a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0308. The approval expires on April 31, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: April 24, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–10710 Filed 4–30–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1503]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Orphan Drug Products

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 May 31, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

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

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.

Orphan Drug Products—21 CFR Part 316 (OMB Number 0910–0167)—Extension

Sections 525 through 528 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360aa through 360dd) give FDA statutory authority to: (1) Provide recommendations on investigations required for approval of marketing applications for orphan drugs, (2) designate eligible drugs as orphan drugs, (3) set forth conditions under which a sponsor of an approved orphan drug obtains exclusive approval, and (4) encourage sponsors to make orphan drugs available for treatment on an ''open protocol'' basis before the drug has been approved for general marketing. The implementing regulations for these statutory requirements have been codified under part 316 (21 CFR part 316) and specifies the content and format of a request for written recommendations concerning the nonclinical laboratory studies and clinical investigations necessary for approval of marketing applications. Section 316.12 provides that, before providing such recommendations, FDA may require results of studies to be submitted for review. Section 316.14 contains provisions permitting FDA to refuse to provide written recommendations under certain circumstances. Within 90 days of any refusal, a sponsor may submit additional information specified by FDA. Section 316.20 specifies the content and format of an orphan drug application which includes requirements that an applicant document that the disease is rare (affects fewer than 200,000 persons in the United States annually) or that the sponsor of the drug has no reasonable expectation of recovering costs of research and development of the drug. Section 316.26 allows an applicant to amend the application under certain circumstances. Section 316.30 requires submission of annual reports, including progress reports on studies, a description of the investigational plan, and a discussion of changes that may affect orphan status. The information requested will provide the basis for an FDA determination that the drug is for a rare disease or condition and satisfies the requirements for obtaining orphan drug status. Secondly, the information will describe the medical and regulatory history of the drug. The respondents to this collection of information are biotechnology firms, drug companies, and academic clinical researchers.

In the **Federal Register** of September 19, 2000 (65 FR 56586), the agency requested comments on the proposed collections of information. No significant comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
316.10, 316.12, and 316.14	0	0	0	0	0
316.20, 316.21, and 316.26	90	1.78	160.20	125	20,025
316.22	5	1	5	2	10
316.27	5	1	5	4	20
316.30	450	1	450	2	900
316.36	.2	3	.6	15	9
Total Burden Hours					20,964

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The information requested from respondents represents, for the most part, an accounting of information already in possession of the applicant. It is estimated, based on the frequency of requests over the past 10 years, that 90 persons or organizations per year will request orphan drug designation and that no requests for recommendations on design of preclinical or clinical studies will be received. Based upon FDA experience over the last decade, FDA estimates that the effort required to prepare applications to receive consideration for sections 525 and 526 of the act (§§ 316.10, 316.12, 316.20, and 316.21) is generally similar and is estimated to

require an average of 95 hours of professional staff time and 30 hours of support staff time per application. Estimates of annual activity and burden for foreign sponsor nomination of a resident, agent, change in ownership or designation, and inadequate supplies of drug in exclusivity, are based on total experience by FDA with such requests since 1983.

Dated: April 24, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–10711 Filed 4–30–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–1450]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, 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.

Type of Information Request: Extension of a currently approved collection; *Title of Information Collection*: Medicare Uniform Institutional Provider Bill and Supporting Regulations in 42 CFR 424.5; *Form Number*: HCFA–1450 (OMB approval #: 0938–0247); *Use*: This standardized form is used in the Medicare/Medicaid program to apply for reimbursement of covered services by all providers that accept Medicare/Medicaid assigned claims; *Frequency*: On occasion; Affected Public: Business or other for-profit, Not-for-profit institutions; *Number of Respondents*: 46,708; *Total Annual Responses*: 147,343,290; *Total Annual Hours Requested*: 1,854,070.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at *http://www.hcfa.gov/regs/prdact95.htm*, or E-mail your request, including your address, phone number, OMB number, and HCFA 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: Wendy Taylor, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: March 19, 2001.

John P. Burke, III,

HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–10814 Filed 4–30–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1182–PN]

RIN 0938–AK75

Medicare Program; Revision of Payment Rates for End-Stage Renal Disease (ESRD) Patients Enrolled in Medicare+Choice Plans

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed notice.

SUMMARY: This notice proposes a new payment methodology, effective January 2002, for beneficiaries with End-Stage Renal Disease (ESRD) who are enrolled in Medicare+Choice (M+C) plans. The proposed methodology would implement section 605 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA). Section 605 requires the Secretary to increase ESRD M+C payment rates, using appropriate adjustments, to reflect the demonstration rates (including the risk adjustment methodology associated with those rates) of the social health maintenance organization ESRD capitation demonstrations. Briefly, the approach that we propose follows:

- Base State-level per capita rates on 100 percent of estimated State per capita ESRD fee-for-service expenditures in a base year.
- Adjust State per capita rates by age and sex factors, in order to pay more accurately, given differences in costs among ESRD patients.

The effect of the new ESRD M+C payment methodology would be to increase Medicare's Fiscal Year (FY) 2002 ESRD payments by an estimated $25 million (for 9 months of costs, given the effective date of January 2002). Total ESRD M+C payment increases for FY 2003 through FY 2005 are estimated to be $40 million annually.

The payment methodology proposed in this notice would govern M+C payments for enrollees with ESRD in 2002. M+C organizations are required to submit Adjusted Community Rate (ACR) proposals setting forth their M+C plan benefits, premiums, and cost-sharing for 2002 by July 1, 2001. M+C organizations need information on the payments they will receive for ESRD enrollees to prepare their ACR submissions. Section 605(c) of BIPA provided that this notice had to be published no later than 6 months after the enactment of BIPA or June 20, 2001. Yet section 605(c) also requires that the ''final'' ESRD methodology be published no later than July 1, 2001. In light of these deadlines, and the need of M+C organizations for final information on ESRD payment rates to prepare the ACR proposals, we find that affording the public a full 60-day comment period would be ''impracticable'' and ''contrary to the public interest,'' and that there is ''good cause'' for shortening the 60-day comment period we normally provide to 30 days.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on May 31, 2001.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address ONLY: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1182–PN, P.O. Box 8013, Baltimore, MD 21244–8013.

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or