because these devices are necessary for the administration of a drug that provides a significant public health benefit. The drug, which was approved by FDA on December 23, 1999, is used for the treatment of neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension. The drug improves oxygenation and reduces the need for extracorporeal membrane oxygenation.

The guidance document is intended to set forth the controls and testing that FDA believes ensure the safety and effectiveness of the nitric oxide administration apparatus, nitric oxide gas analyzer, and nitrogen dioxide gas analyzer. It also intends to provide comprehensive directions to enable a manufacturer to submit a 510(k) premarket notification demonstrating substantial equivalence for any or all three device types.

The guidance document identifies the risks associated with these types of devices and contains information that will help manufacturers address those risks. The guidance outlines the controls that should be incorporated in the devices for controlling risks, testing that should be completed for each device, and suggested methods for developing preclinical criteria. Other elements of the guidance document include: (1) General device description; (2) specific description of the information to support applications for each device; and (3) general considerations for each device, such as software and hardware testing.

II. Significance of Guidance

This guidance document represents the agency's current thinking on the premarket notification submissions for the nitric oxide delivery apparatus, nitric oxide analyzer, and nitrogen dioxide analyzer. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the ''Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1157) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance document may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the ''Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. The ''Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer'' will be available at http://www.fda.gov/cdrh/ggpmain.html.

IV. Comments

Interested persons may, on or before April 24, 2000, submit to the Dockets Management Branch (address above) written comments regarding this immediately in effect guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–1535 Filed 1–21–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0298]

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

AGENCY: Health Care Financing Administration.

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 Collection Request: New; *Title of Information Collection:* Evaluation of New Medicare Members of Medicare+Choice Plans; *Form No.:* HCFA–R–0298 (OMB# 0938-New); *Use:* The objective of this survey is to understand the special information needs of new Medicare members, their sources of information, their preferred distribution channels, their understanding of the traditional Medicare program and their understanding of their particular +Choice plan, and the impact National Medicare Education Program activities may have on new members' decisions to choose a +Choice plan or change their plan; *Frequency:* On occasion; *Affected Public:* Individuals; *Number of Respondents:* 3000; *Total Annual Responses:* 3000; *Total Annual Hours:* 1212.

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: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: December 28, 1999.

John Parmigiani,

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

[FR Doc. 00–1602 Filed 1–21–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration.

[Document Identifier: HCFA–R–0262]

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

AGENCY: Health Care Financing Administration

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 Collection Request: Reinstatement, with change, of a previously approved collection for which approval expired; *Title of Information Collection:* The Adjusted Community Rate Proposal (ACRP) M+C Plan Benefit Package and Supporting Regulations in 42 CFR 417.401, 22.1–422.10, 422.50–422.80, 422.100–422.132, 422.300–422.312, 422.400–422.404, and 422.560–422.622; *Form No.:* HCFA–R–0262 (OMB# 0938–0763); *Use:* The plan benefit package data will be used to approve managed care organization benefits, approve adjusted community rate pricing packages, and support both managed care organization and HCFA beneficiary information campaign and marketing efforts. Respondents include any M+C organization that intends to offer an M+C plan in calendar years 2001–2003.

This collection will also allow the HCFA to provide a totally automated submission and review capability, replace text with data format, establish a standard set of benefit descriptions/definitions, provide a framework to describe benefits, reduce variation in benefit descriptions, and eliminate the need to validate Medicare Compare data; *Frequency:* Annual; *Affected Public:* Business or other for-profit, and Not-for-profit institution; *Number of Respondents:* 300; *Total Annual Responses:* 300; *Total Annual Hours:* 900.

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: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: January 7, 2000.

John Parmigiani,

Acting Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–1603 Filed 1–21–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Assessment of the Impact of the National Practitioner Data Bank—NEW

Under the Health Resources and Services Administration (HRSA), Bureau of Health Professions (BHPr), the Division of Quality Assurance (DQA) is planning to conduct a survey to obtain information on the degree of user satisfaction with the National Practitioner Data Bank's (NPDB) querying and reporting processes, how users believe these processes can be improved, and how users perceive the usefulness of information they obtained from the NPDB for licensing and credentialing of health care entities, *e.g.* managed care organizations, State licensing boards for physicians and dentists, and professional societies. The study will also identify and survey non user entities. The information obtained in this study will be interpreted in relation to similar information from previous studies conducted by the DQA and the Office of the Inspector General.

The estimated response burden is as follows:

Questionnaire version	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Users Survey					
Reporting:					
Hospital	1031	1	1031	.25	257.8
Group Practice	210	1	210	.25	52.5
HMOs	161	1	161	.25	40.3