

668B (OMB# 0938-0653); *Frequency*: Biennially; *Affected Public*: Business or other for-profits and not-for-profit institutions. State, Local, or Tribal Government, Federal Government; *Number of Respondents*: 21,000; *Total Annual Responses*: 10,500; *Total Annual Hours*: 2,625. (For policy questions regarding this collection contact Kathleen Todd at 410-786-3385. 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 April 6, 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: February 27, 2009.

Michelle Shortt,

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

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BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10165]

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*: Revision of a currently approved collection; *Title of Information Collection*: Electronic Health Records (EHR) Demonstration Web Enabled Application for Phase II; *Use*: The goal of the Electronic Health Record (EHR) demonstration is to foster the implementation and adoption of EHRs and Health Information Technology (HIT) more broadly as effective vehicles improve the quality of care provided and transform the way medicine is practiced and delivered. Adoption of HIT has the potential to provide significant savings to the Medicare program and improve the quality of care rendered to Medicare beneficiaries. This demonstration is designed to leverage the combined forces of private and public payers to drive physician practices to widespread adoption and use of EHRs. The demonstration is being implemented in two phases. Over 800 applications were received, via a manual (paper) process, from interested practices in the four Phase I sites. Because of the greater number of sites and projected applicants for Phase II, CMS has Web enabled the application. This is expected to make it easier for practices to complete the application accurately and completely, submit it in a timely manner, and allow CMS to process the applications more efficiently and effectively. *Form Number*: CMS-10165(OMB#: 0938-0936-0965); *Frequency*: Reporting—Once; *Affected Public*: Business or other for-profit and not-for-profit institutions; *Number of Respondents*: 1,600; *Total Annual Responses*: 1,600; *Total Annual Hours*: 347. (For policy questions regarding this collection contact Jody Blatt at 410-786-6921. 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 May 5, 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 _____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: February 27, 2009.

Michelle Shortt,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0097]

Agency Information Collection Activities; Proposed Collection; Comment Request; Request for Samples and Protocols

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to the regulations which state that protocols for samples of biological products must be submitted to the agency.

DATES: Submit written or electronic comments on the collection of information by May 5, 2009.