



AUG 17 2000

Memorandum

Date

Michael Mangano

From

for June Gibbs Brown
Inspector General

Subject

Audit of the Mashantucket Pequot Tribal Nation's Use of Federal Discount Drug Programs (CIN: A-01-99-01502)

To

Michael H. Trujillo, M.D., M.P.H.
Director
Indian Health Service

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

Attached are two copies of the U.S. Department of Health and Human Services, Office of Inspector General's (OIG) final report entitled, "*Audit of the Mashantucket Pequot Tribal Nation's Use of Federal Discount Drug Programs*" (CIN: A-01-99-01502).

We would appreciate your views and the status of actions taken or contemplated on our recommendations within the next 60 days. To facilitate identification, please refer to Common Identification Number A-01-99-01502 in all correspondence relating to this report.

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, or through e-mail at jgreen3@os.dhhs.gov.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**AUDIT OF THE MASHANTUCKET
PEQUOT TRIBAL NATION'S USE OF
FEDERAL DISCOUNT DRUG
PROGRAMS**



**JUNE GIBBS BROWN
Inspector General**

**AUGUST 2000
A-01-99-01502**

EXECUTIVE SUMMARY

BACKGROUND

The Mashantucket Pequot Tribal Nation (MPTN) is a federally recognized tribe under the Mashantucket Pequot Land Claims Settlement Act of 1983 and operates various commercial enterprises, including a casino and its wholly owned and operated Pequot Pharmaceutical Network (PRxN). In 1996, MPTN contracted with the Secretary of the Department of Health and Human Services (HHS) to assume management responsibility of the health care programs, previously administered by Indian Health Service (IHS), for its tribal members and other eligible recipients.

The PRxN includes a network and a mail-order pharmaceutical distribution system. These are revenue-producing managed care pharmacy services that are used by MPTN and its health benefit plan members, and marketed to other plans and Indian tribal organizations. The PRxN maintains a dual inventory system to differentiate between its Federal and nonfederal drug purchases. One inventory, which dispenses drugs to MPTN's own health plans and other contracting tribes, includes purchases made using two Federal discount programs: (1) the Federal Supply Schedule (FSS), administered by the Department of Veterans Affairs (VA); and (2) the Public Health Service (PHS) 340B program, administered by the Health Resources and Services Administration (HRSA). The other inventory, which dispenses to outside commercial entities with which MPTN contracts, includes purchases of "nonfederal" drugs that are acquired through normal wholesale prices.

OBJECTIVE

The objective of this audit was to determine whether MPTN, a Connecticut (CT) Indian tribe receiving IHS funding, followed Federal requirements for the use of Federal discount drug pricing programs.

SUMMARY OF FINDINGS

We found that MPTN: (1) extended eligibility for federally discounted drugs to its non-Indian employees without making the required determination that reasonable alternative services were not available to these employees; and (2) did not follow Federal guidelines pertaining to the PHS 340B program.

- ☞ The MPTN did not make the required determination that reasonable alternative services were not available prior to extending eligibility to MPTN's non-Indian employees. The MPTN believed a determination regarding reasonable alternative services was not necessary, and that it was in compliance with eligibility requirements. As a result, in Fiscal Years (FYs) 1998 and 1999, MPTN dispensed \$5.8 million of drugs acquired

through Federal discount programs (the FSS and PHS 340B programs) to its ineligible non-Indian employees. We concluded that reasonable alternative services were, in fact, available to these employees, either through the numerous pharmacies in the area and by the MPTN's own pharmacy (PRxN), which maintains a separate inventory of nonfederally discounted drugs to service its commercial customers. Based on these conditions, we believe MPTN would not be able to satisfy the eligibility requirements for non-Indian employees.

☞ The MPTN did not follow the Federal guidelines requiring entities to identify their 340B drug purchases, and its contract relationships with 16 other tribes do not satisfactorily reflect useful practices suggested in 340B guidelines. The guidelines on identification and contract relationships were published by HRSA to facilitate compliance with two important statutory provisions: section 340B(a)(5)(C), which allows the Secretary or a manufacturer of covered drugs to conduct an audit of the covered entity; and section 340B(a)(5)(B), which prohibits drug diversion. With regard to the drug identification issue, MPTN opted to have a dual inventory system—one inventory that combined Federal discounted drugs (340B and FSS) and another to track its commercial purchases. The MPTN informed us that it was not aware of the Federal requirement regarding 340B purchases. Without such 340B identification—which is a critical control for an entity to prevent drug diversion—we could not determine from the MPTN records how much of the \$7.1 million in drugs dispensed from the tribe's Federal inventory were purchased using the 340B discount program. Regarding the procedures used by MPTN in serving its 16 contracted tribes, problems exist relating to: (1) MPTN serving tribes that have not applied to HRSA for "covered entity" status; and (2) ownership of drugs purchased under the 340B program. Regardless of whether drugs are purchased for MPTN's own purposes or for the contracted tribes, it is critical to know the volume of 340B purchases so that an audit of the entity's records can be conducted, as provided for by the Federal statute authorizing the 340B program.

RECOMMENDATIONS

To correct the findings disclosed in our audit of MPTN, we recommend four areas to be addressed by IHS and six for HRSA, as follows:

We recommend IHS:

1. Direct MPTN to discontinue its practice of providing FSS and PHS 340B drugs to ineligible non-Indian employees.
2. Remove any language from MPTN's 2000 annual funding agreement inferring that it may use the FSS or PHS 340B program to procure drugs on behalf of ineligible individuals. Further, IHS should review all other existing tribal self-determination contracts/compacts and associated funding agreements to

determine whether they contain language that infers tribes may use the FSS or PHS 340B program to procure drugs on behalf of ineligible individuals. Where such language exists, eliminate it in negotiating the next year's agreements.

3. Notify all tribes that the eligibility determination regarding the availability of reasonable alternative services must be made prior to providing services to otherwise ineligible individuals.
4. Work cooperatively with HRSA to instruct all federally recognized tribal entities on the proper use of the discount drug programs, and in particular the PHS 340B program, to obtain pharmaceuticals.

In addition, we recommend that HRSA:

1. Direct MPTN to discontinue providing PHS 340B drugs to ineligible non-Indian employees.
2. Provide MPTN with a notice and hearing to examine the improper dispensing of 340B-acquired drugs. Should there be a finding of drug diversion, HRSA should: (a) if warranted, terminate MPTN as an eligible covered entity; (b) inform appropriate manufacturers that diversion has occurred; and (c) assure that MPTN is not reinstated until it has agreed to meet all PHS 340B program requirements.
3. Work cooperatively with IHS to instruct all federally recognized tribal entities on the proper use of 340B discount drug program to obtain pharmaceuticals.
4. Direct MPTN to determine the amounts of PHS 340B drugs that were dispensed to ineligible non-Indian employees during FYs 1998 and 1999.
5. Inform MPTN that they are required to maintain records of purchases of drugs covered under the PHS 340B program.
6. Advise MPTN to follow HRSA guidelines applicable to contract pharmacies with regard to the servicing of only covered entities, drug ownership, and record keeping.

AGENCY COMMENTS AND OIG RESPONSE

Both IHS and HRSA commented on our draft report. In a July 21, 2000 memorandum, IHS fully concurred with our recommendations and indicated courses of actions to be taken upon issuance of this final report. In an August 2, 2000 memorandum, HRSA fully concurred with all but one of the six recommendations, and in some instances, indicated a planned course of

action to be taken. For the recommendation where HRSA concurred only in part, involving HRSA coordinating with IHS to inform tribes of the proper use of Federal discount drug programs, we followed HRSA's suggestion and limited our recommendation to the 340B program. We also incorporated the editorial and technical changes suggested by HRSA, as appropriate. The IHS and HRSA comments are summarized in the body of our report, and contained in their entirety in Appendices A and B, respectively.

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INTRODUCTION

BACKGROUND

The MPTN Operates Its Own Self-Determination Health Care Activities and Various Commercial Enterprises Including PRxN

The MPTN is located in Ledyard, CT (10 miles from New London, CT, and within 40 miles of Hartford, CT, and Providence, Rhode Island). The MPTN is a

federally recognized tribe under the Mashantucket Pequot Land Claims Settlement Act of 1983 and operates various commercial enterprises.

Self-Determination Health Care Activities

In 1996, MPTN contracted with the Secretary of HHS to assume management responsibility of the health care programs previously administered by IHS for its tribal members and other eligible recipients. Through the Indian Self-Determination Act (Public Law 93-638), tribes are given authority to administer funding and programs outlined in an annual agreement negotiated by IHS on behalf of the Secretary.

In its 1996 Annual Funding Agreement (AFA) under its self-determination contract, MPTN agreed to provide the following health programs, activities, functions, and services for its tribal members and other eligible recipients: comprehensive ambulatory client care, community health, nutrition, health promotion/disease prevention, alcohol/substance abuse, mental health, contract health services, patient services, and support services. The 1998 AFA was amended by MPTN to include the provision of pharmacy services within the category of support services.

Commercial Enterprises Including PRxN

The MPTN owns and operates several commercial enterprises on its reservation. These include the "Foxwoods" Gambling Casino, opened in 1992; and its pharmacy operation, PRxN, established in 1991.

Since opening in 1992, the "Foxwoods" Casino Resort has expanded to include a theater, restaurants, shops, and hotels. It is the largest casino in the country and one of the largest employers in the state, with over 10,000 employees. Due to increased jobs, housing, and other economic development, native people have returned to the reservation and tribal enrollment has increased from 188 members in 1983 to approximately 450 members in 1996.

The PRxN includes a network and a mail-order pharmaceutical distribution system. These are revenue-producing managed care pharmacy services that are used by MPTN and its health

benefit plan members and marketed to other plans and Indian tribal organizations. The pharmacy on-site at the MPTN reservation processes walk-in prescription orders as well as the mail order business. About 40 percent of business is walk-ins, while 60 percent is the mail order services. The MPTN has recently established a satellite pharmacy at the "Foxwoods" casino to accommodate the volume of business from its non-Indian employees and dependents.

Through PRxN, MPTN services: its own tribal health plans, 16 other contracted tribes, and several contracted commercial entities. The PRxN maintains a dual inventory system to differentiate between its Federal and nonfederal drug purchases. The first inventory is maintained to account for MPTN's purchases made using the Federal discount drug programs (FSS for drugs administered by VA, and the PHS 340B discount program, administered by HRSA), and dispensed to its own health plans and contracting tribes. The second inventory accounts for purchases of "nonfederal" drugs, which are acquired through normal wholesale prices and are dispensed to outside commercial entities with which MPTN contracts.

The PRxN, in FYs 1998 and 1999, dispensed about \$7.1 million in pharmaceuticals acquired under Federal discount pricing programs. (The amounts under each Federal discount program, i.e., FSS vs. PHS 340B, cannot be identified from PRxN records.) The discounted drugs were dispensed to MPTN members and dependents, other local Native Americans, non-Indian employees and dependents of the MPTN's commercial enterprises and tribal governmental operations, and 16 other federally recognized tribes with which MPTN contracts. The contracting tribes determine eligibility for the Federal discount drug programs, and provide PRxN with a listing of such individuals, which in some cases includes non-Indian employees.

**Federal Discount Drug Programs
Available to Tribal Self-Determination
Programs**

Because of its status as a federally recognized, self-governing tribal entity, MPTN has access to federally discounted pharmaceuticals in carrying out its IHS self-determination contract. Congress has

enacted separate legislation authorizing the FSS and PHS 340B programs to control prices paid by Federal agencies and certain federally funded entities for pharmaceuticals.

The FSS Drug Discount Program

Under the Veterans Health Care Act (the Act), manufacturers must make their brand-name drugs available through FSS in order to receive reimbursements for drugs covered by Medicaid. The Act requires manufacturers to sell covered drugs to four agencies, including PHS (of which IHS is a part), at no more than 76 percent of the nonfederal average manufacturer's price, the Federal ceiling price. The VA, given responsibility for administering the FSS pharmaceutical schedule by the General Services Administration (GSA), negotiates prices with drug manufacturers. Many FSS prices are less than 50 percent of the nonfederal average manufacturer prices.

Indian tribes that have self-determination contracts with IHS, such as MPTN, are granted access to FSS. This access is allowed because the Indian Self-Determination Act deems tribal organizations having such contracts with IHS as “executive agencies.” With this designation, tribal organizations are eligible to obtain supplies and services, including drugs, from FSS. Organizations eligible to use GSA sources of supply and services are covered by the provisions of the Federal Property and Administrative Services Act of 1949, as amended.

The PHS 340B Program

A tribe with a self-determination contract also has the option of providing pharmaceuticals as a covered entity under Section 602 of the Act, which enacted section 340B of the PHS Act, “Limitation on Prices of Drugs Purchased by Covered Entities.” The 340B program, administered by HRSA’s Office of Pharmacy Affairs, provides that a manufacturer who sells covered outpatient drugs to eligible entities must agree to charge a price that will not exceed the amount determined under a statutory formula.

OBJECTIVE, SCOPE, AND METHODOLOGY

The objective of this audit was to determine whether MPTN, a self-governing Indian tribe receiving IHS funding, followed Federal requirements for the use of Federal discount drug pricing programs.

To accomplish our audit objective, we:

- Reviewed laws, regulations, and guidelines pertaining to the eligibility of a federally recognized Indian tribe to access the FSS and PHS 340B drug pricing programs. We also held discussions with officials from PRxN, IHS, and HRSA regarding the basis for PRxN obtaining prescription drugs from the FSS and PHS 340B programs on behalf of (1) non-Indian employees, including casino and other enterprise employees; and (2) other federally recognized tribal entities and their employees.
- Obtained an understanding of PRxN’s operations, and reviewed PRxN’s contracts with other federally recognized Indian Tribes to provide pharmaceutical services.
- Obtained and analyzed information from PRxN’s records and its primary supplier to determine the amounts of Federal pharmaceuticals acquired through its primary supplier versus other suppliers in FYs 1998 and 1999, and the amounts dispensed for MPTN tribal members, MPTN employees, and contracting tribes.
- Contacted 6 of 16 tribes that contract with MPTN for mail-order pharmacy services to determine if they provide federally discounted drugs to non-Indian employees.

- Provided a draft of our report to IHS and HRSA, summarized their comments in the body of report, and included the full text of the comments in the appendices of this final report.

We conducted our audit in accordance with generally accepted government auditing standards. We performed our field work at the MPTN reservation in Ledyard, CT, and at our regional office in Boston, Massachusetts, during the period July 1999 through April 2000.

FINDINGS AND RECOMMENDATIONS

We found that MPTN: (1) extended eligibility for federally discounted drugs to non-Indian employees without making the required determination that reasonable alternative services were not available to these employees; and (2) did not follow Federal guidelines pertaining to the 340B program. Below we discuss both findings in more detail.

ELIGIBILITY FOR FEDERALLY DISCOUNTED DRUG PROGRAMS

The MPTN did not make the required determination that reasonable alternative services were not available prior to extending eligibility for federally discounted drugs to MPTN's non-Indian employees. The MPTN believed such a determination was not necessary, and that it was in compliance with eligibility requirements. However, we found that MPTN is located in an area serviced with reasonable alternatives and that MPTN's own pharmacy (PRxN) is a reasonable alternative, since it already maintains a separate inventory of nonfederally discounted drugs to service its commercial clients. Based on these conditions, we believe that MPTN would not be able to satisfy the eligibility requirements for non-Indian employees. As a result, in FYs 1998 and 1999, MPTN dispensed \$5.8 million of drugs acquired through Federal discount programs (the FSS and PHS 340B programs) to its ineligible non-Indian employees.

The MPTN's Eligibility for Discounted Drugs is Based on Its Self-Determination Agreement with IHS and is Limited Primarily to Indian Beneficiaries

The MPTN's use of the Federal discount programs is governed by the Indian Health Care Improvement Act (IHCIA), which establishes the conditions for providing IHS benefits to eligible and otherwise ineligible individuals.

The IHCIA specifies two conditions that must be satisfied before an otherwise ineligible individual can be served. A tribe, such as MPTN, operating its own health care activities under a self-determination contract, must consider the same conditions applicable to tribes not operating under a self-determination contract. Specifically, this requires a determination that: (1) benefits to eligible Indians will not be denied or diminished; and (2) there are no reasonable alternative health services available. The IHCIA section 1680(c) part (b)(1)(B) states:

“. . . the governing body of the Indian tribe or tribal organization providing health services under such contract is authorized to determine whether health services should be provided . . . to individuals who are not eligible In making such determinations, the governing body of the Indian tribe or tribal organization **shall take into account the consideration described in subparagraph (A)(ii).**” [emphasis added]

Subparagraph (A)(ii) states that:

“The Secretary is authorized to provide health services under this subsection through health facilities operated directly by the Service to individuals who reside within the service area of a service unit and who are not eligible for such health services under any other subsection of this section or under any other provision of law if--**the Secretary and the Indian tribe or tribes have jointly determined that--(I) the provision of such health services will not result in a denial or diminution of health services to eligible Indians; and (II) there are no reasonable alternative health facility or services, within or without the service area of such service unit, available to meet the health needs of such individuals.**” [emphasis added]

The MPTN’s authority to access FSS was clarified by IHS in a letter to MPTN, dated February 15, 1996. The authorization is limited to procurement required in the performance of its self-determination contract, thereby invoking IHCA as the overriding criteria. Additionally, servicing all the non-Indian employees of a private enterprise does not fall within the scope of a self-determination contract. The IHCA was established to serve the health needs of the American Indian community. The Federal Government’s fiduciary duty extends only to American Indians.

The PHS 340B program also limits the use of discounted drugs to activities required in the performance of MPTN’s self-determination contract. Section 340B(a)(5)(B) of the PHS Act prohibits a covered entity from reselling or otherwise transferring a covered drug to a person who is not a “*patient*” of the entity. A Federal Register Notice, issued on October 24, 1996 by HRSA, defines a patient as an individual who meets all of the specified criteria. Part 3 of this patient criteria stipulates that the individual must be receiving health care services consistent with the services for which grant funding has been provided.¹ The MPTN receives its grant funding under its self-determination contract. Therefore, individuals who are not eligible for IHS services would not be considered “*patients*” of MPTN under the 340B program.

In addition, Section 340B(a)(5)(D) of the PHS Act provides that, after notice and hearing, a covered entity distributing drugs acquired under the Act to individuals who are not patients of

¹The Federal Register Notice (Notice) includes two other patient eligibility criteria—one pertaining to the relationship established between the entity and the individual such that the entity maintains the health care records, and the other regarding the entity retaining the responsibility for the care provided. We did not fully examine MPTN’s compliance with these criteria because we found conclusively that the non-Indian employees did not meet the requirements of Part 3 of the Notice in that they were not beneficiaries of the IHS contract. According to the Notice, **all three** criteria must be met in order for an individual to be considered a “*patient*” eligible to receive 340B discounted drugs. Furthermore, the Notice clearly establishes that an individual will not be considered a patient if the only health care service received from the covered entity is the dispensing of a drug.

the covered entity (this is referred to as “*drug diversion*” in HRSA’s implementing guidelines, Federal Register dated May 13, 1994) shall be liable to the drug manufacturers for the differences between the PHS 340B price and the non-discounted price. Further, HRSA has issued a Federal Register Notice, dated December 12, 1996, allowing it to exclude an entity from the PHS 340B program for such activity if the conduct warrants.

No Determination was Made on Whether Reasonable Alternative Services Exist

Applying the two eligibility conditions of IHCIA, we found that MPTN met the first condition requiring a determination that provision of services to non-eligible individuals would not result in a denial or diminution of services to eligible Indians; but did not meet the

second condition requiring a determination that reasonable alternative services are not available to non-eligible individuals.

Regarding the first condition, we found that the MPTN’s 1998 amended AFA included language indicating that the tribe had addressed the denial or diminution of services to eligible Indians. We noted that the tribe requested additional time to prepare its 1998 AFA to ensure that the health services provided to its members and *employees* were included as an integral part of the agreement. This language was also included in the 1999 AFA; however, the issue of including or excluding this language from the 2000 AFA has not yet been resolved by IHS.

For the second condition, however, we noted MPTN did not make a determination as to whether there were reasonable alternative health facilities or services available to meet the needs of MPTN’s non-Indian employees. Had MPTN made a determination, it could have identified that reasonable alternative services are available to its non-Indian employees. We identified over 40 private pharmacies within 10 miles of the MPTN’s location. In addition, MPTN’s own pharmacy operation, the PRxN, can be considered an alternative in that it had the ability to service non-Indians under the commercial side of its operation. As a result of our research, we believe it would be unlikely for MPTN to argue convincingly that reasonable alternative services are not available to meet the needs of the non-Indian employees.

The MPTN Believed it Met the Conditions of IHCIA

The MPTN believed it complied with IHCIA when it extended the Federal discount programs to otherwise non-eligible individuals. The MPTN also believed that the language of its contract with IHS allowed the

eligibility extension. In contrast, we found that MPTN inappropriately extended eligibility because it had not made a determination demonstrating the lack of alternative care for its non-Indian employees in the geographical area. Without the determination, the contract language alone cannot authorize the extension of the discount drug programs to such employees. Below we discuss MPTN’s view as to why it believed it met the conditions of IHCIA, and our view as to why the tribe misinterpreted the statute and the applicability of the contract language.

***The MPTN's View: It Met the Conditions of IHCIA,
and its IHS Contract Allowed the Extension***

The MPTN, in correspondence to the Office of Inspector General (OIG), presented its view that it was authorized to extend eligibility to its non-Indian employees because it had “*considered*” both conditions set forth in IHCIA; i.e., denial or diminution of services and availability of reasonable alternative services. Further, MPTN believed that language added to its contract with IHS authorized it to provide federally discounted drugs for otherwise ineligible individuals.

With respect to IHCIA, MPTN indicated that both conditions did not actually have to be present in order to extend eligibility. Rather, MPTN believed that by only “*considering*” both conditions set forth in the statute, it had met the intent of IHCIA. In this respect, MPTN believes it took into account the health service needs of its membership, community, and employees; and had determined that the provision of such care and services would not result in a denial or diminution of health services to eligible Indians. Therefore, MPTN believes that it met the conditions of IHCIA.

As for the contract language, MPTN indicated to us that language contained in contracts with IHS and associated modifications demonstrated that the tribe had addressed the first condition, and had indicated that employee needs would be served. This contract language, added to the 1998 AFA, stated that MPTN had taken into account the health care and service needs of its employees, and determined that the provision of such care and services would not result in denial or diminution of health services to eligible Indians. A further contract statement, added under the category of support services, indicated that MPTN would provide all medically necessary pharmacy services for the tribe, beneficiaries of the tribe’s health benefit plans, and other tribes that have a Government-to-Government relationship and their health benefit plans. (The MPTN officials informed us that “beneficiaries of the tribe’s health benefit plans” was intended to cover its non-Indian employees and their dependents.)

***The OIG's View: The MPTN Did Not Qualify for an Extension
of the Drug Discounts to Otherwise Ineligible Individuals***

The MPTN did not take the requisite steps that would provide authorization to use Federal discount drug programs to benefit its non-Indian employees. Beyond IHCIA conditions, MPTN maintains that there is specific language in its contract with IHS authorizing the extension. However, unless the conditions of IHCIA are met regarding the required determinations, the contract language alone cannot extend the program eligibility. In fact, neither IHCIA nor the Indian Self-Determination Act gives MPTN or IHS the ultimate authority to decide eligibility without making the required factual determinations. The IHS officials who have responsibility for negotiating the contract with MPTN believe they did not extend MPTN’s authority to provide federally discounted drugs to its non-Indian employees. Without the factual determination of the lack of reasonable alternative services, IHS does not

have the authority to contractually extend eligibility to ineligible individuals. Irrespective of the current contract language, the annually renewed contract should not include provision of drug benefits to non-Indian employees.

Regarding a factual determination, we report on page 7 that we identified over 40 private pharmacies within 10 miles of MPTN's location in Ledyard, CT. Further, since the PRxN already maintains a separate inventory of nonfederally discounted drugs to service its commercial clients, PRxN itself is an alternate resource. As a result of our research and PRxN's current ability to service commercial customers through a separate inventory, we believe it would be unlikely for MPTN to argue convincingly that alternate resources are not available to meet the needs of the its non-Indian employees.

The MPTN Used Federal Discount Drug Programs to Purchase Over \$5.8 Million in Drugs for its Ineligible Non-Indian Tribal Employees and Dependents; Continuing This Practice Could Jeopardize the Integrity and Future of These Programs

The MPTN has used the FSS and PHS 340B programs to acquire drugs valued at approximately \$5.8 million on behalf of its ineligible non-Indian employees. These individuals are employed primarily in MPTN's commercial enterprises. The MPTN also dispenses discounted drugs for

non-Indian employees of some contracting tribes. Several tribes have asked IHS about use of Federal discount drug programs for non-Indian tribal employees. Continuing and expanding the unauthorized use of the FSS and PHS 340B programs could ultimately jeopardize the integrity and future of programs that Congress intended to primarily help beneficiaries of federally sponsored programs.

Non-Indian Tribal Employees and Dependents

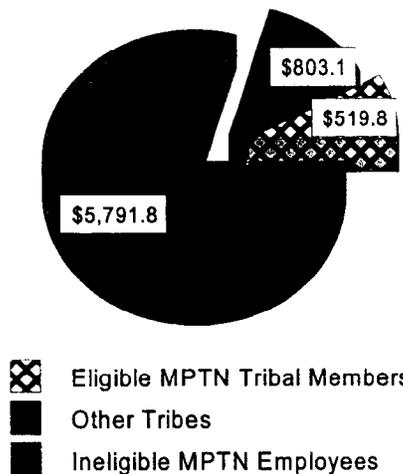
Regarding its drug purchases, MPTN used the Federal discount drug programs to purchase \$5.8 million in drugs for employees and dependents of its commercial enterprises, as well as its tribal Governmental operations, which are covered by its health benefits plan. However, virtually all of the commercial enterprise employees are non-Indians, and thus do not qualify for the programs. While MPTN has only 450 tribal members, it has over 12,000 employees, of which 10,700 receive health benefits. With their dependents, nearly 22,000 people are covered under its health benefits plan, and therefore are provided access to the Federal discount drug programs.

In terms of other tribes served by PRxN (16 contracted tribes), some discount drug purchases were also dispensed to non-Indian employees. In this respect, four of the six tribes we contacted informed us that their notification to MPTN includes non-Indian employees as eligible plan members. We did not attempt to determine the amount of drugs distributed to ineligible non-Indian employees of these tribes.

Based on MPTN records, MPTN's distribution of \$7.1 million in drug purchases for FYs 1998 and 1999 from the Federal drug programs is as follows:

- R Over 82 percent, \$5.8 million, were for drugs dispensed to ineligible MPTN employees and their dependents.
- R About 11 percent, \$803,100, were on behalf of other tribes, some of which were for drugs dispensed to non-Indian tribal employees.
- R About 7 percent, \$519,800, were dispensed to eligible MPTN members and their dependents.

PRxN Federal Sales (000) for FYs 98 & 99



Program Integrity Questions

The continuation of these practices, and potential expansion to other tribes, would seriously diminish the integrity of the programs. Regarding expansion, other tribes have also expressed interest in utilizing FSS, as indicated by a VA letter to drug manufacturers, dated March 1997, indicating it has "been inundated with questions" about the ability of IHS and tribes to use FSS. In addition, in August 1999, a consortium of 11 tribes in Michigan and Wisconsin requested advice from IHS regarding the use of various Federal discount drug programs for *non-Indian tribal employees*, and stated their belief that they could dispense federally discounted drugs to non-Indians. The IHS had not responded when we last contacted responsible officials.

While we believe that IHS and MPTN should maximize the effective use of available discount drug programs, the use of these programs for ineligible individuals employed by a tribal commercial enterprise casts a negative light on the integrity of programs that were intended by Congress to assist Federal beneficiaries. Unauthorized use of the PHS 340B program by MPTN and other tribes could result in these entities having to reimburse manufacturers for the differences in cost. *On a broader policy level, evidence of program abuse could prompt Congress to reconsider the future of discounted drug programs, which would ultimately affect the millions of Federal beneficiaries who now depend upon them for their health care.*

CONCLUSIONS AND RECOMMENDATIONS

The MPTN, during FYs 1998 and 1999, did not follow appropriate eligibility requirements, resulting in MPTN dispensing \$5.8 million of drugs acquired through Federal discount programs (the FSS and PHS 340B programs) to ineligible non-Indian employees and their dependents. The MPTN believes that it did not have to demonstrate that reasonable alternatives were not available, and that it acted within the scope of its contract. Regardless of MPTN's contract, the law requires a determination that no reasonable alternative services are available. Because MPTN is located in an area serviced with reasonable alternatives, with MPTN itself being a reasonable alternative in that its PRxN supplies pharmacy services to other organizations, we believe that the tribe would not be able to satisfy the eligibility requirements for non-Indian employees. Therefore, to preserve the integrity of these vital programs, it is imperative that IHS ensure that MPTN and other tribes do not dispense drugs purchased under Federal discount programs to ineligible non-Indian employees.

We recommend that IHS:

1. Direct MPTN to discontinue its practice of providing FSS and PHS 340B drugs to ineligible non-Indian employees.
2. Remove any language from MPTN's 1999/2000 AFA that infers that it may use the FSS or PHS 340B program to procure drugs on behalf of ineligible individuals. Further, IHS should review all other existing tribal self-determination contracts/compacts and associated funding agreements to determine whether they contain language inferring tribes may use the FSS or PHS 340B program to procure drugs on behalf of ineligible individuals. Where such language exists, eliminate it in negotiating the next year's agreements.
3. Notify all tribes that the eligibility determination regarding the availability of reasonable alternative services, required by IHCA, must be made prior to providing services to otherwise ineligible individuals.
4. Work cooperatively with HRSA to instruct all federally recognized tribal entities on the proper use of the discount drug programs, and in particular the PHS 340B program, to obtain pharmaceuticals.

In addition, we recommend that HRSA:

1. Direct MPTN to discontinue providing PHS 340B drugs to ineligible non-Indian employees.
2. Provide MPTN with a notice and hearing in accordance with Section 340B(a)(5)(D) of the PHS Act. Should there be a finding of drug

diversion, HRSA should (a) if warranted, terminate MPTN as an eligible covered entity; (b) inform appropriate manufacturers that diversion has occurred; and (c) assure that MPTN is not reinstated until MPTN has agreed to meet all PHS 340B program requirements.

3. Work cooperatively with IHS to instruct all federally recognized tribal entities on the proper use of 340B discount drug program to obtain pharmaceuticals.

AGENCY COMMENTS AND OIG RESPONSE

The IHS and HRSA comments are summarized below, and contained in their entirety in Appendices A and B, respectively.

The IHS Comments Describe Actions to be Taken to Implement Recommendations

In a July 21, 2000 memorandum to OIG, IHS concurred with all four of our recommendations, and indicated planned actions to be taken to implement them. With regard to IHS' planned actions on our recommendation to instruct all federally recognized tribal entities on the proper use of the discount drug programs, it indicated that a letter would be sent to its "Area Directors" with instructions on the proper use of the programs. We want to reiterate that our recommendation went beyond IHS' own "Area Directors" and was aimed at notifying all federally recognized tribal entities. We suggest that IHS modify its planned course of action to include this broader audience.

The HRSA Comments Describe Actions to be Taken to Implement Recommendations

In an August 2, 2000 memorandum, HRSA fully concurred with all but one of the recommendations, and in some instances, indicated a planned course of action to be taken. With respect to Recommendation #1, HRSA has already advised PRxN of possible violations, and after having an opportunity to review all relevant documentation, will follow up with additional correspondence to MPTN with specific direction to discontinue providing 340B drugs to non-patients. For the recommendation where HRSA concurred only in part, involving HRSA coordinating with IHS to inform tribes of the proper use of Federal discount drug programs, we followed HRSA's suggestion and limited our recommendation to the 340B program. Accordingly, we expect HRSA to fully implement this revised recommendation. We also incorporated the editorial and technical changes suggested by HRSA, as appropriate.

ISSUES REGARDING PURCHASES OF PHS 340B COVERED DRUGS

The MPTN did not follow the Federal guidelines requiring entities to identify their 340B drug purchases, and its contract relationships with 16 other tribes do not satisfactorily reflect useful practices suggested in 340B guidelines. The guidelines on identification and contract relationships were published by HRSA to facilitate compliance with two important statutory provisions: section 340B(a)(5)(C), which allows the Secretary or a manufacturer of covered drugs to conduct an audit of the covered entity; and section 340B(a)(5)(B), which prohibits drug diversion. With regard to the drug identification issue, MPTN opted to have a dual inventory system—one inventory that combined Federal discounted drugs (340B and FSS) and another to track its commercial purchases. The MPTN informed us that it was not aware of the Federal requirement regarding 340B purchases. Without such 340B identification—which is a critical control for an entity to prevent drug diversion—we could not determine from MPTN records how much of the \$7.1 million in drugs dispensed from the tribe’s Federal inventory were purchased using the 340B discount program. Regarding the procedures used by MPTN in serving its 16 contracted tribes, we identified problems relating to: (1) MPTN serving tribes that have not applied to HRSA for “covered entity” status; and (2) ownership of drugs purchased under the 340B program. Regardless of whether drugs are purchased for MPTN’s own purposes or for the contracted tribes, it is critical to know the volume of 340B purchases so that an audit of the entity’s records can be conducted, as provided for by the Federal statute authorizing the 340B program.

Maintain Separate Purchasing Accounts for 340B Covered Drugs; and Provide Contract Pharmacy Services Only to Eligible Covered Entities who Purchase 340B Drugs

The HRSA guidelines for proper implementation of the 340B program require covered entities and contract pharmacies to follow certain practices which are intended to prevent drug diversion. Specifically, covered entities should maintain separate purchasing accounts for 340B drugs, which would facilitate the conduct of an audit of the entity’s records, as provided for in the 340B statute. Furthermore, to facilitate compliance with statutory prohibitions on drug diversion, contract pharmacies should ensure that they dispense 340B drugs to only covered entities of the 340B program that have their own purchasing arrangement giving them ownership of the drugs.

Separate Accounts for 340B Drug Purchases

Section 340B(a)(5)(C) of the PHS Act provides that a covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug to audit records of the covered entity that directly pertain to the entity’s compliance with the statutory requirements prohibiting both duplicate discounts or rebates and the resale of drugs to persons not considered patients. The HRSA guidelines in Federal Register Notice, issued May 13, 1994, require the entity to maintain separate purchasing accounts and dispensing records for 340B covered drugs.

Section (C)(5) states: “All entities receiving statutory prices are required to maintain records of purchases of covered outpatient drugs” This is a critical control of the 340B program. Segregation of drugs purchased under the 340B discount program enables the Secretary and/or manufacturer of a covered drug to conduct an audit of a covered entity’s records in accordance with the statute. It further serves to prevent diversion of drugs and maintain the integrity of the program.

Contract Pharmacy Services

Regarding MPTN’s contracts with 16 other tribes, PRxN serves as their “contract pharmacy,” a relationship on which HRSA has issued guidelines regarding implementation and responsibilities of each party. The guidelines, issued in an August 23, 1996 Federal Register Notice, prescribe a suggested model agreement between only enrolled “covered entities” of the 340B program and the contract pharmacy. According to HRSA, the guidelines were published to provide examples of good faith compliance with 340B provisions. The guidelines for contract pharmacy services serve to provide a “model agreement” which would be compliant with the drug diversion prohibition contained in section 340B(a)(5)(B).

The model agreement clearly identifies the covered entity as the party responsible for the drug purchases, and includes a suggestion for using a “ship to, bill to” arrangement with the drug manufacturer, where the drugs are purchased and billed to the covered entity but shipped to the contract pharmacy. The model agreement indicates that a contract pharmacy can provide a number of pharmacy services to the covered entity, including dispensing, record keeping, drug utilization review, formulary maintenance, patient profile, and counseling. The guidelines also state that the contract pharmacy’s record keeping should be consistent with customary business practices and be suitable to prevent the diversion of 340B drugs to individuals who are not patients of the covered entity.

The MPTN Records Do Not Identify Purchases of 340B Covered Drugs; and Problems Exist with MPTN’s Contract Pharmacy Relationships with 16 Other Tribes

The MPTN’s inventory records do not separately identify purchases of 340B covered drugs from those purchased using FSS, as required by HRSA guidelines. In addition, MPTN’s contractual relationships with 16 other tribes do not meet certain guidelines. Specifically, in its capacity as a contract pharmacy, MPTN has not ensured that 340B drugs were dispensed only to covered entities of the

340B program, and has also inappropriately assumed ownership of the drugs purchased for the other 16 tribes.

340B Drug Purchases are Not Identified

While MPTN maintains a Federal and nonfederal inventory, its records do not identify purchases made or drugs dispensed relating to the PHS 340B program. The MPTN purchases

almost 90 percent of its drugs from a single supplier. The supplier provides drugs from the FSS and PHS 340B program that are utilized by MPTN for its own health plans (tribal members and non-Indian employees), other local Native Americans, and the contracting tribes. The supplier also provides drugs to MPTN for its commercially marketed plans. The supplier identifies the drugs provided to MPTN as either Federal or nonfederal, depending on which inventory MPTN is replenishing at the time.

We contacted officials from MPTN's supplier, who informed us they cannot identify within their records whether they provided MPTN the FSS or PHS 340B price. It was their understanding that the manufacturers provide the best price (FSS or PHS 340B) to MPTN at the time of the order. Representatives from two manufacturers that sell federally discounted drugs to MPTN informed us that current sales to MPTN through the major supplier are predominately under the PHS 340B pricing program.

The discounted drugs (Federal inventory) were dispensed to MPTN members and dependents, other local Native Americans, non-Indian employees and dependents of the MPTN's commercial enterprises and tribal Governmental operations, and 16 other federally recognized tribes with whom MPTN contracts. (See chart on page 10)

Contract Relationships Do Not Meet Guidelines

The MPTN Unaware of HRSA Requirements; Contracted Tribes not Contacted

The contract relationships between MPTN and 16 other tribes do not meet Federal guidelines of the 340B program. First, cognizant HRSA officials have informed us that 15 of the 16 tribes have not applied to be considered "covered entities" under the 340B program. By not being considered covered entities, these contracting tribes are not authorized to receive 340B discounted drugs. Second, MPTN has assumed ownership of the tribes' discounted drugs when, according to the HRSA guidelines outlined in a Federal Register Notice dated August 23, 1996, such ownership should remain with the covered entity for which the purchases are being made. Our review of the records showed that MPTN took ownership and dispensed the discounted drugs to individuals associated with the contracting tribes. Finally, since MPTN does not maintain necessary documentation regarding their purchases of federally discounted drugs, we cannot quantify the amount of 340B drugs purchased on behalf of the other tribes. This is problematic given the HRSA guidelines outlined in the August 23, 1996 Federal Register Notice advising contract pharmacies to have a record keeping system in place ensuring, among other things, the collection of pertinent drug purchasing information. According to HRSA, implementation of practices similar to those suggested in the agency's guidelines will help demonstrate good faith compliance with 340B statutory provisions prohibiting drug diversion.

In response to our inquiries, MPTN officials told us they were not aware that a separate accounting for purchases under the PHS 340B program was required. We note that a separate

accounting does not require a separate inventory, only that these purchases are identified as purchases under the PHS 340B program to enable adequate tracking of the uses made of 340B drugs. In terms of the contracting tribes, we did not question them with respect to their understanding of 340B requirements.

Cannot Determine Amounts of PHS 340B Covered Drugs Dispensed for Ineligible Non-Indian Employees or Other Tribes

Because MPTN does not identify purchases under the PHS 340B program, we could not determine from MPTN records how much of the \$5.8 million in drugs dispensed from MPTN's Federal inventory for ineligible non-Indian employees were PHS 340B covered drugs. Regarding the contracting tribes,

which did not have the designation of contract entity to be authorized to receive 340B drugs, we also could not determine how much of the \$803,100 was for 340B drugs that MPTN dispensed to these other tribes. These amounts would be critical to know so that an audit of the entity's records can be conducted, as provided for by Section 340B(a)(5)(C) of the PHS Act. As mentioned above, the use of these programs for ineligible individuals employed by a tribal commercial enterprise casts a negative light on the integrity of programs that were intended by Congress to assist Federal beneficiaries.

RECOMMENDATIONS

We recommend that HRSA:

4. Direct MPTN to determine the amounts of PHS 340B drugs that were dispensed to ineligible non-Indian employees during FYs 1998 and 1999.
5. Inform MPTN that they are required to maintain records of purchases of drugs covered under the PHS 340B program.
6. Advise MPTN to follow HRSA guidelines applicable to contract pharmacies with regard to the servicing of only covered entities, drug ownership, and record keeping.

THE HRSA COMMENTS

The HRSA concurred with these recommendations.

APPENDICES



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 21 2000

Indian Health Service
Rockville MD 20857

TO: Assistant Inspector General
For Public Health Service Audits

FROM: Director
Office of Management Support

SUBJECT: IHS Comments on the OIG Draft Report, "Audit of
Mashantucket Pequot Tribal Nation's Use of Federal
Discount Drug Program," (CIN: A-01-99-01502)

The Indian Health Service is pleased to offer the attached
comments on the Office of Inspector General draft report, "Audit
of Mashantucket Pequot Tribal Nation's Use of Federal Discount
Drug Programs," (CIN: A-01-99-01502).

If you have any questions regarding this memorandum, please call
Mr. Charles Miller, Management Analyst, Management Policy Support
Staff, Office of Management Support, at (301) 443-9597.


ROBERT G. McSwain

Attachment

Indian Health Service Comments on the Office of
Inspector General Draft Report, "Audit of Mashantucket
Pequot Tribal Nation's Use of Federal Discount Drug
Program," (CIN: A-01-99-01502)

OIG Recommendation #1

Direct MPTN to discontinue its practice of providing FSS and PHS 340B drugs to ineligible non-Indian employees.

IHS Comments

We concur. The IHS Nashville Area Office (NAO) will send a letter to the Pequot tribe directing them to cease this practice immediately. The letter will be sent within 30 days after the issuance of the OIG final report.

OIG Recommendation #2

Remove any language from MPTN's 2000 annual funding agreement inferring that it may use the FSS or PHS 340B program to procure drugs on behalf of ineligible individuals. Further, IHS should review all other existing tribal self-determination contract/compacts and associated funding agreements to determine whether they contain language that infers tribes may use the FSS or PHS 340B program to procure drugs on behalf of ineligible individuals. Where such language exists, eliminate it in negotiating the next year's agreements.

IHS Comments

We concur. The IHS NAO will remove all language from MPTN's 2000 annual funding agreement which might infer that it may use the FSS or PHS 340B program to procure drugs on behalf of ineligible individuals. This will be completed within 30 days after the issuance of the OIG final report.

IHS will also review all other existing tribal self-determination contract/compacts and associated funding agreements to determine whether they contain language that infers tribes may use the FSS or PHS 340B program to procure drugs on behalf of ineligible individuals. Where such language exists, the IHS will eliminate it in negotiating the next year's agreements. IHS will complete this by the beginning of fiscal year 2001 or calendar year contract/AFA cycle.

OIG Recommendation #3

Notify all tribes that the eligibility determination regarding the availability of reasonable alternative services must be made prior to providing services to otherwise ineligible individuals.

IHS Comments

We concur. The Director, IHS, will send a letter to All Area Directors instructing them to contact all contractors within their jurisdiction to notify them of the eligibility determination regarding the availability of reasonable alternative services that must be made prior to providing services to ineligible individuals. The Director, IHS, will issue this letter within 30 days after issuance of the final report.

OIG Recommendation #4

Work cooperatively with HRSA to instruct all federally recognized tribal entities on the proper use of the FSS and PHS 340B programs to obtain pharmaceuticals.

IHS Comments

We concur. The Director, IHS, will issue a letter to All Area Directors instructing them to follow the proper use of the FSS and PHS 340B programs to obtain pharmaceuticals and will send an information copy to HRSA. This will be completed within 30 days after the issuance of the OIG final report.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 4 2000

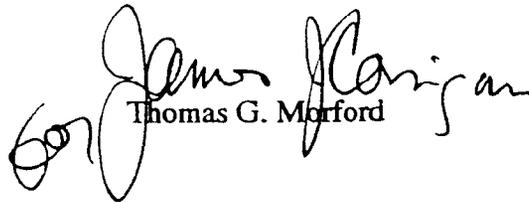
Health Resources and
Services Administration
Rockville MD 20857

TO: Assistant Inspector General for Public Health Service Audits

FROM: Deputy Administrator

SUBJECT: OIG Draft Report - Audit of Mashantucket Pequot Tribal Nation's Use of
Federal Discount Drug Programs (A-01-99-01502) Issued June 2000

We have reviewed the subject draft report. Attached are HRSA's comments. Thank you for the opportunity to review and comment on the draft report.


Thomas G. Morford

Attachment

HEALTH RESOURCES AND SERVICES ADMINISTRATION
COMMENTS TO THE OIG DRAFT AUDIT REPORT
THE MASHANTUCKET PEQUOT TRIBAL NATION'S (MPTN)
USE OF FEDERAL DRUG DISCOUNT PROGRAMS
CIN A-01-99-01502
Issued June 2000

GENERAL COMMENTS

The HRSA "guidelines" were published to provide examples of good faith compliance with 340B provisions. The guidelines, which are based on statutory requirements, include a combination of direct mandates from section 340B and necessary actions to comply with the 340B provisions. For example, to demonstrate compliance with drug diversion prohibition of section 340B(a)(5)(B) and the audit requirements of section 340B(a)(5)(C), it is necessary to maintain the purchasing and dispensing records of 340B drugs. In addition, some of the guidelines describe practices that would be considered compliant. For example, the contracted pharmacy services guideline provides a model contract.

OIG RECOMMENDATION

Direct MPTN to discontinue providing PHS 340B drugs to ineligible non-Indian employees.

HRSA RESPONSE

We concur that actions necessary to address the concerns of ineligible patients receiving 340B drugs be initiated. HRSA's Office of Pharmacy Affairs (OPA) sent a letter dated June 27, 2000, advising the Pequot Pharmaceutical Network that it has come to the attention of OPA that MPTN's use of drugs purchased under the 340B Drug Purchasing Program may have violated the conditions governing participation. OPA, after we have an opportunity to review all relevant documentation, including this audit report, will send a letter specifically directing the MPTN's Pharmaceutical Network and the Tribal government not to provide 340B medications to non-patients.

OIG RECOMMENDATION

Provide MPTN with a notice and hearing to examine the improper dispensing of 340B acquired drugs. Should there be a finding of drug diversion, HRSA should: (a) if warranted, terminate MPTN as a eligible covered entity; (b) inform appropriate manufacturers that diversion has occurred; and (c) assure that MPTN is not reinstated until it has agreed to meet all PHS 340B program expectations.

HRSA RESPONSE

We concur that actions necessary to address the concerns of diversion raised in this report be initiated. We recommend that "program expectations" be changed to "requirements".

OIG RECOMMENDATION

HRSA will work cooperatively with the Indian Health Service (IHS) to instruct all Federally recognized tribal entities on the proper use of the Federal Supply Service (FSS) and the PHS 340B drug program to obtain pharmaceuticals.

HRSA RESPONSE

We concur, in part. HRSA will work cooperatively with the IHS regarding the provision of technical assistance and instruction on the 340B requirements for program participation (e.g., audit requirements, duplicate discount and drug diversion prohibitions). We do not agree with the reference to the FSS, inasmuch as HRSA plays no part in FSS activity.

OIG RECOMMENDATION

Direct MPTN to determine the amounts of PHS 340B drugs that were dispensed to ineligible non-Indian employees during FY's 1998 and 1999.

HRSA RESPONSE

HRSA will require that MPTN provide adequate documentation demonstrating that 340B drugs were dispensed consistent with the 340B "patient" definition published in the Federal Register.

OIG RECOMMENDATION

Inform MPTN that they are required to maintain records of purchases of drugs covered under the PHS 340B program.

HRSA RESPONSE

We concur.

OIG RECOMMENDATION

Advise MPTN to follow HRSA guidelines applicable to contract pharmacies with regard to the servicing of only covered entities, drug ownership and record keeping.

HRSA RESPONSE

We concur.

TECHNICAL COMMENTS

Page 6, Footnote 1, first sentence. Delete "pertaining to the entity's maintenance of the individuals health care records" and add "pertaining to the relationship established between the entity and the individual such that the entity maintains the health care records."

Page 6, Footnote 1, third sentence. Delete "all three criteria must be met in order for an individual to be considered a *patient*" eligible to receive 340B discounted drugs." Add "all four criteria must be met in order for an individual to be considered a "patient to receive 340B discounted drugs including the requirement that an individual will not be considered a "patient" if the only health care service from the covered entity is the dispensing of a drug."