemed to meet the CLIA requirements for the laboratories found in part 493 of our regulations and, therefore, is not subject to routine inspection by a State survey agency to determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by CMS, or by any other validly authorized agent.

III. Evaluation of the American Osteopathic Association Request for Approval as an Accreditation Organization Under CLIA

The following describes the process used to determine that requirements of the AOA accreditation program are equal to or more stringent than the CLIA condition level requirements, and that the AOA has met requirements of subpart E of 42 CFR part 493.

The AOA formally reapplied to CMS for approval as an accreditation organization under CLIA for all specialties and subspecialties. We evaluated the AOA application to determine compliance with our implementing and enforcement regulations, and the deeming/exemption requirements of the CLIA rules.

We verified that the AOA accreditation program requirements and methods require the laboratories it accredits to be in compliance with the following subparts of part 493 as explained below, and that the

organization meets or exceeds the following subparts of part 493 as explained below:

Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

The AOA submitted the specialties and subspecialties that it would accredit; a comparison of its accreditation requirements to CLIA condition level requirements; a description of its inspection process and its proficiency testing (PT) monitoring process; its data management and analysis system; a listing of the size, composition, education and experience of its inspection teams; its investigative and complaint response procedures; its notification agreements with CMS; its procedures for removing or withdrawing laboratory accreditation; its current list of accredited laboratories; and its announced or unannounced inspection process.

The AOA met the requirements of part 493 subpart E as they apply to accreditation organizations.

Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

The AOA requirements are equal to the CLIA requirements at § 493.801 through § 493.865.

Subpart J—Facility Administration for Nonwaived Testing

The AOA requirements are equal to the CLIA requirements at § 493.1100 through § 493.1105.

Subpart K—Quality System for Nonwaived Testing

The AOA requirements are equal to or more stringent than the CLIA requirements at § 493.1200 through § 493.1299.

Subpart M—Personnel for Nonwaived Testing

The AOA requirements are equal to or more stringent than the CLIA requirements at § 493.1351 through § 493.1495 for laboratories that perform moderate and high complexity testing.

Subpart Q—Inspections

The AOA requirements are equal to or more stringent than the CLIA requirements at § 493.1771 through § 493.1780. The AOA will continue to perform onsite inspections every 2 years.

Subpart R—Enforcement Procedures

The AOA meets the requirements of subpart R to the extent that they apply

to accreditation organizations. The AOA policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, the AOA will deny, suspend, or, revoke accreditation in a laboratory accredited by the AOA and report that action to CMS within 30 days. The AOA also provides an appeal process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that the AOA's laboratory enforcement and appeal policies are equal to or more stringent than the requirements of part 493 subpart R as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of AOA accredited laboratories may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or its agents, or the State survey agencies, will be our principal means for verifying that the laboratories accredited by the AOA remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide that we may rescind the approval of an accreditation

organization, such as that of the AOA, for cause, before the end of the effective date of approval. If we determine that the AOA failed to adopt requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its inspection process, we may give it a probationary period, not to exceed 1 year, to allow the AOA to adopt comparable requirements.

Should circumstances result in our withdrawal of the AOA's approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

VI. Collection of Information Requirements

This 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 the accreditation process for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program, codified in 42 CFR part 493 subpart E, are currently approved by OMB under OMB approval number 0938-0686.

Authority: Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: February 13, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E9-5473 Filed 3-26-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Temporary Assistance for Needy Families/National Directory of New Hires Match Results Report.

OMB No.: 0970-0311.

Description: Section 453(j)(3) of the Social Security Act (the Act) allows for matching between the National Directory of New Hires (maintained by the Federal Office of Child Support Enforcement (OCSE)) and State TANF Agencies for purposes of carrying out responsibilities under programs funded under part A of Title IV of the Act. To assist OCSE and the Office of Family Assistance (OFA) in measuring savings to the TANF program attributable to the use of NDNH data matches, the State TANF Agencies have agreed to provide OCSE with a written description of the performance outputs and outcomes attributable to the State TANF Agency's use of NDNH match results. This information will help OCSE demonstrate how the NDNH supports the OCSE's mission and strategic goals.

Respondents: State TANF Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
TANF/NDNH Match Results Report	40	4	0.17	27.20

Estimated Total Annual Burden Hours: 27.20.

In compliance with the requirements of Section 506(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, DC 20447, Attn: ACF Reports Clearance

Officer. E-mail address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: March 23, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9-6804 Filed 3-26-09; 8:45 am]

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