

Dated: February 15, 2013.

Martique Jones,

Deputy 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

[Document Identifier: CMS-R-282]

Agency Information Collection Activities: Proposed Collection; 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) 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.

1. *Type of Information Collection Request:* Extension. *Title of Information Collection:* Medicare Advantage Appeals and Grievance Data Disclosure Requirements (42 CFR 422.111). *Use:* Section 1852(c)(2)(C) of the Social Security Act and 42 CFR 422.111(c)(3) require that Medicare Advantage (MA) organizations and demonstrations disclose information pertaining to the number of disputes, and their disposition in the aggregate, with the categories of grievances and appeals to any individual eligible to elect an MA organization who requests this information. MA organizations and demonstrations remain under a requirement to collect and provide this information to individuals eligible to elect an MA organization, we continue to need the same format and form for reporting. *Form Number:* CMS-R-282 (OCN 0938-0778). *Frequency:* Annually and semi-annually. *Affected Public:*

Private Sector (business or other for-profit and not-for-profit institutions). *Number of Respondents:* 51,370. *Total Annual Responses:* 52,260. *Total Annual Hours:* 5,414. (For policy questions regarding this collection contact Stephanie Simons at 206-615-2420. For all other issues call 410-786-1326.)

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 Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office at 410-786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by April 23, 2013:

1. *Electronically.* You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number __. Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: February 19, 2013.

Martique Jones,

Deputy 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

[Document Identifier: CMS-10430, CMS-10164 and CMS-838]

Agency Information Collection Activities: 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:* Reinstatement of a previously approved collection; *Title:* Information Collection Requirements for Compliance with Individual and Group Market Reforms under Title XXVII of the Public Health Service Act; *Use:* The provisions of title XXVII of the Public Health Service Act (PHS Act) are designed to make it easier for people to get access to health care coverage and to reduce the limitations that can be put on the coverage. Sections 2723 and 2761 of the PHS Act direct CMS to enforce a provision (or provisions) of title XXVII of the PHS Act with respect to health insurance issuers when a state has notified CMS that it has not enacted legislation to enforce or that it is not otherwise enforcing a provision (or provisions) of the individual and group market reforms with respect to health insurance issuers, or when CMS has determined that a state is not substantially enforcing one or more of those provisions. This collection also pertains to notices issued by individual and group health insurance issuers and self-funded non-Federal governmental plans. This collection includes the issuance of certificates of creditable coverage; notification of preexisting condition exclusions; notification of special enrollment rights; and review of issuers' filings of individual and group market products or similar Federal review in cases in which a state is not enforcing a title XXVII individual or group market provision. This information collection is a reinstatement of a previously approved collection (which expired on September 30, 2012 (OMB#: 0938-0702 and OMB#: 0938-0703)) with minimal changes to reflect

laws passed since the previous collection document was approved. While the OMB control number for this proposed collection will remain the same as the previously approved collection, this proposed collection will be given a new CMS Form Number. *Form Number:* CMS-10430 (OCN: 0938-0702); *Frequency:* Annually; *Occasionally;* *Affected Public:* Private Sector; Business or other for-profits and Not-for-profit institutions, and State, Local, or Tribal Governments; *Number of Respondents:* 8,716; *Total Annual Responses:* 39,831,442; *Total Annual Hours:* 3,760,422 hours. (For policy questions regarding this collection contact Lisa Campbell at 301-492-4114. For all other issues call 410-786-1326.)

2. Type of Information Collection
Request: Reinstatement with a change of a previously approved collection; *Title:* Medicare Electronic Data Interchange (EDI) Registration and Electronic Data Interchange (EDI) Enrollment Form; *Use:* The purpose of this collection is to obtain information that will be subsequently used during transaction exchange for identification of Medicare providers/suppliers and authorization of requested Electronic Data Interface (EDI) functions. The EDI Enrollment and the Medicare Registration Forms are completed by Medicare providers, suppliers, or both suppliers and submitted to Medicare contractors. Authorization is needed for providers and suppliers to send and receive HIPAA standard transactions directly (or through a designated 3rd party) to and from Medicare contractors. Medicare contractors would use the information for initial set-up and maintenance of the access privileges. The use of the standard form provides an efficient uniform means by which Medicare captures information necessary to drive Medicare EDI security and EDI access privileges. All EDI providers will complete and sign the EDI Enrollment Form along with the Medicare EDI Registration Form. They will also reconfirm their access privileges annually.

The information collected will be uploaded into Medicare contractor computer systems. Medicare contractors will store this information in a database accessed at the time of provider connection to the Medicare Data Contractor Network (MDCN). When authentication is successful and connectivity is established, transactions may be exchanged. The information will be stored in a computer data base and used to authenticate the user on day-to-day electronic commerce, support the submitter and password administration function, and validate access

relationships between providers/suppliers and their designated EDI submitter/receiver on a per transaction basis. *Form Number:* CMS-10164 (OCN: 0938-0983); *Frequency:* Once; *Affected Public:* Private Sector—Business or other for-profits, Not for-profit institutions; *Number of Respondents:* 240,000; *Total Annual Responses:* 240,000; *Total Annual Hours:* 80,000. (For policy questions regarding this collection contact Claudette Sikora at 410-786-5618. For all other issues call 410-786-1326.)

3. Type of Information Collection
Request: Reinstatement without change of a previously approved collection. *Title of Information Collection:* Medicare Credit Balance Reporting Requirements and Supporting Regulations in 42 CFR 405.371, 405.378 and 413.20; *Use:* Section 1815(a) of the Social Security Act authorizes the Secretary to request information from providers which is necessary to properly administer the Medicare program. Quarterly credit balance reporting is needed to monitor and control the identification and timely collection of improper payments. The information obtained from Medicare credit balance reports will be used by the contractors to identify and recover outstanding Medicare credit balances and by Federal enforcement agencies to protect Federal funds. The information will also be used to identify the causes of credit balances and to take corrective action. *Form Number:* CMS-838 (OCN: 0938-0600); *Frequency:* Yearly; *Affected Public:* Private sector—Business or other for-profits; *Number of Respondents:* 45,838; *Total Annual Responses:* 183,352; *Total Annual Hours:* 550,056. (For policy questions regarding this collection contact Milton Jacobson at 410-786-7553. For all other issues call 410-786-1326.)

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 Email your request, including your address, and phone number as well the OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on March 25, 2013.

OMB, Office of Information and Regulatory Affairs, Attention: CMS

Desk Officer, Fax Number: (202) 395-6974, Email: OIRA_submission@omb.eop.gov.

Dated: February 19, 2013.

Martique Jones,

Deputy 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-3279-N]

Announcement of the Re-Approval of the Commission on Office Laboratory Accreditation (COLA) as an Accreditation Organization Under the Clinical Laboratory Improvement Amendments of 1988

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

ACTION: Notice.

SUMMARY: This notice announces the application of the Commission on Office Laboratory Accreditation (COLA) for approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. We have determined that COLA meets or exceeds the applicable CLIA requirements. In this notice, we announce the approval and grant COLA deeming authority for a period of 6 years.

DATES: *Effective Date:* This notice is effective from February 22, 2013 to February 22, 2019.

FOR FURTHER INFORMATION CONTACT: Raelene Perfetto, (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) (Pub. L. 100-578). CLIA amended section 353 of the Public Health Service Act. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under those provisions, CMS may grant deeming authority to an accreditation organization if its requirements for laboratories accredited under its program are equal to or more stringent than the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). Subpart