

Duchenne Muscular Dystrophy (DMD), FOA DD13-002, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Time and Date: 11:00 a.m.–5:00 p.m., March 28, 2013 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to “Evaluation of Treatments and Services Provided to People with Duchenne Muscular Dystrophy (DMD), FOA DD13-002, initial review.”

Contact Person for More Information: M. Chris Langub, Ph.D., Scientific Review Officer, CDC, 4770 Buford Highway NE., Mailstop F-46, Atlanta, Georgia 30341, Telephone: (770) 488-3585, EE06@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee (CLIAC)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

Times and Dates

8:30 a.m.–5 p.m., March 6, 2013

8:30 a.m.–12 p.m., March 7, 2013

Place: CDC, 1600 Clifton Road, NE., Tom Harkin Global Communications Center, Building 19, Room 232, Auditorium B, Atlanta, Georgia 30333.

Online Registration Required: All CLIAC attendees are required to register for the meeting online at least 5 business days in advance for U.S.

citizens and at least 10 business days in advance for international registrants. Register at <http://wwwn.cdc.gov/cliac/default.aspx> by scrolling down and clicking the appropriate link under “Meeting Registration” (either U.S. Citizen Registration or Non-U.S. Citizen Registration) and completing all forms according to the instructions given. Please complete all the required fields before submitting your registration and submit no later than February 27, 2013 for U.S. registrants and February 20, 2013 for international registrants.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: This Committee is charged with providing scientific and technical advice and guidance to the Secretary of Health and Human Services; the Assistant Secretary for Health; the Director, Centers for Disease Control and Prevention; the Commissioner, Food and Drug Administration; and the Administrator, Centers for Medicare and Medicaid Services. The advice and guidance pertain to general issues related to improvement in clinical laboratory quality and laboratory medicine practice and specific questions related to possible revision of the CLIA standards. Examples include providing guidance on studies designed to improve safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; and the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods and the electronic transmission of laboratory information.

Matters To Be Discussed: The agenda will include agency updates from CDC, the Centers for Medicare & Medicaid Services (CMS), and the Food and Drug Administration (FDA). Presentations and discussions will include activities related to forthcoming FDA infection prevention guidance for the use of fingerstick and point-of-care blood testing devices, especially glucose meters. Other topics will include the harmonization of clinical laboratory test results; and assuring the quality of new DNA sequencing technologies in the clinical laboratory.

Agenda items are subject to change as priorities dictate.

Providing Oral or Written Comments: It is the policy of CLIAC to accept written public comments and provide a

brief period for oral public comments whenever possible. *Oral Comments:* In general, each individual or group requesting to make an oral presentation will be limited to a total time of five minutes (unless otherwise indicated). Speakers must also submit their comments in writing for inclusion in the meeting’s Summary Report. To assure adequate time is scheduled for public comments, individuals or groups planning to make an oral presentation should, when possible, notify the contact person below at least one week prior to the meeting date. *Written Comments:* For individuals or groups unable to attend the meeting, CLIAC accepts written comments until the date of the meeting (unless otherwise stated). However, it is requested that comments be submitted at least one week prior to the meeting date so that the comments may be made available to the Committee for their consideration and public distribution. Written comments, one hard copy with original signature, should be provided to the contact person below. Written comments will be included in the meeting’s Summary Report.

Availability of Meeting Materials: To support the green initiatives of the federal government, the CLIAC meeting materials will be made available to the Committee and the public in electronic format (PDF) on the Internet instead of by printed copy. Refer to the CLIAC Web site on the day of the meeting for materials. http://wwwn.cdc.gov/cliac/cliac_meeting_all_documents.aspx.

Note: If using a mobile device to access the materials, please verify the device’s browser is able to download the files from the CDC’s Web site before the meeting. Alternatively, the files can be downloaded to a computer and then emailed to the portable device. An Internet connection, power source and limited hard copies may be available at the meeting location, but cannot be guaranteed.

Contact Person for Additional Information: Nancy Anderson, Chief, Laboratory Practice Standards Branch, Division of Laboratory Science and Standards, Laboratory Science, Policy and Practice Program Office, Office of Surveillance, Epidemiology and Laboratory Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop F-11, Atlanta, Georgia 30333; telephone (404) 498-2741; fax (404) 498-2219; or via email at NAAnderson@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for CDC and the

Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10455]

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:* New collection; *Title of Information Collection:* Report of a Hospital Death Associated with Restraint or Seclusion; *Use:* Executive Order 13563, Improving Regulation and Regulatory Review, was signed on January 18, 2011. The order recognized the importance of a streamlined, effective, and efficient regulatory framework designed to promote economic growth, innovation, job creation, and competitiveness. Each agency was directed to establish an ongoing plan to reduce or eliminate burdensome, obsolete, or unnecessary regulations to create a more efficient and flexible structure.

The regulation that was published on May 16, 2012 (77 FR 29034) included a reduction in the reporting requirement

related to hospital deaths associated with the use of restraint or seclusion, § 482.13(g). Hospitals are no longer required to report to CMS those deaths where there was no use of seclusion and the only restraint was 2-point soft wrist restraints. It is estimated that this will reduce the volume of reports that must be submitted by 90 percent for hospitals. In addition, the final rule replaced the previous requirement for reporting via telephone to CMS, which proved to be cumbersome for both CMS and hospitals, with a requirement that allows submission of reports via telephone, facsimile or electronically, as determined by CMS. Finally, the amount of information that CMS needs for each death report in order for CMS to determine whether further on-site investigation is needed has been reduced.

The Child Health Act (CHA) of 2000 established in Title V, Part H, Section 591 of the Public Health Service Act (PHSA) minimum requirements concerning the use of restraints and seclusion in facilities that receive support with funds appropriated to any Federal department or agency. In addition, the CHA enacted Section 592 of the PHSA, which establishes minimum mandatory reporting requirements for deaths in such facilities associated with use of restraint or seclusion. Provisions implementing this statutory reporting requirement for hospitals participating in Medicare are found at 42 CFR 482.13(g), as revised in the final rule that published on May 16, 2012 (77 FR 29034).

The 60-day **Federal Register** notice published on November 21, 2012, (77 FR 69848). Subsequently, there was a minor revision to the Health Death Report form. *Form Number:* CMS-10455 (OCN: 0938—New); *Frequency:* Occasionally; *Affected Public:* Private Sector. *Number of Respondents:* 4,900. *Number of Responses:* 24,500. *Total Annual Hours:* 8,085. (For policy questions regarding this collection contact Danielle Miller at 410-786-8818. 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 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 1, 2013*.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, Email: OIRA_submission@omb.eop.gov.

Dated: January 24, 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-276 and CMS-339]

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:* Reinstatement with change of a previously approved collection; *Title:* Prepaid Health Plan Cost Report; *Use:* Health Maintenance Organizations and Competitive Medical Plans (HMO/CMPs) contracting with the Secretary under Section 1876 of the Social Security Act are required to submit a budget and enrollment forecast, semi-annual interim report, interim final cost report, and a final certified cost report in accordance with 42 CFR 417.572-417.576. Health Care Prepayment Plans