

plans to release a second version of the formats in six to nine months, or perhaps sooner, depending on the nature of initial feedback. Once the formats are stabilized, AHRQ plans to release new versions annually. The Agency will follow the same process for formats developed for other settings.

AHRQ realizes that using Version 0.1 Beta paper forms is not the optimal way to collect patient safety data. Over time, computer software (developed in the private sector) will make use of the formats much more efficient. However, because the Agency plans an early second release of the Common Formats, it cautions software developers to understand that the first release of the formats will likely be substantially enhanced.

More information on the feedback process can be obtained through AHRQ's PSO Web site: <http://www.pso.ahrq.gov/index.html>.

Dated: August 21, 2008.

Carolyn M. Clancy,

Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-65]

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 of a currently approved collection; *Title of Information Collection:* Information Collection Requirements in Final Peer Review Organizations Sanction Regulations—42 CFR 1004.4, 1004.50, 1004.60, and 1004.70; *Use:* The Peer Review Improvement Act of 1982 amended Title XI of the Social Security Act (the Act), creating the Utilization and Quality Control Peer Review Organization Program. Section 1156 of the Act imposes obligations on health care practitioners and others who furnish or order services or items under Medicare. This section also provides for sanction actions, if the Secretary determines that the obligations as stated by this section are not met. Quality Improvement Organizations (QIOs) are responsible for identifying violations. QIOs may allow practitioners or other entities, opportunities to submit relevant information before determining that a violation has occurred. The information collection requirements contained in this information collection request are used by the QIOs to collect the information necessary to make their decision. *Form Number:* CMS-R-65 (OMB# 0938-0444); *Frequency:* Reporting—On occasion; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 53; *Total Annual Responses:* 53; *Total Annual Hours:* 14,310.

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 *October 28, 2008*:

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: August 22, 2008.

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-2008-N-0313]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Request for Inspection Under the Inspection by Accredited Persons Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 29, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974, or e-mailed to baguilar@omb.eop.gov. All comments should be identified with the OMB control number 0910-0569. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.