

and easy to obtain from http://www.dnb.com/US/duns_update/.

FOR FURTHER INFORMATION CONTACT: U.S. Department of Health and Human Services, Administration on Aging, Office of Evaluation, Washington, DC 20201, telephone: (202) 357-0145.

Dated: June 30, 2003.

Josefina G. Carbonell,

Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS-10091]

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 (CMS)), 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.

Type of Information Collection Request: New Collection; *Title of Information Collection:* UPIN (UPIN Physician Identification Number) Participating Directory/Accepting New Patients Indicator; *Form No.:* CMS-10091 (OMB# 0938-NEW); *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:* 109,800; *Total Annual Responses:* 10,980; *Total Annual Hours:* 915.

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@cms.hhs.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: C5-14-03, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: June 26, 2003.

Dawn Willingham,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0286]

Agency Information Collection Activities: Proposed Collection; Comment Request; User Fee Cover Sheet; Form FDA 3397

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 Form FDA 3397, User Fee Cover Sheet that must be submitted along with certain drug and biologic product applications and supplements.

DATES: Submit written or electronic comments on the collection of information by September 2, 2003.

ADDRESSES: Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comment on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information