

minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* HIPAA Administrative Simplification Enforcement Non-Privacy Enforcement; *Use:* The Health Insurance Portability and Accountability Act (HIPAA) became law in 1996 (Pub. L. 104-191). Subtitle F of Title II of HIPAA, entitled "Administrative Simplification," requires the Secretary of HHS to adopt national standards for certain information-related activities of the health care industry. The HIPAA provisions, by statute, apply only to "covered entities" referred to in section 1320d-2(a)(1) of this title. Responsibility for administering and enforcing the HIPAA Administrative Simplification Transactions, Code Sets, Identifiers and Security rules has been delegated to CMS. The initial information collected to enforce these rules will be used to initiate enforcement actions. This information collection change clarifies the "Identify the HIPAA Non-Privacy complaint category" section of the complaint form. In this section, complainants are given an opportunity to check the "Unique Identifiers" option to categorize the type of HIPAA complaint being filed. The revised form now includes a "'For a Unique Identifier Complaint" section, that allows a complaint to further categorize their identifier complaint as either a "National Provider Identifier (NPI)" or an "Employer Identification Number (EIN)" complaint. *Form Number:* CMS-10148 (OMB#: 0938-948); *Frequency:* Reporting—On occasion; *Affected Public:* Individuals or households, Business or other for-profit, Not-for-profit institutions, and State, Local, or Tribal governments; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 500.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New

Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395-6974.

Dated: February 13, 2007.

**Michelle Shortt,**

*Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. E7-3028 Filed 2-22-07; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-2540-96]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

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

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), 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 function; (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.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Skilled Nursing Facility and Skilled Nursing Facility Complex Cost Report; *Use:* Providers of services participating in the Medicare program are required under sections 1815(a) and 1861(v)(1)(A) of the Social Security Act to submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries. The CMS-2540-96 cost report is needed to determine the amount of reimbursement, that is due these providers furnishing medical services to Medicare beneficiaries; *Form Number:* CMS-2540-96 (OMB#: 0938-0463); *Frequency:* Reporting—Yearly; *Affected Public:* Business or other for-

profit; *Number of Respondents:* 15,037; *Total Annual Responses:* 15,037; *Total Annual Hours:* 2,947,252.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395-6974.

Dated: February 13, 2007.

**Michelle Shortt,**

*Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1542-N]

#### Medicare Program; Announcement of New Members to the Advisory Panel on Ambulatory Payment Classification (APC) Groups

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (DHHS).

**ACTION:** Notice.

**SUMMARY:** This notice announces five new members selected to serve on the Advisory Panel on Ambulatory Payment Classification (APC) Groups (the Panel). The purpose of the Panel is to review the APC groups and their associated weights and to advise the Secretary, DHHS, (the Secretary) and the Administrator, CMS, (the Administrator) concerning the clinical integrity of the APC groups and their associated weights. We will consider the Panel's advice as we prepare the annual updates of the hospital outpatient prospective payment system (OPPS).

**FURTHER INFORMATION CONTACT:** For inquiries about the Panel, please contact

the Designated Federal Official (DFO): Shirl Ackerman-Ross, DFO, CMS, CMM, HAPG, DOC, 7500 Security Boulevard, Mail Stop C4-05-17, Baltimore, MD 21244-1850, Phone (410) 786-4474.

*E-Mail Address:* The E-mail address for the Panel is as follows: *CMS APCPanel@cms.hhs.gov*. News media representatives must contact our Public Affairs Office at (202) 690-6145.

*Advisory Committees' Information Lines:* The CMS Advisory Committees' Information Line is 1-877-449-5659 (toll free) and (410) 786-9379 (local).

*Web Site:* For additional information regarding the APC Panel membership, meetings, agendas, and updates to the Panel's activities, please search our Web site at the following: *http://www.cms.hhs.gov/FACA/05*

*\_AdvisoryPanelonAmbulatoryPayment ClassificationGroups.asp*. A copy of the Panel's Charter is on that Web site. You may also e-mail the Panel DFO at the above-mentioned e-mail address for a copy of the Charter.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Secretary is required by section 1833(t)(9)(A) of the Social Security Act (the Act), [as amended by section 201(h) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113), and redesignated by section 202(a)(2) of the BBRA] to consult with an expert outside advisory panel regarding the clinical integrity of the APC groups and weights that are components of the hospital OPSS.

The APC Panel meets up to three times annually. The Charter requires that the Panel must be fairly balanced in its membership in terms of the points of view represented and the functions to be performed. The Panel shall consist of up to 15 members who are representatives of providers and a Chair. Each Panel member must be employed

full-time by a hospital, hospital system, or other Medicare provider subject to payment under the OPSS. The Secretary or Administrator selects the Panel membership based upon either self-nominations or nominations submitted by Medicare providers and other interested organizations. All members must have technical expertise to enable them to participate fully in the work of the Panel. This expertise encompasses hospital payment systems; hospital medical-care delivery systems; provider billing systems; APC groups; Current Procedural Terminology and alphanumeric Healthcare Common Procedure Coding System codes; and the use and payment of drugs and medical devices in the outpatient setting, as well as other forms of relevant expertise.

The Charter requires that all members have a minimum of 5 years experience in their area(s) of expertise, but it is not necessary that any member be an expert in all of the areas listed above. For purposes of this Panel, consultants or independent contractors are not considered to be full-time employees of hospitals, hospital systems, or other Medicare providers that are subject to the OPSS. Panel members serve up to 4-year terms. A member may serve after the expiration of his or her term until a successor has been sworn in. All terms are contingent upon the renewal of the Panel's Charter by appropriate action before its termination. The Secretary re-chartered the APC Panel effective November 21, 2006.

**II. Announcement of New Members**

The Panel may consist of a Chair and up to 15 Panel members who serve without compensation, according to an advance written agreement. Travel, meals, lodging, and related expenses for the meeting are reimbursed in accordance with standard Government travel regulations. We have a special interest in ensuring that women, minorities, representatives from various

geographical locations, and the physically challenged are adequately represented on the Panel.

The Secretary, or his designee, appoints new members to the Panel from among those candidates determined to have the required expertise. New appointments are made in a manner that ensures a balanced membership.

The Panel presently consists of the following 13 members and a Chair:

- Edith Hambrick, M.D., J.D., Chair
- Gloryanne Bryant, B.S., R.H.I.A., R.H.I.T., C.C.S.
- Albert Brooks Einstein, Jr., M.D.
- Hazel Kimmel, R.N., C.C.S., C.P.C.
- Sandra J. Metzler, M.B.A., R.H.I.A., C.P.H.Q.
- Frank G. Opelka, M.D., F.A.C.S.
- Louis Potters, M.D., F.A.C.R.
- Lou Ann Schraffenberger, M.B.A., R.H.I.A., C.C.S.-P.
- Judie S. Snipes, R.N., M.B.A., F.A.C.H.E.
- Timothy Gene Tyler, Pharm.D.
- Thomas M. Munger, M.D., F.A.C.C.
- James V. Rawson, M.D.
- Kim Allan Williams, M.D., F.A.C.C., F.A.B.C.
- Robert Matthew Zwolak, M.D., Ph.D., F.A.C.S.

On November 22, 2006, we published the notice titled "Request for Nominations to the Advisory Panel on Ambulatory Payment Classification Groups," (CMS-1305-N) in the **Federal Register** requesting nominations to the Panel replacing Panel members whose terms would expire by September 30, 2007. As a result of that **Federal Register** notice, we are announcing five new members to the Panel. Two new 3½-year appointments commence on March 1, 2007; two new 3½-year appointments commence on April 1, 2007; and one new 4-year appointment commences on October 1, 2007, as indicated below:

New panel members	Terms
Patricia Spencer-Cisek, M.S .....	03/01/2007-09/30/2010
Russ Ranallo, M.S., B.S .....	03/01/2007-09/30/2010
Beverly Philip, M.D .....	04/01/2007-09/30/2010
Michael A. Ross, M.D .....	04/01/2007-09/30/2010
Agatha L. Nolen, M.S., D.Ph .....	10/01/2007-09/30/2011

**Authority:** Section 1833(t) of the Act (42 U.S.C. 1395l(t)). The Panel is governed by the provisions of Pub. L. 92-463, as amended (5 U.S.C. Appendix 2). (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare-Hospital Insurance; and Program No. 93.774, Medicare-Supplementary Medical Insurance Program).

Dated: February 15, 2007.

**Leslie V. Norwalk,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. E7-3040 Filed 2-22-07; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-2221-N]

RIN 0938-ZA98

#### Medicare, Medicaid, and CLIA Programs; Approval of COLA (Formerly the Commission on Office Laboratory Accreditation) as a CLIA Accreditation Organization

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

**ACTION:** Notice.

**SUMMARY:** In this notice, we grant COLA (formerly the Commission on Office Laboratory Accreditation) deeming authority as an accrediting organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. We have determined that the requirements of the COLA accreditation process are equal to or more stringent than the CLIA condition level requirements, and that COLA has met the requirements of subpart E of 42 CFR Part 493. Consequently, laboratories that are voluntarily accredited by COLA and continue to meet COLA 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 us or our designee.

**DATES:** *Effective Date:* This notice is effective from February 23, 2007 to February 25, 2013.

**FOR FURTHER INFORMATION CONTACT:** Raelene Peretto, (410) 786-6876.

**SUPPLEMENTARY INFORMATION:**

### I. Background and Legislative Authority

On October 31, 1988, the 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 Laboratories 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 approves a grant of deeming authority to an accreditation organization to accredit 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.

In general, the approved accreditation organization must:

- Use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories with the frequency determined by us.
- Apply standards and criteria that are equal to, or more stringent than, those condition-level requirements established by us.
- Assure that laboratories accredited by the accreditation organization continually meet these standards and criteria.
- Provide us 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 us 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 by inspecting a sufficient number of laboratories accredited by an approved accreditation organization as well as by any other means that we determine to be appropriate.

### II. Notice of Approval of COLA as an Accreditation Organization

In this notice, we approve COLA (formerly the Commission on Office Laboratory Accreditation) as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements. We have examined the COLA 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 COLA complied with the applicable CLIA requirements and grant COLA approval as an accreditation organization under subpart E, as for the period stated in the "Effective Date" section of this notice for the following specialty and subspecialty areas:

- Microbiology, including Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology.
- Diagnostic Immunology, including Syphilis Serology, General Immunology.
- Chemistry, including Routine Chemistry, Urinalysis, Endocrinology, Toxicology.
- Hematology.
- Immunohematology, including ABO Group & Rh Group, Antibody Detection, Antibody Identification, Compatibility Testing.
- Pathology, including Histopathology, Oral Pathology, Cytology.

As a result of this determination, any laboratory that is accredited by COLA 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 us, or by any other validly authorized agent.

### III. Evaluation of COLA Request for Approval as an Accreditation Organization Under CLIA

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

COLA formally reapplied to us for approval as an accreditation organization under CLIA for the following specialties and subspecialties: