Type of form	Number of respondents	Frequency of response	Hours per response	Total bur- den 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