

**Memorandum**

Date DEC 10 1999

From Deputy Inspector General
for Audit Services

Subject Audit of Comprehensive Hemophilia Treatment Centers' Utilization of the Public
Health Service 340B Drug Pricing Program (CIN: A-01-98-01505)

To Thomas G. Morford
Deputy Administrator
Health Resources and Services Administration

Michael M. Hash
Deputy Administrator
Health Care Financing Administration

Attached are two copies of the U.S. Department of Health and Human Services, Office of Inspector General's final report entitled, "Audit of Comprehensive Hemophilia Centers' Utilization of Public Health Service 340B Drug Pricing Program." The objective of this audit was to determine whether comprehensive Hemophilia treatment centers (HTCs) participating in the Public Health Service (PHS) 340B Program (340B Program) were participating for all of their patients, including Medicaid beneficiaries.

We found that improvements in the 340B Program are needed to ensure that all State Medicaid agencies obtain the full price advantages available under the 340B Program. Officials from 6 of the 23 participating HTCs contacted stated that their entities participate (purchase outpatient drugs at the 340B discount price), but not for their Medicaid beneficiaries. For one selected center, we determined that the State Medicaid Agency could achieve annual savings ranging from \$18,395 to \$27,170 per person if it reimbursed the HTC at the 340B discount prices instead of the Medicaid rate. We recommend that Health Resources and Services Administration (HRSA) and the Health Care Financing Administration (HCFA) work together to achieve a fair and equitable resolution of the issues involving the economical purchasing, and subsequent Medicaid billing, of covered drugs by entities participating in the 340B Program. Officials in HRSA and HCFA concurred with the recommendation.

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We appreciate the cooperation given to us during this audit. We would appreciate your views and the status of any further action taken or contemplated on our recommendation within the next 60 days. If you have any questions, please contact me or have your staff contact Joseph J. Green, Assistant Inspector General for Public Health Service Audits, at (301) 443-3582. To facilitate identification, please refer to Common Identification Number A-01-98-01505 in all correspondence relating to this report.



Thomas D. Roslewicz

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**AUDIT OF COMPREHENSIVE
HEMOPHILIA TREATMENT CENTERS'
UTILIZATION OF THE PUBLIC HEALTH
SERVICE 340B DRUG PRICING
PROGRAM**



**JUNE GIBBS BROWN
Inspector General**

**DECEMBER 1999
A-01-98-01505**



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Audit of Comprehensive Hemophilia Treatment Centers' Utilization of the Public Health Service 340B Drug Pricing Program (CIN: A-01-98-01505)

Thomas G. Morford
Deputy Administrator
Health Resources and Services Administration

Michael M. Hash
Deputy Administrator
Health Care Financing Administration

The purpose of this final report is to inform you that improvements are needed to ensure that all State Medicaid Agencies benefit from the price advantages available to Public Health Service (PHS) grantees under the PHS 340B Drug Pricing Program (340B Program). The objective of this audit was to determine whether comprehensive Hemophilia treatment centers (HTCs) participating in the PHS 340B Program were participating for all of their patients, including Medicaid beneficiaries. Officials from 6 of the 23 participating HTCs contacted stated that their entities participate (purchase outpatient drugs at the 340B discount price), but not for their Medicaid beneficiaries. For one selected center, we determined that a State Medicaid Agency could achieve annual savings ranging from \$18,395 to \$27,170 per person if it reimbursed the HTC at the 340B discount prices instead of the Medicaid rate. (See EXHIBIT) We recommend that the Health Resources and Services Administration (HRSA) and the Health Care Financing Administration (HCFA) work together to achieve a fair and equitable resolution of the issues involving the economical purchasing, and subsequent Medicaid billing, of covered drugs by entities participating in the 340B Program. Officials in HRSA and HCFA concurred with the recommendation.

INTRODUCTION

BACKGROUND

The Congress introduced drug pricing controls in 1990 with the passage of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990). The OBRA 1990 established the Medicaid Drug Rebate Program requiring drug manufacturers to provide State Medicaid Agencies with statutory rebates for covered outpatient drugs. The OBRA 1990 also provided a foundation for Public Law 102-585, *the Veterans Health Care Act of 1992* (VHCA). The VHCA established section 340B of the PHS Act, *Limitation On Prices Of Drugs Purchased By Covered Entities*. The Congress enacted section 340B to establish price controls to effectively limit the cost of drugs to certain Federal grantees (covered entities). The HRSA implemented this statutory mandate by establishing the 340B Program.

Covered entity participation in the 340B Program is currently voluntary and is subject to the HRSA's 340B Program guidelines. Section 340B(a)(4)(G) of the PHS Act includes HTC's in the definition of a covered entity.

OBJECTIVE, SCOPE, AND METHODOLOGY

The objective of this audit was to determine whether HTC's participating in the 340B Program were participating for all of their patients, including Medicaid beneficiaries.

To accomplish our audit objective, we:

- ◆ Met with and maintained ongoing discussions with various PHS program officials including individuals from the: (1) HRSA's Office of Drug Pricing, and (2) HRSA's National Hemophilia Program. In addition, we met with officials from the Secretary's Advisory Committee on Blood Safety and Availability.
- ◆ Contacted officials from 23 of the 43 HTC's that the HRSA identified as participating in the 340B Program. We relied on the information provided by the HTC's without further testing.
- ◆ Reviewed applicable laws, regulations, and guidelines pertaining to the HTC's' eligibility and utilization of the 340B Program.

We conducted our audit in accordance with generally accepted government auditing standards. We performed our audit work at the HRSA in Rockville, Maryland, and at

our regional office in Boston, Massachusetts, during the period May 1998 through July 1998.

We met with appropriate HRSA and HCFA program officials to discuss our draft report on September 23, 1999, at the HRSA's offices in Rockville, Maryland. Based on HRSA and HCFA's verbal comments, we have made appropriate changes to the report. Officials in HRSA and HCFA agreed with our recommendation.

FINDING AND RECOMMENDATION

We found that improvements in the 340B Program are needed to ensure all State Medicaid Agencies obtain the full price advantages available under the 340B Program. In this respect, the Veterans Health Care Act of 1992 does not specifically require a participating entity to purchase drugs for Medicaid beneficiaries at the 340B discount prices. All 23 participating HTC's contacted were able to obtain covered drugs (factor) at the 340B discount prices. Officials from the majority of the 23 participating HTC's informed us that their HTC's purchase drugs for all outpatients, including Medicaid beneficiaries, at 340B discount prices. However, officials from 6 of the 23 participating HTC's contacted stated that their entities participate (purchase outpatient drugs at the 340B discount price), but not for their Medicaid beneficiaries. As a result, the State Medicaid Agencies are reimbursing those six HTC's at rates higher than the 340B discount prices.

While the State Medicaid agencies obtain rebates from manufacturers, the Medicaid rates after rebates are higher than the 340B discount prices. Therefore, the related State Medicaid Agencies did not benefit from the reduced prices they would have been entitled to had the HTC's participated in the 340B Program for their Medicaid beneficiaries. In this regard, we determined that a State Medicaid Agency could achieve annual savings ranging from \$18,395 to \$27,170 per person if it reimbursed the HTC at the 340B discount prices instead of the Medicaid rate. (See EXHIBIT)

While our review was limited to HTC's, we were informed that participating entities other than HTC's were also purchasing drugs for Medicaid beneficiaries outside of the 340B Program. Therefore, there is potential for significant savings if other entities duplicate the practice of the 6 HTC's identified, considering that over 1,200 out of 3,574 eligible HRSA grantees participate in the 340B Program.

The Veterans Health Care Act of 1992 Does Not Specifically Require Participating Entities to Purchase Drugs for Medicaid Beneficiaries at the 340B Discount Prices

A Federal Register Notice dated May 13, 1994, *Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Entity Guidelines*, provides that a participating entity purchasing a drug for a Medicaid beneficiary should bill the State Medicaid Agency a price consistent with the VHCA plus a reasonable dispensing fee. However, the Veterans Health Care Act of 1992 does not specifically require a participating entity to purchase drugs for Medicaid beneficiaries at the 340B discount prices. Therefore, participating entities can bill State Medicaid Agencies prices exceeding the 340B discount price if the drugs are purchased outside of the 340B Program. However, in a Congressional conference report, House Report 4328 dated October 19, 1998, Congress states: "It is viewed that HTC's choosing to distribute factor to their patients [which includes Medicaid beneficiaries] should purchase factor under the 340B Program to obtain the lowest possible price."

Participating Entities Do Not Always Participate in the 340B Program for Medicaid Beneficiaries

While officials from the majority of HTC's contacted informed us that their HTC's purchase drugs for all outpatients (including Medicaid beneficiaries) at 340B discount prices, officials from 6 of the 23 participating HTC's contacted informed us that their entities do not participate in the 340B Program for their Medicaid beneficiaries. In this respect, those six participating HTC's utilized a dual purchasing system whereby the HTC purchased factor for their Medicaid beneficiaries at prices that were higher than the 340B discount prices while paying 340B discount prices for its non-Medicaid beneficiaries.

While our review was limited to HTC's, we were informed that participating entities other than HTC's were also purchasing drugs for Medicaid beneficiaries outside of the 340B Program. Further, there is potential for significant savings if other entities duplicate the practice of the 6 HTC's identified, considering that over 1,200 entities out of 3,574 eligible HRSA grantees participate in the 340B Program. Participation rates for the most significant eligible HRSA grantees are as follows:

- ▶ 659 of 1,964 (34 percent) community health centers;
- ▶ 119 of 300 (40 percent) migrant health centers; and

- ▶ 82 out of 247 (33 percent) health centers for the homeless.

The State Medicaid Agencies are not Obtaining the Full Price Advantages Available Under the 340B Program

According to officials at the six HTC's identified, the State Medicaid Agencies are reimbursing HTC's at the State Medicaid rate and are, therefore, not obtaining the full price advantages available under the 340B Program. Although the State Medicaid Agencies are able to obtain rebates from manufacturers for drugs purchased outside of the 340B Program (under the Medicaid Drug Rebate Program), the final cost to the State Medicaid Agency is higher than the 340B discount price. In this regard, we determined that a State Medicaid Agency could achieve annual savings ranging from \$18,395 to \$27,170 per person, even after considering Medicaid rebates. (See EXHIBIT)

State Medicaid Agencies Reimburse HTC's at a Rate Higher than Acquisition Costs

As mentioned above, the EXHIBIT illustrates that State Medicaid Agencies are not obtaining the full price advantages available under the 340B Program. This occurs because current Medicaid reimbursement practices provide for a financial gain for entities which do not participate in the 340B Program for their Medicaid beneficiaries. In this respect, officials from the 6 participating HTC's, which purchased factor outside of the 340B Program, informed us that their respective State Medicaid Agency's reimbursement methods permitted the HTC's to obtain reimbursements exceeding their actual costs if they did not participate in the 340B Program for their Medicaid beneficiaries. In this respect, Medicaid reimbursement is generally based on a drug's average wholesale price (AWP), which usually exceeds the actual cost paid by the HTC's. Further, those officials informed us that their State Medicaid Agencies would not reimburse the HTC's at amounts above acquisition costs if the HTC's purchased factor at 340B discount prices. The following example is based on data provided by officials from one of the six HTC's that benefitted by not participating in the 340B Program for its Medicaid outpatients.

One participating HTC that purchases factor for its Medicaid clients outside of the 340B Program is reimbursed by its State Medicaid agency at a rate which is 15 percent higher than its acquisition price. In this case, for one person with an average degree of hemophilia, this HTC receives about \$7,000 above acquisition price, plus a reasonable dispensing fee, annually. If this same HTC purchased the same factor at the 340B discount price, its reimbursement would have been limited by Federal register notice to what it paid (the 340B acquisition price) plus a reasonable dispensing fee. Thus, one can see how it is more profitable for some HTCs to purchase factor outside the 340B Program when treating Medicaid clients.

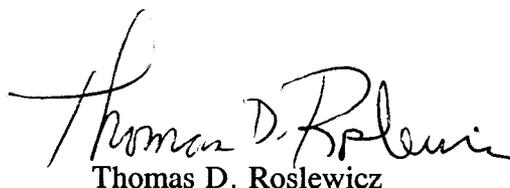
Allowing entities to choose not to participate for one group of patients results in the entities declining to use one Federal program (340B), which offers substantial discounts, at the expense of another Federal program (Medicaid) for reasons relating to the entities' financial gain.

RECOMMENDATION

We recommend that HRSA and HCFA work together to achieve a fair and equitable resolution of the issues involving the economical purchasing, and subsequent Medicaid billing, of covered drugs by entities participating in the 340B Program.

Auditee Comments and Office of Audit Services Response

Both HRSA and HCFA officials agreed with the recommendation. We would appreciate your views and the status of any further action taken or contemplated on our recommendation within the next 60 days. If you have any questions please contact me or have your staff contact Joseph J. Green, Assistant Inspector General for Public Health Service Audits, at (301) 443-3582. To facilitate identification, please refer to Common Identification Number A-01-98-01505 in all correspondence related to this report.


Thomas D. Roslewicz

EXHIBIT

EXHIBIT

COMPARISON OF MEDICAID REIMBURSEMENT RATES TO 340B DISCOUNT PRICES

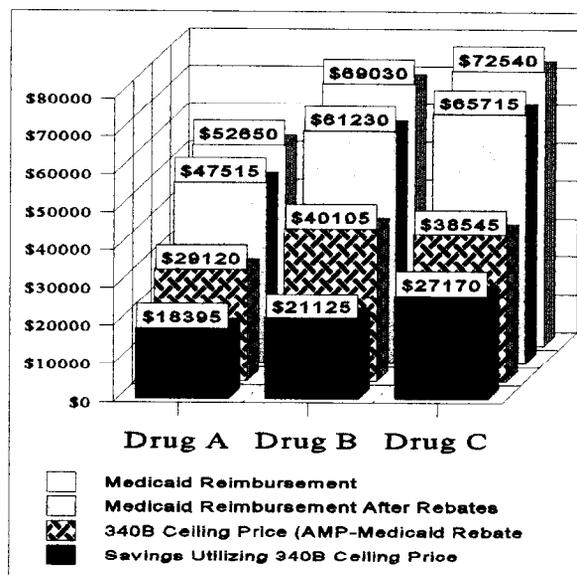
Below, we compare annual Medicaid reimbursements (the drug’s average wholesale price (AWP) less 10 percent) for a Hemophilia Treatment Center (HTC) which does not participate in the 340B Program for its Medicaid beneficiaries to the 340B discount prices. The calculations are for three selected forms of factor and based on the treatment of an individual with an average degree of hemophilia at one selected HTC. Due to confidentiality of drug pricing information we do not disclose quantity purchased.

Medicaid Reimbursement--State
 Medicaid Agencies typically reimburse entities a percentage of a drug’s AWP. For this example, we utilized AWP less 10 percent as it was the most frequently cited Medicaid rate by the State Medicaid Agencies contacted.

Medicaid Reimbursement After Rebates--After reimbursing the entities for its drug purchases, the State Medicaid Agencies receive a statutory rebate from the drug manufacturer.

340B Ceiling Price--This is the average manufacturer price (AMP) less the Medicaid rebate. The AMP is the average price paid by wholesalers to manufacturers.

Savings Utilizing 340B Ceiling Price--This represents the savings State Medicaid Agencies can realize by reimbursing HTCs at the 340B ceiling price rather than the current Medicaid rate even after considering the statutory Medicaid rebate.



Comparison of Payments to HTCs, Before and After Rebates with 340B Ceiling Prices - Three Drugs