

CMS-116 Clinical Laboratory Improvement Amendments (CLIA) Application Form and Supporting Regulations.

CMS-10225 Disclosures Required of Certain Hospitals and Critical Access Hospitals Regarding Physician Ownership.

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

#### Information Collections

##### 1. Type of Information Collection

*Request:* Revision of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendments (CLIA) Application Form and Supporting Regulations; *Use:* The application must be completed by entities performing laboratory’s testing specimens for diagnostic or treatment purposes. This information is vital to the certification process. *Form Number:* CMS-116 (OCN#: 0938-0581); *Frequency:* Biennially and Occasionally; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 242,000; *Total Annual Responses:* 34,200; *Total Annual Hours:* 25,650. (For policy questions regarding this collection contact Sheila Ward at 410-786-3115.)

##### 2. Type of Information Collection

*Request:* Extension of a currently approved collection; *Title of Information Collection:* Disclosures Required of Certain Hospitals and Critical Access Hospitals Regarding Physician Ownership; *Use:* There is no Medicare prohibition against physician investment in a hospital or critical access hospitals (CAH). Likewise, there is no Medicare requirement that a hospital or CAH have a physician on-site at all times, although there is a requirement that they be able to provide basic elements of emergency care to

their patients. Medicare quality and safety standards are designed to provide a national framework that is sufficiently flexible to apply simultaneously to hospitals of varying sizes, offering varying ranges of services in differing settings across the nation. At the same time, however, patients might consider an ownership interest by their referring physician, the presence of a physician on-site or both to be important factors in their decisions about where to seek hospital care. A well-educated consumer is essential to improving the quality and efficiency of the healthcare system. Accordingly, patients should be made aware of the physician ownership of a hospital, whether or not a physician is present in the hospital at all times, and the hospital’s plans to address patients’ emergency medical conditions when a physician is not present. The intent of the disclosures is to increase the transparency of the hospital’s ownership and operations to patients as they make decisions about receiving care at the hospital. *Form Number:* CMS-10225 (OCN: 0938-1034); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 265; *Total Annual Responses:* 57,387,927; *Total Annual Hours:* 1,265,116. (For policy questions regarding this collection contact Teresa Walden at 410-786-3755).

Dated: December 9, 2013.

**Martique Jones,**

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

[FR Doc. 2013-29725 Filed 12-12-13; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifiers CMS-10141, CMS-10227, and CMS-R-138]

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

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of

information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the 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.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by January 13, 2014.

**ADDRESSES:** When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974 OR, Email: *OIRA\_submission@omb.eop.gov*.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS’ Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*.
3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786-1326.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the

**Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Prescription Drug Benefit Program; *Use:* Part D plans use the information to comply with the eligibility and associated Part D participating requirements. We use the information to approve contract applications, monitor compliance with contract requirements, make proper payment to plans, and to ensure that correct information is disclosed to potential and current enrollees. *Form Number:* CMS-10141 (OCN: 0938-0964); *Frequency:* Occasionally; *Affected Public:* Individuals or households, Private sector—Business or other for-profits and Not-for-profit institutions, and State, Local, or Tribal Governments; *Number of Respondents:* 4,100,953; *Total Annual Responses:* 26,301,339; *Total Annual Hours:* 7,572,243. (For policy questions regarding this collection contact Deborah Larwood at 410-786-9500).

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* PACE State Plan Amendment Preprint; *Use:* If a state elects to offer PACE as an optional Medicaid benefit, it must complete a state plan amendment preprint packet described as “Enclosures #3,4,5,6 and 7.” The information, collected from the state on a one-time basis is needed in order to determine if the state has properly elected to cover PACE services as a state plan option. *Form Number:* CMS-10227 (OCN: 0938-1027); *Frequency:* Once and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 21; *Total Annual Responses:* 7; *Total Annual Hours:* 240. (For policy questions regarding this collection contact Angela Taube at 410-786-2638).

3. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Medicare Geographic Classification Review Board (MGCRB) Procedures and Supporting Regulations; *Use:* The information submitted by the hospitals is used to determine the validity of the hospitals' requests and the discretion

used by the Medicare Geographic Classification Review Board (MGCRB) in reviewing and making decisions regarding hospitals' requests for geographic reclassification. *Form Number:* CMS-R-138 (OCN: 0938-0573); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions, and State, Local, or Tribal Governments; *Number of Respondents:* 300; *Total Annual Responses:* 300; *Total Annual Hours:* 300. (For policy questions regarding this collection contact Geri Mondowney at 410-786-1172).

Dated: December 9, 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

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and AIDS Related Research.

*Date:* December 20, 2013.

*Time:* 12:00 p.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Jose H Guerrier, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301-435-1137, [guerriej@csr.nih.gov](mailto:guerriej@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine;

93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS).

Dated: December 9, 2013.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; Review of PAR-11-169 NIAAA U34 applications.

*Date:* January 7, 2014.

*Time:* 11:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, (Teleconference), Rockville, MD 20852.

*Contact Person:* Richard A. Rippe, Ph.D., Scientific Review Officer, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Room 2109, Rockville, MD 20852, 301-443-8599, [ripper@mail.nih.gov](mailto:ripper@mail.nih.gov). (Catalogue of Federal Domestic Assistance Program No. 93.273, Alcohol Research Programs; National Institutes of Health, HHS).

Dated: December 9, 2013.

**Carolyn A. Baum,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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