

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: March 20, 2003.

Dawn Willingham,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS-901 and CMS-3070]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services.

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:* Revision of a currently approved collection; *Title of Information Collection:* Qualification Application: Medicare+Choice Application for HMOs, PPOs, and State

Licensed PSOs; Medicare+Choice Application for Federally Waived PSOs; Medicare+Choice Application for Medicare Savings Account Entities; Medicare+Choice Application for Private Fee-for-Service Plans.; *Form No.:* CMS-901 (OMB# 0938-0470); *Use:* Prepaid health plans must meet certain regulatory requirements to be federally qualified health maintenance organizations or to enter into a contract with CMS to provide health benefits to Medicare beneficiaries. The application is the collection form to obtain the information from a health plan that will allow CMS staff to determine compliance with the regulations.; *Frequency:* Other: One-time submission.; *Affected Public:* Business or other for-profit, Not-for-profit institutions, State, Local or Tribal Government; *Number of Respondents:* 55; *Total Annual Responses:* 55; *Total Annual Hours:* 5,500.

2. *Type of Information Collection Request:* Extension of a previously approved collection; *Title of Information Collection:* Intermediate Care Facility for the Mentally Retarded or Persons with Related Conditions ICF/MR Survey Report Form (3070G-I) and Supporting Regulations at 42CFR 431.52, 431.151, 435.1009, 440.150, 440.220, 442.1, 442.10-442.16, 442.30, 442.40, 442.42, 442.100-442.119, 483.400-483.480, 488.332, 488.400, and 498.3-498.5; *Form No.:* CMS-3070 (0938-0062); *Use:* The survey forms are needed to ensure provider compliance. In order to participate in the Medicaid program as an ICF/MR, a providers must meet Federal standards. The survey report form is used to record providers' level of compliance with the individual standard and report it to the Federal government. We are considering revising this collection to properly reflect the burden imposed by implementing regulations; *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 6,763; *Total Annual Responses:* 6,763; *Total Annual Hours:* 21,600.

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, 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: Dawn Willingham, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: March 20, 2003.

Dawn Willingham,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D-0063]

Medical Devices: Guidance for Industry and FDA: Fiscal Year 2003 Medical Device User Fee and Modernization Act of 2002 Small Business Qualification Worksheet and Certification; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "FY 2003 MDUFMA Small Business Qualification Worksheet and Certification." This guidance explains how you can certify that you qualify as a "small business" within the meaning of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and provides a copy of, and instructions for, Form FDA 3602, "FY 2003 MDUFMA Small Business Qualification Certification." If FDA decides that you are a small business, you will be eligible for reduced or waived small business fees for medical device applications that you submit from October 1, 2002, through September 30, 2003.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "FY 2003 MDUFMA Small Business Qualification Worksheet and Certification" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and