

**Tab 1-8**

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

end of the quarter. HCFA will provide PHS with the data necessary for PHS to determine the ceiling price which will be used for resolving disputes, studies involving pricing data, auditing manufacturers, or other program purposes.

For calendar year 1995, the Medicaid rebate for single source and innovator multiple source drugs is the greater of 15.2 percent of the AMP or the AMP minus BP. In calendar year 1996, and thereafter, the rebate percentage decreases to 15.1 percent. An additional rebate must also be paid for single source and innovator multiple source drugs in the amount by which the increase in the baseline AMP exceeds the increase in the Consumer Price Index—Urban (CPI-U). The PHS ceiling price is computed based on the combined basic and additional rebate amounts calculated for the Medicaid program. For noninnovator multiple source drugs, the rebate percentage is 11 percent of the AMP.

For PHS pricing purposes, the timeframe for reporting the pricing data is a problem with respect to new drugs because there is a time lag for new drug pricing information. For new drugs, manufacturers are permitted to calculate the AMP using the pricing instituted in the first quarter; however, the baseline AMP is not available until the end of the first full quarter after the day on which the drug was first sold. For example, if a new drug was first sold on January 15, the quarterly AMP for the period 1/1 through 3/31 would be calculated using sales from 1/15 through 3/31 while the quarterly baseline AMP for the first full

quarter would not be available. The baseline AMP must be determined for a full quarter; therefore, pricing data for the period 4/1 through 6/30 would be utilized. Thus, for the first and second quarter, the discount for the new drug would be a manufacturer's estimate and later adjusted using only the basic rebate amount.

This time lag is not a problem for the State Medicaid agencies because they bill manufacturers for a rebate after the covered outpatient drugs are dispensed to Medicaid beneficiaries. However, to comply with the requirements of section 340B of the PHS Act, the PHS ceiling price must be determined before the covered outpatient drug is sold to the covered entity.

Because there are no sales data for a new drug from which to determine the PHS ceiling price, the Office of Drug Pricing is proposing to utilize a ceiling price estimated by the manufacturer until sufficient data is available to calculate the AMP and BP of the new drug. Any adjustments necessary to reconcile differences between the first and second quarter estimated ceiling price and the third quarter ceiling price will be in the form of a retroactive charge back or rebate.

Because the manufacturer calculates the PHS ceiling price using a data lag, the manufacturer would estimate the new drug ceiling price for three quarters. For example, a new single source drug that enters the market in February (first quarter) will have an estimated PHS ceiling price for that quarter. The manufacturer must submit AMP and BP pricing data for sales

within that quarter to HCFA within 30 days from the end of the quarter (4/30). HCFA will use this pricing data to calculate the basic rebate amount.

The manufacturer must estimate the ceiling price for the second quarter (April 1–June 30). Sales during the quarter will constitute the baseline AMP and BP. The manufacturer must submit baseline AMP and BP for the second quarter to HCFA within 30 days from the end of the second quarter (7/30). The additional rebate amount does not apply to this quarter since there must be two full quarters of pricing data to generate an additional rebate amount when a price increase exceeds the increase the CPI-U.

Because manufacturers must transmit pricing to wholesalers two weeks before the beginning of the quarter, the total rebate amount (basic plus additional rebate) for the third quarter (July 1–September 30) will not be available at that time.

Manufacturers must submit pricing data to HCFA by 10/30. Thus, the manufacturer must offer the third quarter discount using only the basic rebate amount.

Beginning with the fourth quarter (October 1–December 31), the manufacturer will have the necessary pricing data to calculate a total rebate amount. All retroactive charge backs or rebate adjustments necessary to reconcile the first, second, and third quarters estimated ceiling price must be completed by the end of the fourth quarter, i.e., December 31.

Example: Drug Enters Market February 15.

Calendar quarter	Baseline AMP	Add'l rebate (if applicable)	Pricing due to HCFA	Actual rebate amounts available from HCFA	
				Basic	Add'l
1 (Jan–Mar) .....	.....	.....	4/30	5/15	N/A
2 (April–June) .....	X .....	.....	7/30	8/15	N/A
3 (July–Sept) .....	.....	X .....	10/30	11/15	11/15
4 (Oct–Dec) .....	.....	X .....	1/30	2/15	2/15

Dated: September 26, 1995.  
 Ciro V. Sumaya,  
 Administrator, Health Resources and Services Administration.  
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**DEPARTMENT OF THE INTERIOR**  
**Bureau of Land Management**  
**[AK-964-1410-00-P]**  
**Notice for Publication; F-14841-A2 and F-14841-B2; Alaska Native Claims Selection**

In accordance with Departmental regulations 43 CFR 2650.7(d), notice is hereby given that a decision to issue conveyance under the provisions of Sec. 14(a) of the Alaska Native Claims Settlement Act of December 18, 1971, 43

U.S.C. 1601, 1613(a), will be issued to Brevig Mission Native Corporation for approximately 21,682 acres. The lands involved are in the vicinity of Brevig Mission, Alaska, within Tps. 1 S., Rs. 36, 37 and 38 W.; T.3 S., R. 36 W.; and T. 1 N., R. 39 W., Kateel River Meridian, Alaska.

A notice of the decision will be published once a week, for four (4) consecutive weeks, in The Nome Nugget. Copies of the decision may be obtained by contacting the Alaska State Office of the Bureau of Land Management, 222 West Seventh