DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

JUN 17 2003

TO: Betty James Duke, Ph.D.
Administrator
Health Resources and Services Administration

FROM: Dennis J. Duquette
Deputy Inspector General
for Audit Services

SUBJECT: Review of Hemophilia Treatment Centers' Disposition of Program Income and Patient Choice for Factor Provider for Calendar Year 2000
(A-03-01-00350)

Attached is a copy of our final report providing the results of our review of the disposition of program income by Hemophilia Treatment Centers, which was requested by the Health Resources and Services Administration (HRSA).

In written comments, HRSA concurred with our recommendations and agreed to take corrective actions. The HRSA comments are included as an appendix to our report.

In accordance with the principles of the Freedom of Information Act, 5 United States Code 552, as amended by Public Law 104-231, Office of Inspector General, Office of Audit Services reports are made available to members of the public to the extent information contained therein is not subject to exemptions in the Act.
(See 45 CFR Part 5).

Please send us your final management decision, including any action plan, as appropriate, within 60 days. If you have any questions or comments about this report, please do not hesitate to call me or Donald L. Dille, Assistant Inspector General for Grants and Internal Activities, at (202) 619-1175, or e-mail at ddille@oig.hhs.gov.

To facilitate identification, please refer to report number A-03-01-00350 in all correspondence relating to this report.

Attachment

Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

REVIEW OF HEMOPHILIA TREATMENT CENTERS' DISPOSITION OF PROGRAM INCOME AND PATIENT CHOICE FOR FACTOR PROVIDER FOR CALENDAR YEAR 2000

June 2003
A-03-01-00350

EXECUTIVE SUMMARY

BACKGROUND

The Health Resources and Services Administration (HRSA) requested the Office of Inspector General (OIG) to review Hemophilia Treatment Centers' (HTCs) disposition of program income and their patient choice policies during the calendar year 2000. The HTCs earn program income when they purchase blood-clotting factor (factor) and related drugs at discount prices pursuant to participation in the 340B program and resell them to HTC patients. The 340B program is administered by HRSA's Office of Pharmacy Affairs (OPA).

OBJECTIVES

The objectives of our review were to:

- Assess the disposition of program income earned on sales of factor at prices in excess of the 340B acquisition price;
- Determine how HTCs billed Medicaid for reimbursement;
- Evaluate the adequacy of patient choice policies; and
- Determine pharmacy costs and bad debt expense.

To accomplish our objectives, we made site visits to six HTCs that participated in the 340B program.

RESULTS OF REVIEW

The HTCs generally used program income for patient care and related activities, and had choice policies in place that allowed patients to obtain the factor they needed from providers of their choice. At one of the six HTCs we visited, however, we identified the following problems:

- Inappropriate use of program income; and
- Inappropriate Medicaid billing practices, resulting in overbilling of $613,000.

We believe these problems might have been prevented by improved monitoring by HRSA's Maternal and Child Health Bureau (MCHB), which oversees the HTCs.

RECOMMENDATIONS

We recommend that HRSA:

1. Develop program guidelines, which, at a minimum, include the disposition of program funds and conflicts of interest provisions.

2. Continue to monitor HTCs participating in the 340B program, and increase the areas of monitoring to include the conditions described in this report as a means of ensuring that program funds are used for their intended purpose and in accordance with applicable regulations and cost principles.

3. Emphasize to grantees that HTCs need to adhere to federal regulations limiting Medicaid reimbursement to the acquisition cost of factor plus a reasonable dispensing fee established by the state Medicaid agency.

4. Work with the Centers for Medicaid and Medicare Services (CMS) to ensure that the Medicaid overpayment of approximately $613,000 identified in this report is refunded to the respective state Medicaid program.

In its March 25, 2003 comments to our draft report, HRSA generally agreed with our findings and recommendations. In its response, HRSA stated that it (1) is coordinating efforts to include our recommendations as conditions of grant awards for the June 1, 2003 hemophilia continuation program funding cycle; (2) prepared a draft manual to clarify policy and provide program guidance to HTCs; and (3) will obtain information from HTCs for monitoring. The HRSA also suggested that we clarify language in the report to demonstrate that the method used to claim reimbursement from Medicaid resulted in an overpayment, a clarification that we have made. We have included HRSA's response as an Appendix to this report. We have also summarized its response along with our comments after the Conclusions and Recommendations section of this report.

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INTRODUCTION

BACKGROUND

Section 602 of the Veterans Health Care Act of 1992 (Public Law 102-585) established section 340B of the Public Health Service 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), including HTCs. As a condition of participation in federal programs such as Medicaid, manufacturers of covered drugs are required to sell drugs at discount prices to covered entities. The HRSA implemented section 340B by establishing the 340B program in OPA.

At the time of our review, 48 out of 143 HTCs nationwide participated in the 340B program. The HRSA's OPA is responsible for overseeing the 340B Program; HRSA's MCHB is responsible for overseeing the HTC program, including establishing overall program objectives, providing funding, and monitoring HTC performance.

The HRSA requested our review of a selection of HTCs that receive funding from MCHB and participate in the 340B Program. The HRSA had received several complaints about HTCs and asked OIG to perform this review focusing on specific areas such as disposition of program income, billing procedures, and patient choice.

The HTCs provide diagnosis and treatment services for their patients. Hemophilia is a disorder in which one or more of the plasma proteins needed to form blood clots is missing or deficient. The medications used to stop bleeding are referred to as factors. These medications are infused into the person's vein through a needle to increase the missing factor so that the person can form a normal clot.

We did not disclose the identities of the HTCs visited in this report because some of the data presented in this report could be considered proprietary. Accordingly, when we refer to specific HTCs, we use letter designations for each (A through F) rather than the actual names of the individual HTCs. We did provide the names of the HTCs to HRSA.

OBJECTIVES, SCOPE, AND METHODOLOGY

The objectives of our review were to:

- Assess the disposition of program income earned on sales of factor at prices in excess of the 340B acquisition price;
- Determine how HTCs billed Medicaid for reimbursement;
- Evaluate the adequacy of patient choice policies; and
- Determine pharmacy costs and bad debt expense.

To accomplish our objectives, we judgmentally selected six of the larger HTCs and performed the following procedures:

- Met with various HRSA program officials including individuals from OPA and MCHB.

- Reviewed applicable laws, regulations, guidelines, and grant files pertaining to HTCs' use of program income and patient choice policies.

- Reviewed the HTCs' disposition of program income and assessed whether program income was used for patient care and related activities.

- Reviewed the HTCs' billing processes and practices, particularly Medicaid billings, pharmacy costs, and bad debts.

- Reviewed patient choice policies and assessed whether those policies were adequately designed and fully implemented.

We conducted our review in accordance with generally accepted government auditing standards. Our review was limited in scope and primarily focused on performing procedures necessary to achieve our objectives. Our review, which covered CY 2000, was not intended to be a full scope internal control assessment of the HTCs and was more limited than that which would be necessary to express an opinion on the adequacy of the HTCs operations taken as a whole. The objectives of our review did not require an understanding or an assessment of the overall internal control structure at the HTCs. We performed our review at HRSA in Rockville, Maryland and visited six HTCs in six different states.

RESULTS OF REVIEW

The HTCs generally used program income for patient care and related activities, and had patient choice policies in place that allowed patients to obtain the factor they needed from providers of their choice. At one of the six HTCs we visited, however, we identified the following problems:

- Inappropriate use of program income; and

- Inappropriate Medicaid billing practices, resulting in overbilling of $613,000.

We believe these problems might have been prevented by improved monitoring by HRSA's MCHB.

The following table summarizes the number of factor units sold, acquisition costs, total revenues, program income, total patients served, and the total patients who received factor at the 340B discount prices.

CY 2000 Factor Revenue Summary

HTC	*Factor Units Sold*	*Acquisition Costs*	*Total Factor Revenue*	*Program Income*	*Total Patients Served*	*Total Pharmacy Clients**
A	14,631,288	$7,995,120	$9,662,710	$1,667,590	271	101
B	8,910,126	5,549,852	7,604,424	2,054,572	806	108
C	14,966,321	9,239,608	11,972,643	2,733,035	460	132
D	19,994,241	11,852,217	13,671,668	1,819,451	403	161
E	5,870,536	3,587,402	5,011,324	1,423,922	148	104
F	15,826,417	10,114,657	12,382,139	2,267,482	793	223

*The total number of pharmacy clients is different than total number of patients served because not all patients receive their factor from an HTC affiliated pharmacy at the 340B discount prices.

INAPPROPRIATE USE OF PROGRAM INCOME

Contrary to MCHB guidance, one of the HTCs we visited, HTC C, inappropriately used program income for items such as carrying costs, inflated pharmacy costs, and corporate overhead. This occurred because MCHB did not have sufficient control over grantees and subgrantees. When HTCs inappropriately use program income, they reduce the funds available to provide services to patients.

Guidance for Use of Program Income

The MCHB requires HTCs to use program income for eligible costs as defined by governing statutes, program regulations, applicable cost principles, and the terms and conditions of the award. The Department of Health and Human Services (HHS) Grants Policy Directive Part 3.03 states:

> "*It is HHS policy that grantees be encouraged to earn program income and to maximize such income, consistent with the purpose and nature of the grant or activities carried out under the grant.*"

The policy also identifies three general alternatives for the disposition of program income, including the additive method. The MCHB directs that HTCs use the additive method, which requires that program income be added back to program funds and used to further program objectives. The policy also states that regardless of the method applied, program income may be used only for eligible costs, in accordance with the governing statute, any program regulations, the applicable cost principles, and the terms and conditions of the award.

Use of Program Income for Costs Unrelated to Patient Care

Our review of the program income generated from factor sales showed that at one of the six HTCs we visited, program income was used for inappropriate cost. The HTC C was part of a teaching hospital owned and managed by a large health care network that operated both tax-exempt and taxable entities. The parent company at HTC C controlled

the disposition of program income. Following are examples of inappropriate uses of program income at this HTC:

Carrying Costs

The parent company of HTC C inappropriately added a 16.5 percent cost to the average value of accounts receivable and inventory as carrying costs. The carrying costs included the following components:

Average rate of inflation	4.00%
Technology improvements	2.00%
Expansion of market or demand	2.00%
Alteration of services	3.00%
Economic and political contingencies	2.00%
Cost of debt	3.50%
Total	16.50%

We do not consider the costs described above to be carrying costs because they do not relate to buying, holding, or dispensing factor products. Carrying costs typically include costs such as rent, insurance, utilities, shrinkage, and warehousing. These costs are part of the pharmacy overhead, which is a separate line item cost. In addition, hemophilia factor sales are characterized by a high turnover rate and limited supply that would make the impact of inflation negligible. The HTC management explained that they categorized the above costs as carrying costs because they believed they were entitled to a reasonable return on their working capital.

The parent company of HTC C charged $740,807 in accounts receivable carrying costs and $438,997 in inventory carrying costs during the period of our review. The accounts receivable carrying costs were calculated by multiplying the 16.5 percent by the average accounts receivable outstanding balance of $4,489,700, and the inventory carrying costs were calculated by multiplying 16.5 percent by the average inventory balance of $2,660,587. We believe these funds should have been available to further program objectives.

Inappropriate Allocation Method

The HTC C's parent company inappropriately used gross patient revenues as a basis to allocate corporate overhead costs to various departments and programs. A 12.4 percent ratio (total factor revenue of $11,972,643 divided by gross patient revenue of $96,277,424) was used to allocate the outpatient pharmacy department and corporate overhead costs. We believe that using gross patient revenue as a basis to allocate administrative costs is inequitable and unfair because this allocation method shifts costs disproportionately to high cost drugs such as factor. Furthermore, the cost of a drug does not drive the administrative costs of operating a pharmacy. For example, the cost to fill a $100 prescription and a $100,000 prescription may not be significantly different, but HTC C's allocation method distributes 99.9 percent of the administrative cost to the high

cost drug. We believe that using the number of prescription orders filled or full-time equivalents would have been a more appropriate allocation method.

Inflated Pharmacy Cost, $668,073

The HTC C's parent company inappropriately allocated $668,073 in pharmacy administrative costs to the factor program. The amount allocated to the factor program was calculated by multiplying a 12.4 percent ratio by the outpatient pharmacy department overhead cost of $5,387,682. The overhead cost represented the outpatient pharmacy department administrative costs including management, marketing, accounting, human resources, training, and information systems costs. The $668,073 included about $100,000 in bonuses for management and about $52,000 in marketing and advertising costs. The management of the parent company conceded that the bonuses were not appropriate when asked for justification, and indicated that they would credit the amount charged back to the program. Corporate marketing and advertising are not allowable under Office of Management and Budget Circular A-122, *Cost Principles for Non-Profit Organizations.*

Corporate Overhead, $619,196

The parent company of HTC C inappropriately allocated $619,196 in corporate overhead costs to the factor program. The overhead cost was calculated by multiplying a 12.4 percent ratio by the parent company's overhead cost of $4,993,516. The parent company's overhead cost represented corporate-wide overhead cost allocated to the outpatient pharmacy department and included interest payments, data processing, material management, and general corporate services. The outpatient pharmacy department further allocated a portion of the corporate overhead cost to various departments and programs including the factor program.

Inadequate Program Monitoring

Our review showed that MCHB did not have sufficient controls over the grantees that subcontract with HTCs to ensure program funds are used for their intended purposes and to further program objectives. As part of our review, we assessed MCHB's program controls over the HTCs. The MCHB provides limited monitoring such as requiring the submission of annual financial data, budget projections, and patient statistics; however, it did not receive sufficient information on the relationship between HTCs and related organizations or functions to evaluate their impact on costs. Although the relationships between grantees and subgrantees make monitoring more difficult, subgrantees are subject to the same regulations as grantees.

Funds available for Patient Services are Reduced

Lack of adequate monitoring creates an environment in which operating costs can increase, thereby reducing the funds available for patient services. Because MCHB did

not adequately monitor grantees and/or subgrantees, it was not aware of HTC C's inappropriate use of program funds.

APPROPRIATE MEDICAID BILLING PRACTICES

HRSA Guidelines for billing Medicaid Beneficiaries Who Receive Drugs Purchased at 340B Discount Prices

A Federal Register Notice dated May 13, 1994, Final Notice regarding Section 602 of the Veterans Health Care Act of 1992, states:

> *"If a drug is purchased by or on behalf of a Medicaid beneficiary, the amount billed may not exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at the price consistent with the Veterans Health Care Act of 1992, plus a reasonable dispensing fee established by the State Medicaid agency*."

This Act does not specifically require HTCs to purchase the drugs for Medicaid beneficiaries through the 340B discount program, and some HTCs elected not to purchase drugs for Medicaid beneficiaries.

One HTC Overbilled Medicaid $613,000

The HTC C overbilled Medicaid $613,000 by basing the charge on a fee for each unit sold. Covered entities have two ways to avoid exposing manufacturers to duplicate price reductions. One is for the entities to purchase all of their outpatient drugs, including factor, at 340B prices. If an entity follows this practice, it must give OPA its Medicaid provider number, and it is required to bill Medicaid at actual acquisition price plus the state prescribed dispensing fee. The other alternative is for the entity to "carve out" the outpatient drugs purchased for Medicaid patients and buy these drugs at market prices. If an entity follows this procedure, it could bill the Medicaid state agency at the state defined estimated acquisition cost plus the dispensing fee.

The HTC C purchased factor for Medicaid beneficiaries at 340B prices and billed the State Medicaid program the acquisition cost plus $.23 per unit, or a 37 percent markup. According to the Federal guidelines, this HTC should have billed Medicaid only the acquisition cost plus the reasonable dispensing fee established by the State Medicaid agency. The dispensing fee for HTC C's State is $3.65 per prescription. For the period under review, the difference between the per unit mark up and the allowable dispensing fee was $613,000.

PATIENT CHOICE POLICIES

All six HTCs had formal written patient choice policies in place informing patients of their right to purchase factor from providers of their choice. The policies for some HTCs were better developed than others and included information such as product quality, prices, and general criteria for selecting a vendor.

We found that most HTCs were following their patient choice policies. We reviewed selected patient files for evidence that patient choice policies were fully implemented. At five HTCs, choice policies were documented in the patient files. One HTC, however, had a policy to ensure patients had a choice to purchase factor from providers of their choice, but 46 percent (7 of 15 cases) of patient files selected for review did not contain evidence that the patient was informed of the policy.

OTHER MATTERS

The HRSA requested that we provide information on pharmacy costs and bad debt expenses incurred by the audited HTCs. We found that pharmacy costs varied and were lowest for two of the three HTCs that had in-house pharmacies, and four of the HTCs reported bad debts on their general ledger accounts. The HTCs that successfully controlled pharmacy costs had more funds available for patient care and necessary administrative and support services than they would otherwise have had.

In addition, we found two additional matters that we believe may impact the volume of services that HTCs provide to patients. First, HRSA did not clearly define program income, which may have resulted in some HTCs retaining program income as fund balances. Second, we identified potential conflicts of interest at one HTC that could increase operating costs. More detailed information on these matters is presented below.

Pharmacy Costs

The two HTCs with the lowest per patient pharmacy costs had in-house pharmacies that enabled them to better control pharmacy costs. Pharmacy cost per client varied between $1,850 and $7,721. The HTCs that most successfully controlled pharmacy costs had more funds available for patient care and necessary administrative and support services than they would otherwise have had.

We determined that pharmacy costs, except for the actual costs of factor, were the most significant costs associated with the factor program. The HTCs with 340B programs needed pharmacy services to manage the distribution of factor to their clients. The services generally included purchasing factor, filling prescriptions, packaging, delivery to clients, and managing inventory. We found pharmacy costs varied widely from one HTC to another. The following table summarizes the pharmacy costs and bad debts (arising from passing on the costs of providing factor to indigent patients) for those HTCs.

Schedule of Pharmacy Costs and Bad Debt Expense for CY 2000

HTC	Type of Pharmacy	Pharmacy Costs	Pharmacy Clients	Cost Per Client	Bad Debt
A	*Contract*	$779,847	101	$7,721	*
B	*Contract*	534,608	108	4,950	$176,591
C	*In- house*	668,073	132	5,061	412,674
D	*In- house*	297,773	161	1,850	*
E	*Contract*	547,097	104	5,261	159,290
F	*In- house*	525,832	223	2,358	33,350

*These HTCs did not report any bad debt.

The pharmacy costs shown above did not include the same cost categories. For example, the pharmacy cost for HTC B included factor-billing services. The pharmacy cost for HTC C included parent company overhead costs allocated to the program. The pharmacy cost for HTC F reflected both 340B and non-340B costs. The pharmacy costs for HTCs A, B, and E were based on the number of factor units sold. The HTC D was able to successfully contain its pharmacy costs for several reasons, including establishing an in-house pharmacy, hiring a pharmacist for the factor program, lower overhead cost, and sharing resources with another HTC.

Bad Debt Expense

As illustrated in the chart above, four of the HTCs reported bad debts on their general ledger accounts. Bad debts represent unpaid balances for factor receivables that were not collected after billing and subsequent collection efforts were exhausted.

Fund Balances

We found that some program income may have been retained by HTCs as fund balances. Four of the six HTCs had identified fund balances at the close of their fiscal years for 2000, and three of those had increases in the fund balances during the year. A fund balance represents the residual equities and excess income of an organization as shown below.

Schedule of Fund Balances for CY 2000

HTC	Fund Balances ($)	Fund Balance Increases ($)*
A	N/A	N/A
B	789,077	453,547
C	N/A	N/A
D	435,532	0
E	2,768,811	52,337
F	7,920,899	809,529

* Fund balance increases from prior year were based on the most recent available financial statements at the time of our review. Actual year-end dates varied by HTC. N/A means no fund balance existed.

Although factor revenue represented 79 percent to 98 percent of the total revenue, HTCs had other sources of revenue, such as grants, clinic billings, donations, and fund raising. Therefore, the sources for fund balances were not all necessarily from factor sales.

Potential Conflicts of Interest

Because MCHB does not closely monitor grantees, it may be unaware of conflicts of interest that could increase operating costs. For example, we found that HTC B had the following potential conflicts of interest that were undetected: (1) HTC B's board of directors included the president of the pharmacy; (2) HTC B borrowed money, cosigned for by related parties; and (3) HTC B employed personnel who also worked for the pharmacy, including a physician who received her salary from the pharmacy. Although these relationships are only potential conflicts of interest, MCHB should be aware of their existence, so it can take appropriate and timely action if necessary.

CONCLUSIONS AND RECOMMENDATIONS

The HTCs generally used program income for patient care and related activities, and had patient choice policies in place that allowed patients to obtain the factor they needed from providers of their choice. At one HTC, however, we found problems that we believe are the result of inadequate oversight from HRSA. We recommend that HRSA:

1. Develop program guidelines, which, at a minimum, include the disposition of program funds and conflicts of interest provisions.

2. Continue to monitor HTCs participating in the 340B program, and increase the areas of monitoring to include the conditions described in this report as a means of ensuring that program funds are used for their intended purpose and in accordance with applicable regulations and cost principles.

3. Emphasize to grantees that HTCs need to adhere to federal regulations limiting Medicaid reimbursement to the acquisition cost of factor plus a reasonable dispensing fee established by the state Medicaid agency.

4. Work with the Centers for Medicaid and Medicare Services to ensure that the Medicaid overpayment of approximately $613,000 identified in this report is refunded to the respective state Medicaid program.

HRSA Responses and OIG Comments

Recommendation 1:

HRSA Response

"The MCHB has developed a first draft of a 340B Program Manual for HTCs that further clarifies policy with 340B program guidelines and includes suggested procedures and model practices for implementation. Topic areas included major elements of the Public Health Service Drug Pricing Program; Guidance for HTCs and Appendices including a Compilation of HRSA Guidelines, Section 340B of the Public Health Service Act, and grants management documents regarding program income. The manual is meant to be an adjunct to, but not a replacement for, the existing policies of HRSA Grants Management and the Office of Pharmacy (OPA)."

OIG Comments

The completion and distribution to HTCs of a comprehensive program manual should improve HTC operations and compliance with government regulations.

Recommendation 2:

HRSA Response

"The MCHB is drafting a 340B Program Factor Replacement Product Data Sheet for HTCs to provide information useful for monitoring of 340B program implementation."

OIG Comment

Periodic preparation and reporting to HRSA of this information should provide a valuable tool for monitoring HTC activities with respect to program income to ensure maximum profits benefit hemophilia patients.

Recommendation 3:

HRSA Response

In response to recommendation (1), HRSA acknowledged the development of a first draft of a 340B Program Manual for HTCs. Part of that response included major elements of the 340B Drug Pricing Program.

OIG Comment

The inclusion of drug pricing policies on billing Medicaid for drugs purchased within the 340B program should satisfy the intent of the recommendation.

Recommendation 4:

HRSA Response

The HRSA's response stated that covered entities, such as HTCs, who are reselling factor purchased at 340B prices, "must bill Medicaid at actual acquisition cost (the 340B price) plus the state prescribed dispensing fee." The MCHB indicated that it would work with CMS to resolve the OIG recommendations.

OIG Comment

We believe HRSA's intention to coordinate with CMS to obtain refunds for any factor dispensing fees paid in excess of established OPA regulations should satisfy the intent of the recommendation. In its response, HRSA questioned whether conditions were met for an overpayment and described an alternative scenario that would lead to a different conclusion. To clarify our position on this matter, we changed the report to state unequivocally that the conditions for an overpayment were met and an overpayment resulted.

APPENDIX

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, Maryland 20857

MAR 25 2003

TO: Dennis Duquette
Deputy Inspector General
Audit Services

FROM: Administrator

SUBJECT: Office of Inspector General's Draft Report: "Review of Hemophilia Treatment Centers' Disposition of Program Income and Patient Choice for Factor Provider for Calendar Year 2000" (A-03-01-00350)

Thank you for the opportunity to provide comments on the subject report. Please find those comments attached.

Questions may be referred to John Gallicchio in HRSA's Office of Financial Policy and Oversight at (301) 443-3099.

Betty James Duke

Attachment

Health Resources and Services Administration's Comments on the Office of Inspector General's Draft Report: "Review of Hemophilia Treatment Centers' Disposition of Program Income and Patient Choice for Factor Provider for FY 2000.

The Health Resources and Services Administration (HRSA) thanks the Office of Inspector General for the opportunity to provide comments on the above draft report. We acknowledge the importance of the report findings and recommendations and look forward to working with the Centers for Medicare and Medicaid Services (CMS) in response to OIG's recommendations.

Background

This report is a review based on site visits to 6 hemophilia treatment centers (HTCs), which are covered entities in the 340B Drug Pricing Program. The review was undertaken in 2001 in response to a request from HRSA's Administrator in 2000.

The report makes the following four recommendations:

1. Develop program guidelines, which, at a minimum, include the disposition of program funds and conflict of interest provisions.

2. Continue to monitor HTC's participating in the 340B Program, and increase the areas of monitoring to include the conditions described in this report as a means of ensuring that program funds are used for their intended purpose and in accordance with applicable regulations and cost principles.

3. Emphasize to grantees that HTCs need to adhere to federal regulations limiting Medicaid reimbursement to the acquisition cost of factor plus a reasonable dispensing fee established by the state Medicaid agency.

4. Work with the Centers for Medicare and Medicaid Services to be sure that the Medicaid overpayment of approximately $613,000 identified in this report is refunded to the respective state Medicaid agency.

General Comments

The following are examples of how HRSA's Maternal Child Health Bureau (MCHB) program staff have begun to address the report's findings and recommendations.

- The MCHB is working closely with HRSA's Office of Financial Policy and Oversight (OFPO) on plans to incorporate OIG recommendations as conditions in the notices of grant awards for the June 1, 2003 hemophilia continuation program funding cycle.

- The MCHB has developed a first draft of a 340B Program Manual for Hemophilia Treatment Centers that further clarifies policy on how to comply with 340B program guidelines and includes suggested procedures and model practices for implementation. Topic areas include major elements of the Public Health Service Drug Pricing Program; Guidance for HTCs; and Appendices including a Compilation of HRSA Guidelines, Section 340B of the Public Health Service Act, and grants management documents regarding program income. The manual is meant to be an adjunct to, but not a replacement for, the existing policies of HRSA Grants Management and the Office of Pharmacy Affairs (OPA).

- The MCHB is drafting a 340B Program Factor Replacement Product Data Sheet for HTCs to provide information useful for monitoring of 340B program implementation.

The OIG report should clearly state that covered entities have two ways to avoid causing manufacturers to be exposed to duplicate price reductions. (1) If covered entities purchase all of their outpatient drugs at 340B prices, they must give OPA their Medicaid provider numbers when they register as covered entities and bill Medicaid at actual acquisition cost (the 340B price) plus the state prescribed dispensing fee. OPA then supplies this information to the affected state agencies so that these transactions can be excluded from agencies' claims for Medicaid rebates. (2) Covered entities may choose to "carve out" the outpatient drugs purchased for Medicaid patients. They would buy these drugs at market prices. They should not give their Medicaid provider numbers to OPA, and must bill Medicaid at the state defined estimated acquisition cost plus the dispensing fee. In this case, the state agencies submit rebate claims for these transactions.

The report implies, but does not clearly state, that the overpayment from the state Medicaid agency to the HTC identified as "C" is in reimbursements for factor purchased at 340B prices. However, if the HTC is using the option to purchase drugs at normal market prices for its Medicaid patients and is following the state agency's estimated cost guideline, there is no over billing and the HTC is not operating contrary to HRSA's 340B guidance including the clarification re Medicaid billing published on March 15, 2000.

The report would be much stronger if it provided this detail and clearly stated the situation with HTC C.

ACKNOWLEDGMENTS

This report was prepared under the direction of Stephen Virbitsky, Regional Inspector General for Audit Services. Other principal Office of Audit Services staff who contributed include:

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