TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
§§ 129.35(a)(3)(i) and 129.80(h)	319 (bottlers subject to source water and finished product testing)	6	1,914	0.08	153
§§ 129.35(a)(3)(i) and 129.80(h)	2.5 (bottlers conducting secondary testing of source water)	5	12	0.08	1
§§ 129.35(a)(3)(i) and 129.80(h)	2.5 (bottlers rectifying contamination)	3	7.5	0.25	2
§ 129.80(g) and (h)	95 (bottlers testing finished product only)	3	285	0.08	23
Total Annual Burden					179

[1]There are no capital costs or operating costs associated with this collection of information.

The current CGMP regulations already reflect the time and associated recordkeeping costs for those bottlers that are required to conduct microbiological testing of their source water, as well as total coliform testing of their finished bottled water products. FDA therefore concludes that any additional burden and costs in recordkeeping based on the new testing requirements for source and finished bottled water are negligible. FDA estimates that the labor burden of keeping records of each test is about 5 minutes per test. FDA also requires follow-up testing of source water and finished bottled water products for *E. coli* when total coliform positives occur. FDA expects that 319 bottlers that use sources other than PWSs may find a total coliform positive sample about 3 times per year in source testing and about 3 times in finished product testing, for a total of 153 hours of recordkeeping. In addition to the 319 bottlers, about 95 bottlers that use PWSs may find a total coliform positive sample about 3 times per year in finished product testing, for a total of 23 hours of recordkeeping. Upon finding a total coliform positive sample, bottlers will then have to conduct a follow-up test for *E. coli*.

FDA expects that recordkeeping for the follow-up test for *E. coli* will also take about 5 minutes per test. As shown in table 1 of this document, FDA expects that 2.5 bottlers per year will have to carry out the additional *E. coli* testing, with a burden of 1 hour. These bottlers will also have to keep records about rectifying the source contamination, for a burden of 2 hours. For all expected total coliform testing, *E. coli* testing, and source rectification, FDA estimates a total burden of 179 hours. FDA bases its estimate on its experience with the current CGMP regulations.

Dated: May 18, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–12493 Filed 5–26–09; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10078]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

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 without change of a currently approved collection; *Title of Information Collection:* Matching Grants to States for the Operation of High Risk Pools; *Use:* CMS is requiring this information as a condition of eligibility for grants that were authorized in the Trade Act of 2002, the Deficit Reduction Act of 2005 and the State High Risk Pool Funding Extension Act of 2006. The information is necessary to determine if a state applicant meets the necessary eligibility criteria for a grant as required by law. The respondents will be States that have a high risk pool as defined in sections 2741, 2744, or 2745 of the Public Health Service Act. The grants will provide funds to States that incur losses in the operation of high risk pools. High risk pools are set up by States to provide health insurance to individuals that cannot obtain health insurance in the private market because of a history of illness; *Form Numbers:* CMS–10078 (OMB#: 0938–0887); *Frequency:* Recordkeeping, Reporting—Occasionally; Affected Public: State, Local and Tribal Governments; *Number of Respondents:* 31; *Total Annual Responses:* 31; *Total Annual Hours:* 1,240. (For policy questions regarding this collection contact Paul Scholz at 410–786–6178. 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 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,* or call the Reports Clearance Office on (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 *July 28, 2009:*

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 (CMS–10078), Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: May 21, 2009.

Michelle Shortt,

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

[FR Doc. E9–12530 Filed 5–28–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–643 and CMS–359/360]

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

AGENCY: Centers for Medicare & Medicaid Services.

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:* Hospice Survey and Deficiencies Report; *Use:* In order to participate in the Medicare program, a hospice must meet certain Federal health and safety conditions of participation. This form is used by State surveyors to record data about a hospice's compliance with these conditions of participation in order to initiate the certification or recertification process. *Form Number:* CMS–643 (OMB#: 0938–0379); *Frequency:* Reporting—Yearly; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 3377; *Total Annual Responses:* 1130; *Total Annual Hours:* 1130. (For policy questions regarding this collection contact Kim Roche at 410–786–3524. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Comprehensive Outpatient Rehabilitation Facility (CORF) Eligibility and Survey Forms and Information Collection Requirements at 42 CFR 485.54 through 485.66; *Use:* In order to participate in the Medicare program as a CORF, providers must meet Federal conditions of participation. The certification form is needed to determine if providers meet at least preliminary requirements. The survey form is used to record provider compliance with the individual conditions and report findings to CMS. *Form Number:* CMS–359/360/R–55 (OMB#: 0938–0267); *Frequency:* Reporting—Occasionally; *Affected Public:* Private Sector: Business or other for-profits; *Number of Respondents:* 476; *Total Annual Responses:* 60; *Total Annual Hours:* 223,285. (For policy questions regarding this collection contact Georgia Johnson at 410–786–6859. 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 E-mail 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 *June 29, 2009.*

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

Dated: May 21, 2009.

Michelle Shortt,

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

[FR Doc. E9–12529 Filed 5–28–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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: Heart, Lung, and Blood Initial Review Group; Heart, Lung, and Blood Program Project Review Committee.

Date: June 18, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jeffrey H. Hurst, PhD, Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7208, Bethesda, MD 20892–7924, 301–435–0303, *hurstj@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 21, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–12583 Filed 5–28–09; 8:45 am]

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