DEPARTMENT OF HEALTH & Office of inspector General

Memorandum

Date

From 'Deputy Inspector General
for Audit Services

Subject Audit of the Utilization of the Public Health Service 340B Drug Pricing Program (A-01-98-01500)

TO Claude E. Fox, M.D., M.P.H.
Administrator
Health Resources and Services Administration

Attached is our final report entitled *Audit of the Utilization of the Public Health Service 340B Drug Pricing Program.* The objective of our audit was to determine whether eligible Public Health Service (PHS) funded entities effectively utilized the PHS 340B Drug Pricing Program (340B Program).

Officials in your office have verbally concurred with our finding and recommendations, set forth in the attached report. We appreciate the cooperation given us in this audit.

We would appreciate your views and the status of any further action taken or contemplated on our recommendations 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-O 1-98-O 1500 in all correspondence relating to this report.

Thomas D. Roslewicz

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

AUDIT OF THE UTILIZATION OF THE PUBLIC HEALTH SERVICE 340B DRUG PRICING PROGRAM

JUNE GIBBS BROWN
Inspector General

JULY1998
A-01-98-01500

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Memorandum

JUL 16 1998

Date

From Deputy Inspector General
for Audit Services

Subject Audit of the Utilization of the Public Health Service 340B Drug Pricing Program (A-01-98-01500)

To Claude E. Fox, M.D., M.P.H.
Administrator
Health Resources and Services Administration

The purpose of this final report is to apprise you of the results of the Office of Inspector General, Office of Audit Services' *Audit of the Utilization of the Public Health Service 340B Drug Pricing Program,* Common Identification Number (CIN) A-01-98-01500. The objective of our audit was to determine whether eligible Public Health Service (PHS) funded entities effectively utilized the PHS 340B Drug Pricing Program (340B Program).

As disclosed in a previous Office of Inspector General *(OIG)* report on *State AIDS Drug Assistance Programs' Use of Drug Price Discounts (CIN: A-01 -97-01501),* the 340B Program has the potential to enable eligible nonparticipating entities to provide additional services by accessing lower priced drugs. We recommended that the Health Resources and Services Administration (HRSA) require AIDS Drug Assistance Programs (ADAPs) to participate in the 340B Program unless ADAPs demonstrate that participation is not cost efficient or not possible.

The HRSA recognizes the potential of the 340B Program and is taking positive action by extending the intent of the ADAP recommendation to other HRSA grantees. As such, the HRSA, consistent with Departmental regulations and Office of Management and Budget (OMB) cost principles, has drafted a Federal Register (FR) Notice requesting comments on a proposed grant award condition *requiringparticipation* in the 340B Program for all eligible entities that: (1) receive HRSA grants listed in section 340B(a)(4) of the PHS Act, and (2) purchase or reimburse for covered outpatient drugs. The HRSA could grant waivers to entities demonstrating good causes for nonparticipation.

The Congress enacted section 340B of the PHS Act to provide an effective means of lowering drug prices for covered entities. Although the 340B Program provides access to drugs at discounted prices, covered entity participation is *voluntary.* The HRSA's Office of Drug Pricing's (ODP) database indicates that approximately 66 percent of eligible HRSA grantees do not participate in the 340B Program. Consequently, the HRSA's eligible nonparticipating grantees may not be purchasing covered outpatient drugs at the best prices.

We believe the HRSA's action to require eligible entities to participate in the 340B Program could result in savings to be used for additional services to patients. We commend the HRSA for its action and recommend that the HRSA: (1) continue its efforts to require eligible entities to participate in the 340B Program, and (2) periodically inform us of the status of these efforts.

INTRODUCTION

BACKGROUND

The Congress introduced drug pricing controls in 1990 with the passage of the Omnibus Budget Reconciliation Act (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) which enacted section 340B of the Public Health Service (PHS) Act (Limitation On Prices Of Drugs Purchased By Covered Entities).

Section 340B of the PHS Act requires the Secretary of the Department of Health and Human Services (DHHS) to enter into pharmaceutical pricing agreements with manufacturers that sell covered outpatient drugs to covered entities. An agreement stipulates that a manufacturer will charge covered entities prices for covered outpatient drugs that will not exceed ceiling prices specified in section 340B(a)(1) and (2). Section 340B(a)(4) defines a "covered entity".

The DHHS's HRSA established the 340B Program to implement the provisions of section 340B of the PHS Act. A manufacturer's decision to participate in the 340B Program is voluntary. However, a manufacturer not participating will not receive Federal Medicaid matching funds for covered outpatient drugs of the Medicaid Program. Entity participation in the 340B Program is also voluntary, at this time, and is subject to the HRSA's 340B Program guidelines.

OBJECTIVE, SCOPE, AND METHODOLOGY

The objective of this audit was to determine whether eligible Public Health Service funded entities effectively utilized the 340B Program. To accomplish our objective, we:

- Reviewed applicable laws, regulations, and guidelines pertaining to the establishment and implementation of the 340B Program.

- Met with and maintained ongoing discussions with various DHHS program officials including personnel from the HRSA's ODP and an official from the Office of General Counsel. In doing so, we obtained relevant information regarding the 340B Program and covered entity participation.

- Reviewed the ODP's September 1997 database to identify eligible HRSA grantees that do not participate in 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 November 1997 through April 1998. Since HRSA is taking positive action, we are concluding our audit work without detailed substantive testing. We discussed the contents of this report with HRSA officials who verbally concurred with our finding and recommendations.

FINDING AND RECOMMENDATIONS

Currently, covered entity participation in the 340B Program is voluntary. As disclosed in our prior report *State AIDS Drug Assistance Programs' Use of Drug Price Discounts (CIN: A-01-97-01501)*, the 340B Program has the potential to enable eligible nonparticipating entities to provide additional services by accessing lower priced drugs. We recommended that the HRSA require ADAPs develop purchasing and distribution systems enabling ADAPs to participate in the 340B Program unless ADAPs can demonstrate that participation is not cost efficient or not possible. The HRSA recognizes the potential of the 340B Program and is taking positive action by extending the intent of that recommendation to other HRSA grantees. As such, the HRSA, consistent with Departmental regulations and OMB cost principles, has drafted a FR Notice to request comments on a proposed grant award condition requiring eligible HRSA grantees to participate in the 340B Program.

The ODP's database indicates that approximately 66 percent (2,351 of 3,574) of eligible HRSA grantees do not participate in the 340B Program. As such, we believe HRSA's action to require eligible HRSA grantees to participate in the 340B Program could result in savings to be used for additional services provided to patients. We commend the HRSA for its action and recommend that the HRSA continue its efforts to require eligible entities to participate in the 340B Program and periodically inform us of the status of these efforts.

Criteria Consistent with the HRSA's Proposal

The Congress enacted section 340B of the PHS Act to provide an effective means of lowering drug prices for covered entities. Further, the Code of Federal Regulations, Title 42, Chapter 1, Part 50, Subpart E (Maximum Allowable Cost for Drugs) stipulates that it is the policy of the DHHS Secretary that program funds which are utilized for the acquisition of drugs be expended in the most economical manner feasible.

The OMB Circulars A-87 (Cost Principles for State, Local, and Indian Tribal Governments) and A- 122 (Cost Principles for Non-Profit Organizations) establish principles for determining allowable costs incurred under Federal awards. The circulars state a cost is reasonable if, in its nature and amount, it does not exceed that which would be incurred by a prudent person under the circumstances prevailing at the time the decision was made to incur the cost. We believe a prudent person would seek the best possible price, i.e., the 340B Program, unless it were not cost efficient or possible.

Condition

The HRSA has drafted a FR Notice to request public comments on a proposed grant award condition requiring participation in the 340B Program. Participation would be required for all eligible entities that: (1) receive HRSA grants listed in section 340B(a)(4) of the PHS Act, and (2) purchase or reimburse for covered outpatient drugs. The current proposal allows the HRSA to grant waivers to entities demonstrating good causes for nonparticipation.

The current draft HRSA proposal is being circulated throughout the various HRSA Bureaus for comment. The approval of the Secretary of DHHS and the OMB will be required before the HRSA's proposal can be published in the Federal Register. Subsequently, the HRSA will analyze and consider the public comments prior to proposing a FR Final Notice. The FR Final Notice will also require the approval of the Secretary of DHHS and OMB prior to publication.

Cause for the HRSA Proposal

Currently, covered entity participation in the 3403 Program is voluntary and a significant number of covered entities do notparticipate. The ODP's database indicates that approximately 66 percent (2,35 1 of 3,574) of eligible HRSA grantees do not participate in the 340B Program. Those entities do not participate in the 340B Program because they: (1) have not requested participation (some entities in this category do not purchase or distribute covered drugs), or (2) do not meet the HRSA's 340B Program guidelines. The following table summarizes the number and types of eligible HRSA grantees as listed on the ODP's database.'

HRSA Grantee Acronyms	HRSA Grantee Types	Total Grantees on ODP's Database	Total Participating in the 340B Program	Total Not Participating in the 340B Program
340S	School Based Programs	28	11	17
CH	Community Health Centers	1964	659	1305
MH	Migrant Health Centers	300	119	181
BL	Black Lung Clinics	7	1	6
RWI	Ryan White Title I Entities	55	23	32
RWII	Ryan White Title II Entities	173	98	75
HV	Ryan White Title III Entities	218	68	150
HM	Hemophilia Treatment Centers	189	57	132
HO	Health Centers for the Homeless	247	82	165
NH	Native Hawaiian Health Centers	6	0	6
PH	Health Centers for Public Housing Residents	24	19	5
SPNS	Special Projects of National Significance	76	5	71
FQHC	Federally Qualified Health Centers	153	45	108
FQHCLA	FQHC Look-alikes [2]	134	36	98
	TOTALS:	3,574	1.223	2.351

[1] The HRSA officials apprised us that the database is a "working database". As such, the above numbers may fluctuate. However, the HRSA officials agreed that the overall percentage of nonparticipating entities is accurate.

[2] Although FQHC Look-alikes are not HRSA grantees, they are subject to HRSA's proposed FR Notice.

The HRSA's proposal to require participation in the 340B Program is consistent with: 1) the DHHS Secretary's policy that program funds which are utilized for the acquisition of drugs be expended in the most economical manner feasible; and 2) OMB Circulars A-87 and A-122 which stipulate that reasonable costs will not exceed that which would be incurred by a prudent person.

Effect

Our prior review of 1996 drug expenditure data for five eligible State ADAPs disclosed those ADAPs could have purchased an additional eight percent or $4.4 million of drug therapies, subject to some additional distribution costs, had they participated in the 340B Program. That review showed that the 340B ceiling prices were the lowest prices available for the nonparticipating ADAPs reviewed. Accordingly, we believe that the HRSA's eligible nonparticipating grantees may not be purchasing covered outpatient drugs at the best possible prices. We are confident that eligible nonparticipating entities may realize a savings by utilizing the 340B Program and could use the potential savings for additional services to patients. Thus, we believe it is incumbent upon eligible entities which do not wish to participate in the 340B Program to demonstrate that it is not feasible or cost efficient.

RECOMMENDATIONS

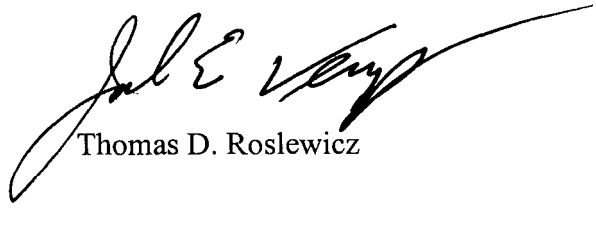
We commend the HRSA for its efforts and recommend that the HRSA:

(1) Continue its efforts to require eligible entities to participate in the 340B Program, and

(2) Periodically inform us of the status of these efforts.

We would appreciate your views and the status of any further action taken or contemplated on our recommendations 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 -98-01500 in all correspondence related to this report.



Thomas D. Roslewicz