

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://cms.hhs.gov/regulations/prd/default.asp>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 29, 2004.

**Melissa Musotto,**

*Acting, Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.*

[FR Doc. 04-2704 Filed 2-6-04; 8:45 am]

BILLING CODE 4120-03-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

[Document Identifier: CMS-R-308]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare and 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 and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), 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 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:* New Collection; *Title of Information Collection:* Instrument/Tool for Refinement of a Prospective Payment System for Patients in Inpatient Psychiatric Hospitals, and units: A pilot test; *Form No.:* CMS-10107 (OMB# 0938-NEW); *Use:* This is a request to pilot test an instrument to refine the PPS for inpatient psychiatric facilities. This testing will include assessing the feasibility of administering this instrument, and testing the reliability, validity, time and process of administration.; *Frequency:* Other: Per stay per diem; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and State, Local or Tribal Government; *Number of Respondents:* 1,120; *Total Annual Responses:* 1,120; *Total Annual Hours:* 2,464.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* The State Children's Health Insurance Program and Supporting Regulations in 42 CFR 431.636, 457.50, 457.60, 457.70, 457.340, 457.350, 457.431, 457.440, 457.525, 457.560, 457.570, 457.740, 457.750, 457.810, 457.940, 457.945, 457.965, 457.985, 457.1005, 457.1015, and 457.1180; *Form No.:* CMS-R-308 (OMB# 0938-0841); *Use:* States are required to submit title XXI plans and amendments for approval by the Secretary pursuant to section 2102 of the Social Security Act in order to receive funds for initiating and expanding health insurance coverage for uninsured children. States are also required to submit State expenditure and statistical reports, annual reports and State evaluations to the Secretary as outlined in title XXI of the Social Security Act and furnish assorted notices to recipients; *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Government; *Number of Respondents:* 88; *Total Annual Responses:* 12,187,482; *Total Annual Hours:* 838,714.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at <http://cms.hhs.gov/regulations/prd/default.asp>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to

the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Melissa Musotto, Room C5-14-03, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: January 29, 2004.

**Melissa Musotto,**

*Acting, Paperwork Reduction Act Team Leader, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.*

[FR Doc. 04-2705 Filed 2-6-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003N-0482]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Mammography Facilities, Standards, and Lay Summaries for Patients

**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 March 10, 2004.

**ADDRESSES:** The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**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.

**Mammography Facilities, Standards, and Lay Summaries for Patients—21 CFR Part 900 (OMB Control Number 0910-0309)—Extension**

Public Law 102-539, the Mammography Quality Standards Act of 1992 (MQSA) (42 U.S.C. 263b) as amended by the Mammography Quality Standards Reauthorization Act (MQSRA) of 1998 (Public Law 105-248) establishes the authority for a Federal certification and inspection program for mammography facilities; regulations and standards for accreditation bodies for mammography facilities; and standards for mammography equipment, personnel, and practices, including quality assurance. MQSRA extended the life of the MQSA program for 4 years

from its original expiration date of 1998 until 2002, and also modified some of the provisions. The most significant modification from a report and recordkeeping viewpoint under § 900.12(c)(2) was that mammography facilities were required to send a lay summary of each examination to the patient.

FDA, under this regulation, collects information from accreditation bodies and mammography facilities by requiring each accreditation body to submit an application for approval and to establish a quality assurance program. On the basis of accreditation, facilities are certified by FDA and must prominently display their certificate. FDA uses the information to ensure that private, nonprofit organizations or state

agencies meet the standards established by FDA for accreditation bodies to accredit facilities that provide mammography services.

Information collected from mammography facilities has also been used to ensure that the personnel, equipment, and quality systems has and continues to meet the regulations under MQSA and will be used by patients to manage their health care properly. The intent of these regulations is to assure safe, reliable, and accurate mammography on a nationwide level. The most likely respondents to this information collection will be accreditation bodies and mammography facilities seeking certification.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

| 21 CFR Section   | Number of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours | Total Capital Costs | Total Operating & Maintenance Costs |
|------------------|-----------------------|-------------------------------|------------------------|--------------------|-------------|---------------------|-------------------------------------|
| 900.3            | 1                     | 0.33                          | 0.33                   | 60                 | 20          | \$50                |                                     |
| 900.3(b)(3)      | 1                     | 0.33                          | 0.33                   | 60                 | 20          |                     |                                     |
| 900.3(c)         | 5                     | 0.33                          | 1.67                   | 15                 | 25          |                     |                                     |
| 900.3(e)         | 1                     | 0.1                           | 0.1                    | 1                  | 0.1         |                     |                                     |
| 900.3(f)(2)      | 1                     | 0.1                           | 0.1                    | 200                | 20          |                     |                                     |
| 900.4(c)&(2)     | 9,200                 | 0.33                          | 3,067                  | 1                  | 3,067       |                     |                                     |
| 900.4(e)         | 9,450                 | 1                             | 9,450                  | 8                  | 75,600      |                     |                                     |
| 900.4(f)         | 276                   | 1                             | 276                    | 7                  | 1,932       |                     |                                     |
| 900.4(h)         | 5                     | 1                             | 6130                   | 1                  | 6,130       |                     |                                     |
| 900.4(i)(2)      | 1                     | 0.33                          | 0.33                   | 1                  | 0.33        |                     |                                     |
| 900.6(c)(1)      | 1                     | 0.1                           | 0.1                    | 1                  | 0.1         |                     |                                     |
| 900.11(b)(1)     | 9,200                 | 0.33                          | 3,067                  | 2                  | 6,134       |                     |                                     |
| 900.11(b)(2)     | 250                   | 1                             | 250                    | 2                  | 500         |                     |                                     |
| 900.11(b)(3)     | 5                     | 1                             | 5                      | .5                 | 2.5         |                     |                                     |
| 900.11(c)        | 9,200                 | 0.04                          | 368                    | 5                  | 1,840       |                     | \$1,000                             |
| 900.12(c)(2)     | 9,200                 | 3,478                         | 36,000,000             | 5 minutes          | 3,000,000   | \$50                |                                     |
| 900.12(j)(1)     | 25                    | 1                             | 25                     | 1                  | 25          |                     |                                     |
| 900.12(j)(2)     | 25                    | 0.08                          | 2                      | 50                 | 100         |                     |                                     |
| 900.15(c)        | 9,200                 | 0.05                          | 46                     | 2                  | 92          |                     |                                     |
| 900.15(d)(3)(ii) | 9,200                 | 0.0001                        | 0.92                   | 2                  | 1.8         |                     | \$10                                |
| 900.18(c)        | 9,300                 | 0.00032                       | 3                      | 2                  | 6           |                     | \$30                                |
| 900.18(e)        | 10                    | 0.0100                        | 0.1                    | 1                  | 0.10        |                     | \$10                                |
| FDA Form 3422    | 800                   | 1                             | 800                    | .25                | 200         |                     |                                     |
| Total            |                       |                               |                        |                    | 3,095,716   |                     | \$1,040                             |

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

| 21 CFR Section | Number of Recordkeepers | Annual Frequency of Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours | Total Operating & Maintenance Costs |
|----------------|-------------------------|-----------------------------------|----------------------|------------------------|-------------|-------------------------------------|
| 900.3(f)(1)    | 5                       | 0.02                              | 0.1                  | 200                    | 20          | \$18,400                            |
| 900.4(g)       | 1                       | 0.33                              | 0.33                 | 1                      | 0.33        |                                     |
| 900.12(c)(4)   | 9,200                   | 1                                 | 9,200                | 1                      | 9,200       |                                     |
| 900.12(e)(13)  | 9,200                   | 52                                | 478,400              | 0.125                  | 59,800      |                                     |
| 900.12(f)      | 9,200                   | 1                                 | 9,200                | 5                      | 46,000      |                                     |
| 900.12(h)      | 9,200                   | 2                                 | 18,400               | 0.5                    | 9,200       | \$18,400                            |
| Total          |                         |                                   |                      |                        | 124,220     |                                     |

<sup>1</sup>There are no capital costs associated with this collection of information.

The most likely respondents to this information collection will be accreditation bodies and mammography facilities seeking certification. The total

capital cost associated with these regulations is \$50 (§ 900.3(b)(3)). This is a one-time start up cost associated with the application for approval as an

accreditation body. The total operating and maintenance cost associated with these requirements is \$19,440. This is the cost that facilities bear to maintain

records under the initial and final mammography regulations.

Dated: January 29, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-2641 Filed 2-6-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Proposed Information Collection: Request for Public Comment: 60-Day Notice

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Request for Public Comment: 60-day Proposed Collection; Hoz'ho'nii: An Intervention to Increase Breast and Cervical Cancer Screening Among Navajo Women.

**SUMMARY:** In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, to provide a 60-day advance opportunity for public comment on proposed information collection projects, the Indian Health Service (IHS) is publishing for comment a summary of a proposed information collection to be submitted to the Office of Management and Budget (OMB) for review.

#### Proposed Collection

*Title:* Hoz'ho'nii: An Intervention to Increase Breast and Cervical Cancer Screening Among Navajo Women.

*Type of Information Collection*

*Request:* Previously Approved Collection.

*Form Number:* None.

*Need and Use of the Information*

*Collection:* The information is needed to evaluate a culturally appropriate educational outreach program designed

to increase breast and cervical cancer screening among Navajo women ages 20 and older. The purpose is to identify barriers that may prevent Navajo women from participating in breast and cervical cancer screening by comparing changes in knowledge, attitudes, and behaviors of three study groups; educational outreach only, education outreach plus chapter-based clinic, and a control group. Results will be used to assess the impact of the impact of the educational outreach program, improve breast and cervical cancer screening, and to guide the IHS and Tribal health programs in the delivery of culturally appropriate intervention to reduce mortality rates from breast and cervical cancer among Navajo women.

*Affected Public:* Individuals.

*Type of Respondents:* Individuals.

The table below provides the estimated burden response for this information collection:

ESTIMATED BURDEN RESPONSE TABLE

| Data collection instrument | Estimated number of respondents | Responses per respondent | Average burden hour per response * | Total annual burden hrs. |
|----------------------------|---------------------------------|--------------------------|------------------------------------|--------------------------|
| KAB Pretest .....          | 450                             | 1                        | 0.42 hr (25 minutes) .....         | 188.0 hrs                |
| KAB Post test .....        | 450                             | 1                        | 0.42 hr (25 minutes) .....         | 188.0 hrs                |
| Interviews .....           | 30                              | 1                        | 0.25 hr (15 minutes) .....         | 8.0 hrs                  |
| <b>TOTAL</b> .....         | <b>930</b>                      | <b>1</b>                 | .....                              | <b>384.0 hrs</b>         |

\* For ease of understanding, burden hours are also provided in actual minutes.

There are no Capital Costs, Operating Costs and/or Maintenance Costs to report for this information collection

*Request for Comments:* Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the agency processes the information collected in a useful and timely fashion; (c) the accuracy of public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimate are logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*Send Comments and Requests For Further Information:* Send your written comments, requests for more information on the proposed collection, or requests to obtain a copy of the data collection instrument(s) and instructions to: Ms. Christina Ingersoll,

IHS Reports Clearance Officer, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20852-1601, call non-toll free (301) 443-5938, send via facsimile to (301) 443-1522, or send your E-mail requests, comments, and return address to: [cingerso@hqe.ihs.gov](mailto:cingerso@hqe.ihs.gov).

*Comment Due Date:* Your comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: January 26, 2004.

**Charles W. Grim,**

*Assistant Surgeon General, Director, Indian Health Service.*

[FR Doc. 04-2642 Filed 2-6-04; 8:45 am]

BILLING CODE 4160-16-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Notice of Intent To Prepare an Environmental Impact Statement for the National Emerging Infectious Disease Laboratories Facility in Boston, MA

**AGENCY:** National Institutes of Health (NIH), DHHS.

**ACTION:** Notice of intent to prepare an environmental impact statement for the National Emerging Infectious Diseases Laboratories facility in Boston, MA—extension of comment period and rescheduling of public meeting.

**SUMMARY:** The Department of Health and Human Services (DHHS), National Institutes of Health (NIH), announced its intent to prepare an environmental impact statement (EIS) to evaluate a proposed new National Emerging Infectious Disease Laboratories facility in Boston, MA in the **Federal Register** on January 9, 2004. The Public Scoping meeting has been rescheduled to