

ensure that drugs purchased under the 340B Drug Pricing Program are not diverted to individuals who are not patients of the covered entity. Such records can include: prescription files, velocity reports, and records of ordering and receipt. These records will be maintained for the period of time required by State law and regulations.”

(3) “Prior to the contract pharmacy providing pharmacy services pursuant to this agreement, the covered entity will have the opportunity, upon reasonable notice and during business hours, to examine the tracking system. For example, such a tracking system may include quarterly sample comparisons of eligible patient prescriptions to the dispensing records and a six (6) month comparison of 340B drug purchasing and dispensing records as is routinely done in other reconciliation procedures. The contract pharmacy will permit the covered entity or its duly authorized representatives to have reasonable access to contract pharmacy’s facilities and records during the term of this agreement in order to make periodic checks regarding the efficacy of such tracking systems. The contract pharmacy agrees to make any and all adjustments to the tracking system which the covered entity advises are reasonably necessary to prevent diversion of covered drugs to individuals who are not patients of the covered entity.”

(4) “The pharmacy will dispense covered drugs only in the following circumstances: (a) Upon presentation of a prescription bearing the covered entity’s name, the eligible patient’s name, a designation that the patient is an eligible patient of the covered entity, and the signature of a legally qualified health care provider affiliated with the covered entity; or (b) receipt of a prescription ordered by telephone or other means of electronic transmission that is permitted by State or local law on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient. The covered entity will furnish a list to the pharmacy of all such qualified health care providers and will update the list of providers to reflect any changes. If a contract pharmacy is found to have violated the drug diversion prohibition, the contract pharmacy will pay the covered entity the amount of the discount in question so that the covered entity can reimburse the manufacturer.”

Dated: December 22, 2006.

Elizabeth M. Duke,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of “Patient”

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: Section 602 of Public Law 102-585, the “Veterans Health Care Act of 1992,” enacted Section 340B of the Public Health Service (PHS) Act “Limitation on Prices of Drugs Purchased by Covered Entities.” Section 340B provides that in order to obtain Medicaid reimbursement for its covered outpatient drugs, a manufacturer must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price to covered entities for outpatient drugs that will not exceed an amount determined under a statutory formula. Section 340B is administered as the “340B Drug Pricing Program” and is commonly referred to as “the 340B Program.”

Section 340B states that it is illegal for covered entities to sell medications purchased under the 340B Program to persons who are not considered “patients” of the covered entity. The purpose of this notice is to inform interested parties of proposed clarifications to the definition of “patient” for whom the covered entity can purchase discounted pharmaceuticals under the 340B Program. This clarification is necessary to protect the integrity of the 340B Program and to assist covered entities and other participants in their compliance efforts.

DATES: The public is invited to submit comments on the proposed guidelines by March 13, 2007. After consideration of the comments submitted, the Secretary will issue final guidelines.

ADDRESSES: Address all comments to Mr. Bradford R. Lang, Public Health Analyst, Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Parklawn Building, Room 10C-03, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mr. Jimmy Mitchell, Director, OPA, HSB, HRSA, 5600 Fishers Lane, Parklawn Building, Room 10C-03, Rockville, MD 20857, or by telephone through the Pharmacy Services Support Center at 1-800-628-6297.

SUPPLEMENTARY INFORMATION:

Introduction

Section 340B(a)(4) of the PHS Act and section 1927(a) of the Social Security Act list the various types of organizations eligible to participate in and purchase discounted drugs under the 340B Program. Eligibility for participation in the 340B Program is strictly limited to the specific categories of entities specified in these statutes.

Section 340B(a)(5)(B) of the PHS Act prohibits entities from selling (or otherwise transferring) drugs purchased under the 340B Program to anyone who is not a patient of the covered entity. Responsibility for ensuring compliance with this provision rests with the covered entity. Congress did not define the term “patient” in Section 340B, and initial HRSA guidelines implementing the 340B Program directed covered entities to “develop and institute adequate safeguards to prevent the transfer of discounted outpatient drugs to individuals who are not eligible for the discount” in order to prevent diversion. To accomplish this, entities were encouraged to utilize a separate purchasing account and separate dispensing records (See 59 FR 25110).

As covered entities, manufacturers, and others began to implement the 340B Program, it became apparent that additional clarification of the patient definition was needed and on October 24, 1996, HRSA issued additional guidelines regarding the definition of a covered entity “patient” (61 FR 55156). These guidelines stated that the following definition of patient would apply for the purposes of the 340B Program:

An individual is a “patient” of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) 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 Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

An individual will not be considered a "patient" of the entity for purposes of 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.

An individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under Title XXVI of the PHS Act will be considered a "patient" of the covered entity for purposes of this definition if so registered as eligible by the State program. (61 FR 55157-8).

The definition of a "patient" was developed in order to identify those individuals eligible to receive 340B drugs from covered entities. Because of the large number of covered entities and the wide diversity of eligible groups (e.g., comprehensive hemophilia treatment centers, HIV/AIDS programs funded through the Ryan White CARE Act, black lung clinics, consolidated health centers, Disproportionate Share Hospitals (DSH), and Title X clinics), it was essential that HRSA work closely with each Federal program office to develop a definition flexible enough to describe accurately each covered entity's patients.

As of October 1, 2005, participation in the 340B Program has grown to more than 12,000 entities. Through covered entity networking, contracting, and other arrangements, additional questions about the definition of a 340B patient have arisen. HRSA believes that the existing patient definition provides sufficient guidance to answer many of these questions. However, it is possible that some 340B covered entities may have interpreted the definition too broadly, resulting in the potential for diversion of medications purchased under the 340B Program. Therefore, HRSA finds it necessary to issue this Notice, and to include several examples that further illustrate the guidance. While similar to the existing patient definition, this clarification provides covered entities with more explicit guidance regarding the relationship between a covered entity and an individual that makes that individual a "patient" of the covered entity.

Related to the definition of a "patient" is the question of which entities are eligible to provide 340B drugs. HRSA has been receiving an increasing number of questions specifically related to which entities qualify for inclusion in the 340B Program under Section 340B(a)(4)(L) of

the PHS Act. HRSA invites comments with respect to which elements should be required in private non-profit hospitals' contracts with State or local governments "to provide health care services to low income individuals who are not entitled to benefits under Title XVIII of the Social Security Act or eligible for assistance under the State plan * * *" under Section 340B(a)(4)(L)(i) of the PHS Act. HRSA is also seeking comments regarding the different situations where private, non-profit hospitals are formally granted government powers under Section 340B(a)(4)(L)(i) of the PHS Act.

Final guidelines will replace all previous 340B Program guidance addressing the definition of a patient, including, but not limited to, the "Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility," 61 FR 55156 and any individual correspondence issued by HRSA on the subject.

Definition of a Patient

Under these proposed guidelines, the criteria determining whether an individual is a "patient" of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) are:

1. The covered entity has established responsibility for the outpatient health care services it provides to the individual, such that the covered entity maintains ownership, control, maintenance, and possession of records of the individual's health care, including records that appropriately document health care services that result in the use of, or prescription for, 340B drugs;

2. The individual receives outpatient health care services that result in the use of, or a prescription for, 340B drugs as part of the diagnosis and treatment from a health care provider who is employed by the covered entity, or provides health care to patients of the covered entity under a valid, binding, and enforceable contract. If the individual received health care services from a health care provider employed by or under contract with the covered entity, then the individual may be referred for followup care for the same condition by that health care provider, to an outside health care provider and still remain a patient of the covered entity for purposes of this guidance, so long as ongoing responsibility for the outpatient health care service that results in the use of (or prescription for) 340B drugs, remains with the covered entity; and

3. The outpatient health care services the individual receives from the covered entity that result in the use of, or prescription for, 340B drugs are:

- a. Part of a health care service or range of services for which grant funding or Federally-Qualified Health Center look-alike status has been provided to the covered entity; or

- b. Provided by a Disproportionate Share Hospital (DSH) or by a location that qualified as a provider-based facility within a DSH under 42 CFR 413.65. If the individual received care from such DSH or qualifying provider-based facility, then the individual may be referred for followup care for the same condition by such a health care provider to an outside health care provider and still remain a patient of the covered entity for purposes of this rule, so long as the covered entity (either the DSH or a qualified provider-based facility) retains ongoing responsibility for the outpatient health care service that results in the use of (or prescription for) 340B drugs. To demonstrate the necessary retention of ongoing responsibility for the health care it is expected that, at a minimum, the covered entity will provide health care to the individual in the DSH or the qualified provider-based facility of the DSH within 12 months after the time of referral.

The individual's health care relationship with the covered entity is the most important factor in determining whether an individual satisfies the criteria above. For a prescription to qualify under 340B, the covered entity must be primarily responsible for the health care which results in the use of, or prescription for 340B drugs. An individual will not be considered a "patient" of the entity for purposes of 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. An individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under Title XXVI of the PHS Act will be considered a "patient" of the covered entity for purposes of this definition if so registered as eligible by the State program.

The first criterion of the patient definition above requires covered entities to establish a relationship with each individual such that the covered entity maintains records of the individual's health care. The covered entity will document in the individual's health care records the health care service provided and the drugs

prescribed or used in the covered entity for this individual. A shared electronic record where several parties have access and ability to add/edit the records from their physical location would satisfy the requirements of the 340B Program guidelines, as long as the covered entity maintains control, ownership, maintenance, and possession of the individual's health care record. Mere contractual right to obtain records from a health care provider, without actual control and maintenance of the record, would not satisfy the requirements of the 340B Program.

The second criterion of the patient definition requires that the responsibility for the health care services that result in the use of, or prescription for, 340B drugs remains with the covered entity. Where a referral is utilized for specialty health care, in order to result in a valid 340B prescription, the referral must be for followup care for the same condition and must originate from a health care provider who is employed by or under a valid, binding, and enforceable contract with the covered entity which retains ongoing responsibility for the health care and treatment of the individual.

For the purpose of this guidance, the provision of administrative services alone, such as case management services from someone other than a health care provider, is not sufficient to demonstrate the necessary health care services set forth in the definition above. The statute requires that 340B drugs be provided for the patients of the covered entity, as opposed to offering other services to individuals who are patients of health care providers who are not part of a covered entity as defined in the statute. In cases where an individual has received health care services from a non-covered entity resulting in a prescription, the administrative act of recording such information, incorporating it into the health record, and filling the prescription does not constitute health care services for the patient's health care for purposes of the 340B Program.

To demonstrate responsibility for the health care that results in the use of, or prescription for 340B drugs, health care must be provided by the covered entity through health care providers who meet the second criterion and who have the capacity and authority to issue the 340B prescription. Mere acceptance *pro forma* or rubberstamping of an outside health care provider's diagnosis or medical opinion does not demonstrate such responsibility. While the health care providers of the covered entity can take into account the diagnosis and

prescription of other health care providers, they must exercise their own judgment in taking responsibility for their own patients.

The third criterion of the patient definition above requires that 340B drugs be prescribed only in conjunction with outpatient services. Furthermore, subsection (a) clarifies that the provision of 340B drugs must fall within the scope of the grant funding or Federally Qualified Health Center look-alike status which forms the basis for the eligibility of the covered entity to participate in the 340B Program.

Subsection (b) of the third criterion likewise provides clarification for DSHs that the use of, or prescription for, 340B drugs must be within the scope of the basis for including such institutions in the 340B Program. In order for an outpatient facility of a DSH to be eligible for the 340B Program, it must be demonstrated that the outpatient facility is an integral part of the DSH. HRSA has chosen to rely on the category of provider-based facilities as set forth by the Centers for Medicare and Medicaid Services (CMS) under Title XVIII of the Social Security Act (Medicare). This decision has been made because HRSA believes that the requisite integration of facilities necessary to demonstrate that the secondary facility is functioning as part of the DSH under 42 CFR 413.65 is appropriate for facilities eligible under the 340B Program. Compliance with the rule for provider-based facilities would provide clear guidance to DSHs that wish to prescribe 340B drugs to patients at these outpatient facilities and ensure that the individuals are truly patients of the DSH. Ultimately the facility's provider-based status must be reflected in the covered entity's Medicare Cost Report. The covered entity may provide a copy of the attestation provided to its fiscal intermediary pursuant to 42 CFR 413.65 to demonstrate compliance with this guideline until such time as the facility is listed on the DSH's Medicare Cost Report. The DSH shall retain the responsibility to promptly notify the OPA in the event that the outpatient facility's provider-based status is rejected or otherwise called into question.

Examples

The following examples describe the issues that HRSA has identified as problematic and the relationships that do not meet the definition of "patient" for purposes of compliance with the 340B Program guidelines.

Example 1: Certain Case Management Constructs

HRSA has become aware that some covered entities may be using case management arrangements that inappropriately expand their "patient" populations, diverting 340B drugs to individuals who are not eligible patients of the 340B covered entity. In some cases, the covered entities claim to provide the requisite "health care services" through a third party that operates through a case management construct or call center. Although the covered entity may retain records of the encounters, supervise personnel, oversee billing, payment, and other administrative tasks in the program, the covered entity is not providing the actual outpatient health care services that can be linked to the prescriptions written for the individuals in question.

An individual whose sole relationship with a covered entity is through case management services or other administrative measures, not accompanied by actual medical services from a health care provider that meets criterion 2, would not be considered a patient of the covered entity eligible to receive 340B drugs.

Example 2: Loose Affiliation Networks

Some DSHs have been contracting with health care providers to create a loose affiliation model for outpatient health care services. The individuals, receiving services from affiliated health care providers, have been filling prescriptions written by these health care providers with 340B drugs. The "contracts" are often simple, one-page documents that do not create contractually enforceable duties or obligations for either the health care provider or covered entity. These affiliation models claim to meet the patient definition by specifying that the individual's health care records would be available at the covered entity, that "responsibility for the patient" would also reside with the covered entity, and that in some instances, individuals would be seen by a case manager at the covered entity at specified intervals.

Under this model, the services being provided directly by the covered entity are often more appropriately characterized as administrative services rather than health care services. Ultimately, the treatment plan followed is determined by the affiliated health care provider and not the covered entity. The ongoing responsibility for the individual's health care resides with the affiliated health care provider and not the covered entity. The individuals enrolled in these programs are treated

by health care providers too loosely affiliated with the covered entity for the ongoing responsibility to rest with the covered entity for the patient's health care resulting in the use of, or prescription for, 340B drugs.

This model improperly seeks to expand the definition of a patient beyond that envisioned by Congress in prohibiting the resale of 340B drugs outside the eligible covered entity limits. In particular, HRSA is concerned that the affiliation model extends the ability of covered entities to purchase 340B drugs for individuals who are not receiving healthcare from a health care provider employed by or having a valid, binding, and enforceable contract with the covered entity. In the DSH context, since such affiliated healthcare providers may have privileges without actually being required to provide health care services at the DSH, HRSA believes that it is reasonable to require that either the prescribing, or the referring, health care provider be employed by or have a valid, binding, and enforceable contract with the covered entity to provide outpatient medical care to patients of the DSH.

Example 3: Provider-Based Designations

HRSA is concerned that a number of DSHs may be attempting to expand their eligible facilities to include locations that are not integrated parts of the qualifying DSH. As noted above, HRSA has chosen to rely on a location's status as a provider-based facility as provided under 42 CFR 413.65 to demonstrate that the secondary facility is functioning as part of the DSH. While HRSA is aware of the 35 mile distance exemption that exists for certain 340B-DSHs under 42 CFR 413.65(e)(3)(i), these DSH provider-based facilities remain subject to the other requirements as set forth in 42 CFR 413.65. This requirement also applies to nursing home facilities, rehabilitation hospitals, hospice, and home health agencies. Please note that even if these facilities qualify as part of the DSH, only patients receiving outpatient health care services in these facilities would be eligible to receive 340B drugs. In addition, if HRSA suspects that these entities are being improperly designated as provider-based facilities, HRSA will decline to add the facilities to the HRSA 340B database of covered entities until it has received portions of the Medicare Cost Report demonstrating provider-based status and/or the attestation of provider-based status the covered entity provides to its fiscal intermediary pursuant to 42 CFR 413.65. Likewise, if HRSA discovers that certain covered entities may have improperly listed facilities on

the 340B database with the implication that they are provider-based, HRSA will request the covered entity to provide the relevant portions of the Medicare Cost Report and/or attestation within 45 days to verify the facility's provider-based status and to verify that such health care services are being provided on an outpatient basis. If HRSA does not receive appropriate documentation to verify provider-based status within this time period, it will remove the facility from the 340B covered entity database. The covered entity shall be required to notify HRSA immediately if its provider-based status has been rejected or questioned by CMS or its fiscal intermediary. In cases where provider-based status has been rejected, the facility will be removed from the 340B covered entity database immediately.

Example 4: Employees

HRSA receives many questions about whether employees of a covered entity are "patients" for purposes of the 340B Program. These questions come from covered entities that provide health care coverage to employees under their own self-insured health plan, and those whose employees have third party health coverage as an employment benefit. Employees of a covered entity, regardless of their health care coverage, are not considered patients of the covered entity for the purpose of the 340B Program unless they receive health care from a provider employed by or under contract with the covered entity. The fact that the person is an employee of the covered entity, or that they receive health care benefits from their covered entity-employer is not relevant. The relevant circumstance is that the employee is a patient of the covered entity. If an employee is a patient of another provider in the community, and is referred to and receives health care from the covered entity, they can receive 340B drugs only if the other provisions of the patient definition are met. Where a covered entity operates a self-insured health plan, the covered entity retains the requisite responsibility for the individual as a patient only if the individual receives outpatient health care services under the terms of this notice. Responsibility for the patient does not extend to cover the individual if the covered entity's sole responsibility for the individual is as the administrator of its self-insured plan. Meeting administrative requirements for maintaining employee health records so as to ensure that the employees are compliant with both State and Federal health care provider regulations alone, is not sufficient for the purpose of establishing patient eligibility for the

340B Program. Rather, the covered entity must provide health care to these individuals that results in the use of, or prescription for, 340B drugs.

Furthermore, employees who merely receive required health physicals as a condition of their employment by a covered entity with no other health care provided are not patients of the covered entity.

Example 5: Indian Tribes and Tribal Organizations

In the case of Indian tribes or tribal organizations, any attempt to serve non-Indian Health Service beneficiaries must receive prior formal approval by the Indian Health Service.

Example 6: Grantee Subgrantees and Subcontractors

In certain circumstances, organizations may be functioning as subgrantees to grantees who are eligible to purchase 340B drugs (section 340B(a)(4) of the PHS Act). In these situations, subgrantees are reminded that they must meet the standards set forth in 45 CFR Part 74 and 45 CFR Part 92, as applicable. As subgrantees of a covered entity's grant, these organizations are eligible to access 340B drugs for only those patients to whom they are providing health care services under the scope of their subgrant. In these instances, individuals may only receive 340B drugs for the pharmaceuticals utilized under the scope of the project for which grant funds were received by the subgrantee. Subgrantees must register with HRSA in order to participate in the 340B Program and must be listed in the HRSA 340B database of covered entities to purchase 340B drugs.

Subgrantees must maintain information systems that permit them to segregate the 340B eligible patient population from the rest of their patients, and to order 340B drugs only for 340B eligible patients.

If an entity is a subcontractor of a covered entity, rather than a subgrantee, all 340B drugs must be purchased by the covered entity. The covered entity, in turn, must maintain records documenting its purchase of 340B drugs for its subcontractors. Both the covered entity and the subcontractor would be responsible for ensuring the 340B drugs were ordered only for the portion of the subcontract which is within the scope of a covered entity's grant.

Dated: December 22, 2006.

Elizabeth M. Duke,
Administrator.

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