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COUNTY OF SACRAMENTO
OFFICE OF THE COUNTY COUNSEL
Inter-Department Correspondence

COPY

June 17, 2005

To: Geoff Davey
County Executive Office

Bill Kelly, Chief Deputy
Sheriff's Department

From: Michele Bach
Supervising Deputy

Subject: Participation In Federal 340B Pharmacy Discount Program

You have inquired as to whether discounted drugs under the Federal 340B Pharmacy Discount Program ("340B Program") may be provided to patients of Correctional Health Services, Juvenile Medical Services and the Mental Health Treatment Center. It is this Office's opinion that the County's historic practice of dispensing 340B Program drugs to patients of Correctional Health Services, the Mental Health Treatment Center and Juvenile Medical Services is legally prohibited.

DISCUSSION

1. Legal Authority for 340B Program Pharmacy Discount Program

In 1992, Section 340B of the Public Health Service (PHS) Act was enacted. 42 USC §256b. It requires pharmaceutical manufacturers whose drugs are covered by the Medicaid program to enter into an agreement with the secretary of Health and Human Services by which the manufacturers are obligated to comply with the terms of Section 340B. 42 USC §256b(a)(1). Under the 340B Program participation agreement, a manufacturer is required to provide discounts on covered drugs¹ purchased by specified PHS and government-supported facilities, i.e., "covered entities." Manufacturers are prohibited from charging more than the 340B Program ceiling price. Thus, the 340B

¹ Only outpatient or over the counter drugs are subject to the Section 340B discount. 42 USC §256b(a)(2). An outpatient drug includes most drugs and biologicals which may be dispensed only by prescription and which require approval by the Food and Drug Administration or a license under the PHS Act. A covered outpatient drug excludes certain settings (e.g. such services as emergency room, hospice, dental, physician, nursing facilities, x-ray, lab and renal dialysis) in some instances. 42 USC §1396r-8(k)(2). An over the counter drug means a drug that may be sold without a prescription and which is prescribed by a physician or other person authorized to prescribe such drug under state law. 42 USC §256b(a)(2)(B)(ii).

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Program price is the highest price that a covered entity would have to pay for select outpatient and over-the-counter drugs.

Eligibility for 340B Program pricing generally hinges on federal funding. Only "covered entities" are entitled to receive the discounted drugs. Eligible entities include specified Public Health Services grantees, including federally qualified health centers (FQHCs),² state operated AIDS drug assistance programs, the Ryan White CARE Act Title 1, Title 11 and Title III programs, tuberculosis, black lung, family planning, and sexually transmitted disease clinics, hemophilia treatment centers, public housing primary care clinics, homeless clinics, urban Indian clinics and Native Hawaiian health centers. 42 USC §256b(a)(4). Eligible entities also include FQHC "look alike"³ and disproportionate share hospitals if they carry out a state or local government health care program, have a disproportionate share adjustment percentage greater than 11.75 percent and do not belong to a group purchasing organization for outpatient drugs. 42 USC §1886(d)(1)(B).

Prior to 1996, community health centers, migrant/seasonal farm worker health centers, health care for the homeless health center and health centers for residents of public housing were funded under different grant structures. However, the Health Center Consolidation Act of 1996 brought all of those entities under one grant structure. These programs are now referred to as "PHS 330 funded programs." 42 USC § 254b. Individually identified grant funded programs are now designated as a Consolidated Health Center.

A covered entity may provide discounted drugs only to its patients. Resale or transfer of a 340B Program drug to a person who is not a patient of the covered entity is called diversion and is specifically prohibited. 42 USC §256b(a)(5)(B).

An individual is a "patient" of a covered entity only if 1) the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and 2) the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity; and 3) the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or FQHC look-alike status has been provided to the entity. 61 Fed. Reg. 55156. Disproportionate share hospitals are exempt from this requirement. *Id.* Thus, a

² An FQHC is defined in 42 USC §1396d(l)(2)(B) as an entity that receives certain specified grant funding or meets the requirements for receiving such grant funding.

³ FQHC look-alike status is available to those health centers that do not receive Section 330 funding, but operate and provide services similar to grant-funded programs. 63 Fed. Reg. 56656-02. In part, FQHC look-alike designation requires that the entity serve a federally-designated Medically Underserved Area or Medically Underserved Population as well as meet the statutory, regulatory and program requirements for grantees supported under Section 330 of the PHS Act.

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covered entity may provide 340B Program drugs to patients of the entity, and the types of drugs purchased must be consistent with the scope of the grant funded services.

An individual is not considered a patient of the entity for purposes of Section 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting. *Id.*

If individuals other than patients of the covered entity obtain covered outpatient drugs from the covered entity's pharmacy, the entity must develop and institute adequate safeguards to prevent transfer of discounted outpatient drugs to individuals who are not eligible for the discount (e.g., separate purchasing accounts and dispensing records). 59 Fed.Reg. 25110. A larger institution that contains an eligible entity within its structure is required to establish separate purchasing accounts and maintain separate dispensing records for the eligible entity. *Id.* Finally, the covered entity is prohibited from using the covered outpatient drug in excluded services (e.g., inpatient services). If an entity offers services excluded from the drug discount program, it must develop a separate method for purchasing and dispensing drugs for excluded services. *Id.*

Section 340B also provides that a drug purchased through the Section 340B Program shall not be subject to both a 340B Program discount and a Medicaid rebate. 42 USC §256b(a)(5)(A). This restriction is intended to protect manufacturers from giving duplicate discounts on the same drug, i.e., a 340B Program discount at time of purchase, plus a Medicaid rebate paid to the state after the drug is billed to Medicaid.

2. Analysis

You have advised that DHHS has been designated as a Consolidated Health Center based on its receipt of grant funding for Health Care for the Homeless. In addition, the County has been designated as a covered entity for the Ryan-White AIDS drug program, STD and TB care.

For many years, DHHS has apparently passed its 340B Program drug discounts through to Correctional Health, the Mental Health Treatment Center and Juvenile Medical Services. This Office does not know whether DHHS has utilized 340B Program drugs for patients in any other programs that it directly operates besides those for which it has received grant funding. With respect to Correctional Health, the discontinuance of 340B Program discounted drugs could result in approximately a \$1.5 million cost increase. The cost increases to the Mental Health Center and Juvenile Medical Services are unknown.

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Under the Guidelines enacted by the Health Resources and Services Administration (HRSA), Department of Health and Human Services, it is clear that a designation as a covered entity is related exclusively to a programmatic/funding determination, rather than to the legal status of the entity. With the exception of disproportionate share hospitals and FQHC look-alikes, covered entity status is dependent upon the receipt of PHS Act Section 330 funding.

In addition, a covered entity is limited to dispensing drugs purchased through the 340B Program only for patients of the covered entity.⁴ A covered entity is expressly prohibited from reselling or transferring the discounted drug to a person who is not a patient of the entity. 42 USC §256b. Guidelines implemented by the Pharmacy Affairs Branch of the HRSA clarify this issue by specifying that an individual is a patient of the covered entity if 1) the covered entity has an established relationship with the individual; 2) the individual receives health care services from a health care profession who is either directly employed by the covered entity or who provides health care under contractual or other arrangements such that the individual's care remains the responsibility of the covered entity; and 3) the individual receives a health care service or range of services for which grant funding or FQHC look-alike status has been provided. 61 Fed.Reg. 55156, 5517-58.

Thus, 340B Program drugs may be dispensed only consistent with the scope of the grant funded services. Those drugs may be dispensed only for the individuals who receive health care services for which the grant funding or FQHC look-alike status has been provided. This conclusion is further supported by the promulgated guidelines which recognize that a covered entity may provide services to patients who are not otherwise eligible for the discounted drugs. In such circumstances, the guidelines require that the entity develop and institute safeguards to prevent transfer of discounted drugs to non-eligible individuals. 59 Fed. Reg. 25110. Accordingly, drugs purchased through the 340B Program cannot be diverted to non-patients of the covered entity, to ineligible entities within the same facility or to excluded services of the covered entity.

Based on the information provided, the County's historic practice of dispensing 340B Program drugs to patients of Correctional Health Services, the Mental Health Treatment Center and Juvenile Medical Services is not consistent with the prohibition against transfer of such drugs to anyone other than a patient of the covered entity. While DHHS may be a covered entity, it has been so designated only with respect to the services for which it receives grant funding for Health Care for the Homeless, Ryan-White AIDS drug program, STD and TB funding. Individuals who receive health care for other purposes or through other programs do not constitute "patients" of the covered entity.

⁴ Eligibility to access Section 340B Program drugs is not contingent upon purchasing such drugs with federal grant funds. A covered entity may use any revenues or funds available to it to produce Section 340B Program drugs. 63 Fed. Reg. 56656; see H.R. Rep. No. 102-384, 102d Cong., 2d Sess. Pt. 2 at 16 (1992).

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If you have any questions, please feel free to contact me.


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