



NOV 28 2000

Indian Health Service
Rockville MD 20857

Dear Tribal Leaders and Other Interested Parties:

Several questions have been raised by tribes and tribal organizations participating in Indian Self-Determination and Education Assistance Act (ISDA) contract and compact programs regarding the purchase of drugs under Federal discount drug programs.

One purpose of this letter is to provide additional guidance and clarification for determining the proper use of the discount drug programs to obtain pharmaceuticals particularly through the Public Health Service Act (PHSA) 340B program. Another purpose of this letter is to notify all tribes that any decision to extend eligibility to non-IHS beneficiaries pursuant to Section 813 of the Indian Health Care Improvement Act (IHCIA) must be made jointly by the tribe and the Indian Health Service (IHS) prior to providing services to otherwise ineligible individuals.

Recently, an audit (CIN: A-01-99-01502) conducted by the Office of Inspector General (OIG), found that a tribe did not make the pre-requisite finding, required by Section 813 of the IHCIA (25 U.S.C. 1680c), for extending eligibility to individuals not otherwise eligible for IHS services. Specifically, the OIG concluded that a tribe lacked the authority to purchase and use Federal discount drugs for such individuals. To avoid potential liability, I believe it is important to clarify the requirements of 25 U.S.C. 1680c relating to Federal discount drug programs.

Tribes and tribal organizations having a current ISDA contract or compact with the Department of Health and Human Services (HHS) may be eligible to purchase discount drugs under several Federal programs described below.

Section 201(a) of the Federal Property and Administrative Services Act (Federal Supply Service Drug Discount Program)

Under the Veterans Health Care Act (VHCA) of 1992, manufacturers must make their brand-name drugs available through the Federal Supply Service (FSS) to receive reimbursements for drugs covered by Medicaid. The Department of Veterans Affairs (VA), is responsible for administering the FSS pharmaceutical schedule by the General Services Administration (GSA). The VA negotiates

prices with drug manufacturers. Many FSS prices are less than 50 percent of the non-Federal average manufacturer prices. Indian tribes that have ISDA contracts with the IHS, are granted access to the FSS. This access is allowed because the ISDA deems tribal organizations having ISDA contracts with IHS as "executive agencies." With this designation, tribal organizations are eligible to obtain supplies and services, including drugs, from the FSS. Organizations eligible to use GSA sources of supply and services are covered by the provisions of the Federal Property and Administrative Services Act (FPASA) of 1949, as amended.

Section 603 of the Veterans Health Care Act (Prime Vendor)

Under Section 603 of the VHCA, manufacturers must make their drugs available to the four specified agencies, including the IHS, at no more than 76 percent of the non-Federal average manufacturer's price (many FSS prices are less than 50 percent of the non-Federal average price). The IHS supply centers purchase these drugs from the VA "prime vendor" at discount prices, i.e., the FSS. Historically, tribes could only access the prime vendor through the IHS procurement process. However, with the enactment of the Tribal Self-Governance Amendments of 2000, Public Law 106-260, tribes carrying out ISDA contracts are deemed an executive agency and part of the IHS. While the final decisions rests with the VA, tribes may now have authority to access the prime vendor directly rather than through the IHS procurement process, or they may continue to purchase discount drugs through the IHS procurement process which uses the prime vendor.

Section 602 of the Veterans Health Care Act (340B Drug Pricing Program)

In addition to accessing discount drugs from the FSS schedule, a tribe carrying out an ISDA contract or compact may purchase discount drugs under Section 602 of the VHCA. This Section of the VHCA enacted Section 340B of the PHSA, which is administered by the Office of Pharmacy Affairs (formerly the Office of Drug Pricing) in the Health Resources and Services Administration (HRSA), an agency within the HHS.

Section 340B of this law limits the cost of drugs to Federal purchasers and to certain grantees of Federal agencies. Significant savings on pharmaceuticals may be seen by participants in this program. Under the "340B program" a manufacturer that sells covered outpatient drugs to eligible entities, including tribes with ISDA contracts or compacts, must agree to a discounted price determined by a statutory formula.

Specific eligibility information and frequently asked questions are available on the Office of Pharmacy Affairs web site at:

<http://www.hrsa.gov/odpp>

EXTENDING ELIGIBILITY FOR SERVICES

Section 813 of the IHCIA (25 U.S.C. 1680c) provides the circumstances under which the IHS or a tribe may extend eligibility to otherwise ineligible individuals.

Section 1680c of the IHCIA states that a tribe must consider two criteria before extending eligibility to non-IHS beneficiaries. First, the "provision of such health services will not result in a denial or diminution of health services to eligible Indians." [25 U.S.C. 1680c (b) (1) (A) (ii) (I)] Second, "there is no reasonable alternative health facility or services..available to meet the health needs of such individuals." [25 U.S.C. 1680c (b) (1) (A) (ii) (I)] (Upon request by a tribe, the IHS is authorized to provide health services to individuals who are not eligible for such health services, if IHS and the tribe jointly make two determinations.)

Under the IHCIA, eligibility may be extended to non-IHS beneficiaries only when a determination has been made according to the statutory criteria. There are circumstances, particularly in rural areas, where there is no reasonable alternative health facility and where the provision of health services to non-IHS beneficiaries will not result in decreasing services to eligible beneficiaries. However, in most areas, there are reasonable alternative health facilities. If the two statutory criteria are not met and the tribe extends eligibility to non-IHS beneficiaries, it may be operating "outsidewthe scope of its ISDA contract or compact. In such a case, the tribe may be exposed to legal and financial ramifications.

INTERRELATIONSHIP BETWEEN THE PURCHASE OF DISCOUNT DRUGS AND EXTENSION OF ELIGIBILITY

This portion of the letter describes the interrelationship between the purchase of discounted drugs and the extension of eligibility under Section 813 of the IHCIA.

For purposes of Section 201(a) of the FPASA, a tribe is deemed part of the IHS when carrying out its ISDA contract or compact. Therefore, any determination to extend eligibility for pharmacy services to non-IHS beneficiaries involves the IHS. The determination required by Section 1680c must be made by both the tribe and the IHS. If a tribe desires to extend eligibility for pharmacy services to non-IHS individuals, the IHS and the tribe must jointly make the determination that providing such services would not result in a denial or decreased services to eligible Indians and that there are no reasonable alternative pharmacy services available to meet the needs of such individuals. [25 U.S.C. 1680(b)(1)(A)] Without a joint determination, a tribe may not access Federal discount drug programs to serve such individuals under its contract or compact.

Legislative history indicates that tribes may not provide pharmacy services to non-Indian tribal employees. In reviewing the legislative history of the ISDA, it is clear that the Congress intended the amendment to Section 450j(k) to authorized the purchase of prescription drugs at Federal discounts by tribal contractors and compactors only for IHS beneficiaries served under the tribe's contract or compact. Tribes may not purchase drugs under Federal discount programs for resale to non-IHS eligibles or dispense drugs purchased through Federal discount programs to non-Indian employees of the tribe.

Office of the Inspector General Report on Pharmacy Programs under Indian Self-Determination Act Contracts and Compacts

The OIG recommended that all ISDA contracts, compacts, and funding agreements (FA) be reviewed. In an October 31, 2000, memorandum to Area Directors, I asked them to identify FA that contain language extending pharmacy benefits inappropriately to non-IHS eligibles.

There are circumstances, particularly in rural areas, where there is no reasonable alternative health facility and where the provision of health services to non-IHS beneficiaries will not result in decreased services to eligible beneficiaries. However, in most areas, there are reasonable alternative health facilities. Without a joint determination by the IHS and the tribe, if the two statutory criteria in Section 813 are not met and the tribe extends eligibility to non-IHS beneficiaries, it may be operating "outside" the scope of its ISDA contract or compact. In such a case, the tribe should be aware that it may be exposed to legal and financial ramifications.

If a contract, compact, or FA contains unauthorized language, I have asked the Area Director to negotiate with the tribe to remove the unauthorized language.

If you have any questions regarding the above, please contact your Area Director.

Sincerely yours,

/Michael H. Trujillo/

Michael H. Trujillo, M.D., M.P.H., M.S.
Assistant Surgeon General Director