Federal Project Officer: J. Donald Sherwood, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–16–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

3. Approved Conceptual Proposals (Award of Waivers Pending)

No conceptual proposals were awarded during the month of June.

4. Approved Proposals

No proposals were approved during the month of June.

5. Disapproved Proposals

No proposals were disapproved during the month of June.

6. Withdrawn Proposals

No proposals were withdrawn during the month of June.

IV. Requests for Copies of a Proposal

Requests for copies of a specific Medicaid proposal should be made to the State contact listed for the specific proposal. If further help or information is needed, inquiries should be directed to HCFA at the address above.

(Catalog of Federal Domestic Assistance Program, No. 93.779; Health Financing Research, Demonstrations, and Experiments.)

Dated: September 22, 1995.

Bruce C. Vladek,

Administrator, Health Care Financing Administration.

[FR Doc. 95–24400 Filed 9–29–95; 8:45 am]

BILLING CODE 4120–01–P

Health Resources and Services Administration

Proposed Data Collections Available for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Projects

1. *National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Regulations and Forms* (OMB No. 0915–0126)—Extension, No Change—The Data Bank forms and regulations received a short-term approval in June 1995. As part of the terms of clearance, HRSA was required to submit an updated analysis of small medical malpractice payments (concerning the issue of monetary threshold reporting of claims) and provide OMB with an updated chart of the distribution of malpractice awards. The requirements have been satisfied and the results of the analysis have been forwarded to OMB. The Data Bank regulations and forms are now being resubmitted for a 3-year approval. This request is for an extension with no changes. The burden estimates are as follows:

Title	Number of respondents	Frequency of response	Number of responses	Hours per response	Total burden hours
60.6(a) Reporting Corrections of Errors and Omissions	2,800	1.04	2,925	.25	731
60.6(b) Revisions to Original Report Actions	350	1.06	370	.75	278
60.7(b) Reporting Medical Malpractice Payments	150	105.33	15,800	.75	11,850
60.8(b) Reporting Licensure Action by State Boards	125	21.02	2,630	.75	1,973
60.9(a) Reporting Privileging and Professional Society Actions	1,000	1.08	1,075	.75	806
60.9(c) Request for Hearings by Entitles Found in Noncompliance	1	1	1	8.00	8
60.10(a)(1) Hospital Queries on Applicants; 60.11(a)(1) Other Hospital Queries; 60.11(a)(6) Queries for Professional Review	7,200	38.33	276,000	.08	23,000
60.10(a)(2) Biennial Queries by Hospitals	6,000	186.83	1,121,000	.08	93,417
60.11(a)(2) Practitioner Queries	29,000	1	29,000	.25	7,250
60.11(a)(3) State Licensure Board Queries	70	171	12,000	.08	1,000
60.11(a)(4) Queries by Nonhospital Health Care Entities	1,860	139.78	260,000	.08	21,667
60.11(a)(5) Queries by Attorneys	10	1	10	.25	3
60.11(a)(7) Queries for Research Purposes	100	1	1	1.00	100
60.14(b) Practitioner's Disputing Data Bank Reports	1,080	1	1,080	.17	180
60.14(b) Practitioner Requests for Secretarial Review	100	1	100	8.00	800
60.14(b) Practitioner Statements	2,700	1	2,700	1.00	2,700
Biennial Entity Verification Document	5,750	1	5,750	.25	1,438
Entity File Update	1,150	1	1,150	.25	288

Note: Estimated Total Annual Burden: 167,489

2. *Survey of Exchange Visitor Physicians Remaining in the United States on a Waiver*—NEW—Announcement is made of the intention to survey exchange visitor physicians, i.e., physicians who entered the United States on a J–1 visa to engage in graduate medical education, who have been granted waivers to the return home requirement. Exchange visitor foreign physicians receive a J–1 visa and agree to return to their home country or country of last residence for a minimum of two years upon completing their training. The Department of Health and Human Services needs information about practice specialty and site of these physicians to make informed decisions regarding the implementation of waiver policy. A survey will be conducted to obtain the following items of information: (1) marital status; (2) basis of waiver; (3) initial and current geographic location; (4) initial and current medical specialty; (5) number of years of training completed in the U.S.; (6) changes of venue after initial practice site; (7) sequence of specialties after initial practice specialty.

Type of form	Number of respondents	Frequency of response	Hours per response	Total burden hours
Survey of Physicians with J–1 Visa Waivers	1,457	1	.50	729

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: September 27, 1995.

J. Henry Montes,

Associate Administrator for Policy Coordination.

[FR Doc. 95–24460 Filed 9–29–95; 8:45 am]

BILLING CODE 4160–15–P

Public Health Service

Notice Regarding Section 602 of the Veterans Health Care Act of 1992; New Drug Pricing

AGENCY: Public Health Service, HHS.

ACTION: Final notice.

SUMMARY: Section 602 of Public Law 102–585, the ''Veterans Health Care Act of 1992,'' enacted section 340B of the Public Health Service Act (''PHS Act''), ''Limitation on Prices of Drugs Purchased by Covered Entities.'' Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

The purpose of this notice is to inform interested parties of final guidelines regarding new drug pricing.

EFFECTIVE DATE: November 1, 1995.

FOR FURTHER INFORMATION CONTACT: Marsha Alvarez, R. Ph., Director, Drug Pricing Program, Bureau of Primary Health Care, 4350 East-West Highway, Bethesda, MD 20814, Phone (301) 594–4353, FAX (301) 594–4982.

SUPPLEMENTARY INFORMATION:

(A) Background

Proposed guidelines for new drug pricing were announced in the Federal Register at 60 FR 27983 on May 26, 1995. A comment period of 30 days was established to allow interested parties to submit comments. The Office of Drug Pricing received two letters with comments concerning the mechanism for drug price calculation and retroactive drug price adjustment. Further, a letter was received with general comments commending the PHS for the development of an approach that avoids unnecessary administrative costs for manufacturers while assuring that covered entities receive the discount in a timely fashion.

The following section presents a summary of all major comments, grouped by subject, and a response to each comment. All comments were considered in developing this final notice. Also, changes were made to increase clarity and readability.

(B) Comments and Responses

Mechanism for Price Calculation

Comment: PHS does not calculate the ceiling price. Manufacturers determine this price, while the Health Care Financing Administration (''HCFA'') provides Average Manufacturer Price, (''AMP''), baseline AMP, and Best Price, (''BP''), data to PHS for auditing purposes.

Response: We agree, in part. The notice has been changed to reflect that HCFA would provide the data necessary to calculate the ceiling price, if necessary for resolving disputes, collecting pricing data, auditing a manufacturer, or other such program purposes.

Comment: AMP may be calculated using pricing data from a partial quarter, while the calculation of the baseline AMP utilizes data from the first full quarter after the day on which the drug was first sold.

Response: We agree. The notice has been changed accordingly.

Retroactive Pricing Adjustment

Comment: The Veterans Affairs new drug policy, implementing section 603 of the Veterans Health Care Act of 1992, does not require a manufacturer to issue a retroactive rebate for the purchase of a new drug for the first thirty days. A similar policy should be considered for PHS policy implementing section 602 (section 340B of the PHS Act).

Response: No change. Section 340B of the PHS Act requires all participating manufacturers to provide covered outpatient drugs at the discounted price. The law was effective December 1, 1992; therefore, any new covered outpatient drug must be discounted as of the date it is introduced into the market. We have attempted to implement this immediate discount mechanism by reasonably permitting manufacturers to estimate ceiling prices during the initial months of sale.

Comment: A manufacturer's obligation to make retroactive payments to covered entities should not be contingent upon the covered entity submitting a request for the retroactive rebate, providing such information, or taking any other action. The manufacturer must be unilaterally responsible for paying the rebates.

Response: No change. The mechanism for retroactive pricing adjustment was developed with the understanding most manufacturers sell drugs through wholesalers and would have difficulty determining to which entity the new drug was sold. Further, and more importantly, there was an attempt to evenly split the administrative burden of the process between the manufacturer and the entity. If an entity wishes a pricing adjustment, the dollar amount in question, one would expect, must be significant enough to balance the administrative burden involved in documenting and developing the request. While this type of requirement should decrease the numbers of smaller requests, still the manufacturer must remit all documented pricing adjustments requested which may result in a large number of checks or credits being cut by manufacturers.

Comment: Establish a 30-day deadline by which the pricing reconciliation must be paid.

Response: We agree. The notice has been changed to reflect a requirement that all pricing adjustments be completed by the end of the fourth quarter of sales (e.g., introduced on 1/15/95 and pricing adjustments due by 12/30/95). This has moved the deadline back ninety days from the proposed deadline.

(C) New Drug Pricing Revised Guidelines

Set forth below are the final guidelines for new drug pricing.

New Drug Pricing

Calculation of the current quarter PHS ceiling price for each covered outpatient drug, as provided in section 340B(a)(1) of the PHS Act, is based upon data supplied to the Medicaid Drug Rebate Program (i.e., AMP, baseline AMP and BP). The manufacturer calculates pricing information for all of its covered outpatient drugs and sends this pricing data to HCFA within 30 days after the