



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

OCT 10 1995

The Honorable David Pryor
Ranking Minority Leader
United States Senate
Special Committee on Aging
Washington, D.C. 20510-6400

Dear Senator Pryor:

As the Ranking Member of the Senate Special Committee on Aging, you requested in a letter dated June 28, 1995, that the Office of Inspector General conduct a study to determine the changes in best prices available to the Medicaid prescription drug rebate program, with particular attention to increases above the prevailing inflation in consumer prices. You were interested in determining whether current measures available to the Health Care Financing Administration were adequate in discouraging prescription drug manufacturers from raising best prices above the rate of inflation. To meet your request, we reviewed the best prices as reported by drug manufacturers for the Medicaid drug rebate program. Our objectives were to determine:

- ✓ the extent that best prices have increased over and above the consumer price index-urban (CPI-U); and
- ✓ the monetary impact of indexing best price to the CPI-U on the Medicaid drug rebate program.

Our work was limited to the procedures necessary to respond to your request. Our study of best price for selected drug products showed that drug manufacturers have consistently increased best prices in excess of the CPI-U for a large number of the drug products that we reviewed. The number of drug products with best price increases in excess of the CPI-U rose almost every quarter since the inception of the rebate program.

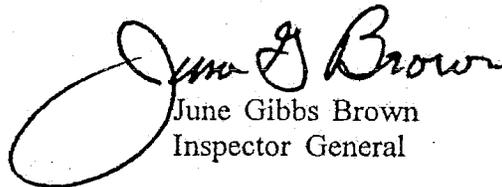
For example, in the first quarter (April through June 1991) 94 of 363 drug products reviewed had an average price increase of 38.3 percent over the CPI-U. Five quarters later, 225 of 401 drug products reviewed had an average price increase of 59.7 percent over the CPI-U. We calculated that rebates to the States would have been increased by about \$123 million in 1993 had the best prices been indexed to the CPI-U based on the quarter ending December 1992. Although we did determine the

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number of drug products that increased based on indexing best price in Calendar Year 1994, we did not make any projections because utilization was not yet available for all States at the time of this study. The enclosure "Potential Impact on the Use of an Indexed Best Price Calculation in the Medicaid Drug Rebate Program" provides you with the details of our review.

We plan to continue reviewing the Medicaid drug rebate program and welcome any comments you may have on this study and the drug rebate program in general. If you have any questions, please call me or have your staff contact Dennis Duquette, Deputy Inspector General for Management and Policy, at (202) 205-9117.

Sincerely,



June Gibbs Brown
Inspector General

Enclosure

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**SPECIAL REPORT
FOR
THE RANKING MEMBER OF THE SENATE
SPECIAL COMMITTEE ON AGING**

**POTENTIAL IMPACT ON THE USE
OF AN INDEXED BEST PRICE
CALCULATION IN THE
MEDICAID DRUG REBATE PROGRAM**



**JUNE GIBBS BROWN
Inspector General**

**OCTOBER 1995
A-06-94-00039**

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P***POTENTIAL IMPACT ON THE USE
OF AN INDEXED BEST PRICE CALCULATION
IN THE MEDICAID DRUG REBATE PROGRAM***

S***SUMMARY***

Drug manufacturers best prices have consistently increased in excess of inflation, as measured by the Consumer Price Index (CPI-U), for a large number of the drug products we reviewed. For example, in the first quarter we reviewed, (April through June 1991) 94 of 363 drug products had an average price increase of 38.3 percent over the CPI-U. Five quarters later, 225 of 401 drug products reviewed had an average price increase of 59.7 percent over the CPI-U (see Attachment II). These large increases in best prices have had an effect on the amount of drug rebates. We calculated that rebates to the States would have been increased by about \$123 million in 1993 had the best prices been indexed to the CPI-U based on the quarter ending December 1992.

B***BACKGROUND***

The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) authorized States to collect rebates from drug manufacturers for drug purchases made under the Medicaid program. Drug manufacturers were required to pay quarterly rebates beginning with the quarter ended March 31, 1991. The basic rebate amount is determined as a specified percentage of the average manufacturer price (AMP)¹ for a drug. The percentage differs between brand name drugs and generic drugs. However, for brand name drugs, if the difference between AMP and the manufacturer's best price for that drug is greater than the specified percentage of AMP, then the rebate is the difference between AMP and the best price.²

The OBRA '90 also contained a provision to discourage drug manufacturers from raising AMP amounts. For brand name drugs, the basic rebate amount³ is increased by the amount that AMP increases over and above the consumer price index for all urban consumers. The AMP was indexed to the CPI-U as of October 1, 1990. This additional rebate does not apply to generic drugs. There was no similar indexing of best price, even though best price is part of the basic rebate calculation for brand name drugs.

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METHODOLOGY

Our work was limited to the procedures necessary to respond to Senator Pryor's request.⁴ The objectives of our review were to determine (1) the extent that best prices have increased over and above the CPI-U and (2) the potential monetary impact of indexing best price to the CPI-U on the Medicaid drug rebate amount. Our objectives did not require that we identify or review any internal control systems. Our objectives also did not require us to evaluate all possible situations involving the indexing of best price. There are circumstances in which basing rebates on an indexed best price could result in a drug manufacturer paying more in rebates related to indexing than the actual increases over the CPI-U.

We included, in our review, the brand name drugs that appeared in the *American Druggist*, February 1993 article entitled, "The Top 200." This source was used to identify the high volume brand name drugs. We identified 133 drugs, representing 406 different drug products, for which best price information was reported to the Health Care Financing Administration (HCFA) by the drug manufacturers. The remaining 67 drugs were either generic drugs, for which best price is not reported, or brand name drugs that did not participate in the rebate program. We obtained pricing information on best prices for 406 different drug products for the 16 quarters ending December 31, 1994. We reviewed the 1993 *Redbook* to obtain National Drug Codes (NDC). We obtained best price, AMP, and drug utilization from the Medicaid Drug Rebate System maintained at HCFA central office. Best price was obtained for the 16 quarters ending December 31, 1994. And, drug utilization data was obtained for the four quarters ending December 31, 1993.

Since the definition of best price was changed starting in the last quarter of 1992, we divided our analysis of best price increases into two periods because of the enactment of the Veterans Health Care Act of 1992 (VHCA). The first period was the six quarters ending September 30, 1992, with the first quarter of 1991 being used as the base period for indexing best price to the CPI-U. If best price was not reported for a drug product for the first quarter of 1991, we used the first quarter that best price was reported as the base period. The second period was the eight quarters ending December 31, 1994, with the fourth quarter of 1992 being used as the base period for indexing.

We reviewed sections of OBRA '90 pertaining to the drug rebate program. We also reviewed HCFA's periodically released policy directives issued to drug manufacturers and State Medicaid programs (Release Memorandums). We obtained CPI-U values pertaining to the period of our review.

We used actual data from HCFA's drug rebate data base to calculate the effects of indexing best price. We did not independently verify any information obtained from third party sources. Our review was conducted in our Little Rock, Arkansas office from July to September 1995.

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BEST PRICE INCREASES

We compared the best price data submitted by manufacturers to our calculated indexed best price to determine whether best price had increased more than the CPI-U and the extent that any increases exceeded the CPI-U (Attachment I is an example of a rebate calculation using the current method of computing rebates compared to indexing best price). Best price information was not available for each drug product for all quarters. (Attachments II and III shows the details of our comparisons.) Our results show that manufacturers were continuously increasing their best prices faster than the rate of inflation as measured by the CPI-U.

EFFECT OF LIMITING BEST PRICE INCREASES ON REBATES

To determine the potential effect that increases in best price (beyond the rate of inflation) had on rebates, we calculated the difference in rebates that would have resulted from using an indexed best price. We calculated the basic rebates for the four quarters ending December 31, 1993, using the reported best prices. We then recalculated the rebates using best prices that were indexed from the final quarter of 1992. If an indexed best price exceeded the reported best price, we did not recalculate the rebate. We multiplied the differences in rebates for each quarter in 1993 by reported utilization for each drug product.

Quarter	93-1	93-2	93-3	93-4
Average Rebate Increase from Indexing	8.6¢	9.2¢	9.8¢	10.6¢
Utilization	295,348,837	330,434,782	337,755,102	321,698,113
Additional Rebate from Indexing (In Millions)	\$25.4	\$30.4	\$33.1	\$34.1
Annual Totals	1993 - \$123.0 Million			

As the table shows, drug rebates would have increased by \$25.4 million in the first quarter of 1993 to \$34.1 million in the fourth quarter of 1993 for the 406 drug products reviewed, if best price had been indexed as of the fourth quarter of 1992. Additionally, the increase in rebates would have been even greater had best price been indexed since the start of the rebate program. For our review, we only showed the impact if best price had been indexed as of the fourth quarter of 1992. Upon request, we could perform additional best price calculations for Calendar Year (CY) 1994.

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CONCLUSIONS

Drug manufacturers have consistently increased best prices in excess of the CPI-U since the inception of the Medicaid drug rebate program. While OBRA '90 contained a provision to discourage drug manufacturers from raising AMP above the CPI-U, there was no similar provision to limit best price increases. If increases in best price had been indexed (i.e., limited) to the CPI-U as recently as the last quarter of 1992, we estimate that drug rebates would have increased by about \$123 million in 1993 for the 406 drug products included in our review. Since rebates collected in 1993 amounted to \$1.5 billion, the \$123 million is relatively significant.

DRUG REBATE FORMULA
 Rebate Calculation Using Current Method of Computing Rebates Compared to Indexing Best Price

Definition: In CY 1993, the rebate calculation was the greater of 15.7 percent of AMP or the difference between AMP and the manufacturer's best price.

Example of Rebate Calculation Using Current Method of Computing Rebates Compared to Indexing Best Price for the Second Quarter of 1993

Base AMP	1.073568
Base Best Price	0.873833
AMP 2/93	1.253081
Best Price 2/93	0.908500
Indexed AMP 2/93	1.161751 (1.073568/132.7) *143.6 ¹
Indexed Best Price 2/93	0.888057 (.873833/141.3) *143.6 ²
Utilization 2/93	50,324,045

1993 Basic Rebate = Greater of 15.7 percent of AMP or AMP minus BP

AMP	1.253081	AMP	1.253081
Best Price	-0.908500		x .157
Greater of	<u>0.344581</u>	or	.196734

Additional Rebate = AMP minus indexed AMP³

AMP	1.253081
Indexed AMP	-1.161751
Amount added to Basic Rebate	<u>0.091330</u>

Total Rebate = Basic Rebate plus Additional Rebate

Basic Rebate	0.344581
Additional Rebate	+0.091330
Unit Rebate	0.435911
Utilization	x50,324,045
Total Rebate	<u>\$21,936,805</u>

¹Indexing consists of dividing the base AMP by the base period CPI-U multiplied by the current CPI-U.

²Indexing consists of dividing the base best price by the base period CPI-U multiplied by the current CPI-U.

³The basic rebate amount is increased by the amount that AMP increases over the CPI-U.

⁴Indexing best price would have increased the rebate on this drug by \$1,028,774 (\$22,965,579 - \$21,936,805)

1993 Rebate Calculation Using Indexed Best Price

AMP	1.253081	AMP	1.253081
Indexed Best Price	-0.888057		x .157
Greater of	<u>0.365024</u>	or	.196734

Additional Rebate = AMP minus indexed AMP³

AMP	1.253081
Indexed AMP	-1.161751
Amount Added to Basic Rebate	<u>0.091330</u>

Total Rebate = Basic Rebate plus Additional Rebate

Basic Rebate	0.365024
Additional Rebate	+0.091330
Unit Rebate	0.456354
Utilization	x 50,324,045
Total Rebate	<u>\$22,965,579⁴</u>

¹Indexing consists of dividing the base AMP by the base period CPI-U multiplied by the current CPI-U.

²Indexing consists of dividing the base best price by the base period CPI-U multiplied by the current CPI-U.

³The basic rebate amount is increased by the amount that AMP increases over the CPI-U.

⁴Indexing best price would have increased the rebate on this drug by \$1,028,774 (\$22,965,579 - \$21,936,805)

ATTACHMENT II

Number of Drugs
With Increases Over CPI-U
6 Quarters Ending September 1992

Percentage Increase Over CPI-U	Calendar Year Quarter					
	91-2	91-3	91-4	92-1	92-2	92-3
50% or more	14	15	17	32	44	46
40% to 49.9%	2	5	5	11	12	13
30% to 39.9%	5	6	5	13	14	21
20% to 29.9%	6	13	17	40	39	42
10% to 19.9%	20	24	32	32	45	43
Less than 10%	47	85	94	94	82	60
Total w/Increases	94	148	170	222	236	225
% w/Increases	25.9	39.9	45.5	57.5	59.1	56.1
Average % Increase	38.3	24.6	24.3	30.2	36.2	59.7
Total Compared	363	371	374	386	399	401

We found that best prices increased over and above the CPI-U for a large number of drug products and that the average percentage increases over CPI-U were significant. The table also shows a steady increase in the number of drug products with best price increases exceeding the CPI-U. The average percentage increases ranged from 24.3 percent to 59.7 percent. The number of drug products which had increases rose from 94 to a high of 236.

ATTACHMENT III

Number of Drugs
With Increases Over CPI-U
8 Quarters Ending December 1994

Percentage Increase Over CPI-U	Calendar Year Quarter							
	93-1	93-2	93-3	93-4	94-1	94-2	94-3	94-4
50% or more	27	30	32	39	51	55	59	60
40% to 49.9%	4	8	7	8	6	8	11	13
30% to 39.9%	7	7	8	10	10	17	12	12
20% to 29.9%	13	20	22	15	29	26	26	31
10% to 19.9%	29	38	34	42	49	39	36	42
Less than 10%	95	97	104	113	120	113	118	103
Total w/Increases	175	200	207	227	265	258	262	261
% w/Increases	43.1	49.5	51.1	55.9	65.3	63.5	64.5	64.3
Avg. % Increase	42.8	42.3	45.5	49.2	48.4	60.4	61.4	60.5
Total Compared	406	404	405	406	406	406	406	406

This table depicts the results of our comparisons for the second period of our study (that period following enactment of the VHCA). Despite changing the base period for indexing to the last quarter of 1992, best prices continued to increase at a much faster rate than the CPI-U for about half of the drug products. The number of drug products with increases above the CPI-U continued to increase almost every quarter. The number of drug products with increases rose from 175 to 261. About half of the drug products with increases over the CPI-U exceeded the CPI-U by more than 10 percent for each quarter.

As the table shows, the average increase in best prices continued during CY 1994 to be larger than the average inflation rate. We were not able to use this information to calculate the value of additional potential drug rebates because drug utilization from all States was not available at the time of our review.

ENDNOTES

1. *Average Manufacturer's Price (AMP) is the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.*
2. *The best price was originally defined by OBRA '90 as the lowest price available from the manufacturer to any purchaser. The Veterans Health Care Act (VHCA) of 1992 later amended the definition of best price to exclude drugs purchased by the Department of Veterans Affairs, Department of Defense, Public Health Service, various smaller entities and clinics, and drugs listed on the Federal Supply Schedule. The effective date of VHCA was October 1, 1992.*
3. *This additional rebate does not apply to generic drugs.*
4. *Letter Received from the Ranking Member of the Special Committee on Aging, dated June 28, 1995.*