Respondents	Number of respondents	Number responses/respondent	Avg. burden/response (in hours)	Total burden (in hours)
Screener interview	19,344	1	5/60	1,612
Telephone interview	8,000	1	30/60	4,000
Total	27,344			5,612

Dated: October 3, 2003.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 03–25695 Filed 10–9–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–10091 and CMS–R–299]

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:* Extension of a currently approved collection.

Title of Information Collection: UPIN (Unique Physician Identification Number) Participating Physicians Directory.

Form No.: CMS–10091(OMB# 0938–0905).

Use: In November of 2000, CMS launched the Participating Physicians Directory on *http://www.medicare.gov.* This particular directory was created to provide beneficiaries with the names, addresses, and specialties of Medicare participating physicians who have agreed to accept assignment on all Medicare claims and covered services. CMS is adding information from already existing sources; in addition, CMS wants to collect a new data element ''Accepting New Patients Indicator'' which is essential to a beneficiary's search for a physician.

Frequency: On occasion.

Affected Public: Business or other for-profit.

Number of Respondents: 10,980.

Total Annual Responses: 10,980.

Total Annual Hours: 915.

2. *Type of Information Collection Request:* Revision of a currently approved collection.

Title of Information Collection: A project to Develop an Outcome-Based Continuous Quality Improvement System and Core Outcome and Comprehensive Assessment Data Set for PACE.

Form No.: CMS–R–299 (OMB# 0938–0791).

Use: The purpose of this project is to develop an outcome-based continuous quality improvement (OBCQI) system and core comprehensive assessment data set for the PACE program by (a) developing and testing a set of data items for core outcome and comprehensive assessment (COCOA), (b) testing risk-adjustment methods so each site's outcomes can be appropriately evaluated, (c) designing an OBCQI approach to improve quality in a systematic, evolutionary manner, and (d) testing the usefulness of the data items for assessment and care planning. A three-phase field test will result in the refinement of the draft COCOA data items and protocols needed. Findings from the project are intended to guide the possible implementation of a national approach for OBCQI and core comprehensive assessment for PACE.

Frequency: On occasion and Semi-annually.

Affected Public: Individuals or Households and Not-for-profit institutions.

Number of Respondents: 8,320.

Total Annual Responses: 116,038.

Total Annual Hours: 16,959.98.

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/pra/default.asp,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *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: October 2, 2003.

Dawn Willinghan,

CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–25764 Filed 10–9–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–2649, CMS–730 and CMS–80]

Agency Information Collection Activities: Submission for OMB Review; 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:* Extension of a currently approved collection.

Title of Information Collection: Request for Reconsideration of Part A Medicare Claims and Supporting Regulations in 42 CFR, 405.711.

Form No.: CMS–2649 (OMB# 0938–0045).

Use: Section 1869 of the Social Security Act authorizes a hearing for any individual who is dissatisfied with the intermediary's determination or amount of benefit paid. This form is used so that a party may request a reconsideration of the initial determination.

Frequency: Monthly, Quarterly, Annually.

Affected Public: Individuals or Households and Not-for-profit institutions.

Number of Respondents: 60,000.

Total Annual Responses: 60,000.

Total Annual Hours: 15,000.

2. *Type of Information Collection Request:* Extension of a currently approved collection.

Title of Information Collection: Employee Building Pass Application and File.

Form No.: CMS–730 & CMS–80 (OMB# 0938–0812).

Use: The purpose of this system is to control United States Government Building Passes issued to all Centers for Medicare & Medicaid Services (CMS) employees and non-CMS employees who require continuous access to CMS buildings in Baltimore and other CMS and HHS Buildings.

Frequency: As needed.

Affected Public: Federal Government and Business or other for-profit.

Number of Respondents: 2000.

Total Annual Responses: 2000.

Total Annual Hours: 500.

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/pra/default.asp,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *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: October 2, 2003.

Dawn Willinghan,

CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–25765 Filed 10–9–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0311]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device User Fee and Modernization Act Small Business Qualification Certification (Form FDA 3602)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Submit written comments on the collection of information by November 10, 2003.

ADDRESSES: 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 written 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.

MDUFMA Small Business Qualification Certification (Form FDA 3602)—(OMB Control Number 0910–0508)—Extension

Medical Device User Fee and Modernization Act (MDUFMA) amends the Federal Food, Drug, and Cosmetic Act to provide for user fees for certain medical device applications. The initial fees (for fiscal year (FY) 2003) are set by statute; FDA will publish a **Federal Register** notice by August 1, 2003, announcing the fees for FY 2004. To avoid harming small businesses, MDUFMA provides for reduced or waived fees for applicants who qualify as a ''small business.'' This means there are two levels of fees, a standard fee, and a reduced or waived small business fee.

Presently, a ''small business'' is an applicant who reported no more than $30 million ''gross receipts or sales'' on its Federal income tax return for the most recent tax year; the applicant must count the ''gross receipts or sales'' of all of its affiliates, partners, or parent firms when calculating whether it meets the $30 million threshold. An applicant must pay the full standard fee unless it provides evidence demonstrating to FDA that it meets the ''small business'' criteria. The evidence required by MDUFMA is a copy of the most recent Federal income tax return of the applicant, and any affiliate, partner, or parent firm. FDA will review these materials and decide whether an applicant is a ''small business'' within the meaning of MDUFMA.

Form FDA 3602 will be available in a forthcoming guidance document, ''MDUFMA Small Business Qualification Worksheet and Certification.'' This guidance will describe the criteria FDA will use to decide whether an entity qualifies as a MDUFMA small business and will help prospective applicants understand what they need to do to meet the small business criteria for FY 2004 and subsequent fiscal years. FDA will publish this guidance by August 1, 2003.

Respondents will be businesses or other for-profit organizations.

In the **Federal Register** of July 18, 2003 (68 FR 42742), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.