
Proposed Guidance: 340B Drug Discount Program

Introduction

On Friday, August 28, 2015, the Health Resources and Services Administration (HRSA) published the long-awaited proposed “omnibus” guidance for the 340B drug pricing program.¹ The proposed regulations address a number of issues that have arisen since the program’s creation in 1992 and will update guidance documents developed through the life of the program to help participants comply with the statute.

The 340B program allows a qualifying “covered entity” to purchase outpatient prescription drugs at discounted prices. These discounts are intended “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”²

The proposed guidance includes a discussion of the types of covered outpatient facilities; clarification of the definition of “patient”; new requirements for contract pharmacies; a modification to the prohibition against use of group purchasing organizations (GPOs); and a new “reasonable cause” standard for manufacturer audits of covered entities.

Guidance is an agency’s best current thinking on a topic. It is not legally binding; however, once finalized, it is intended to guide the actions and policies of 340B covered entities and drug manufacturers in complying with the statute.

Covered entities

As the number and type of covered entities have grown over the lifetime of the program, the proposed guidance addresses the criteria for determining the existence of a qualifying relationship between a hospital-covered entity (parent) and off-site outpatient facilities and clinics. The agency states that a “parent-child” relationship exists if the hospital-covered entity provides its most recently filed Medicare cost report that shows that:

¹ Federal Register Vol. 80, No. 167 pages 52300 – 52324 (<http://www.gpo.gov/fdsys/pkg/FR-2015-08-28/pdf/2015-21246.pdf>)

² H.R. Rep. No. 102-384(II), at 12 (1992)

- Each of the facilities or clinics is listed on a line of the cost report that is reimbursable under Medicare; and
- The services provided at each of the facilities or clinics have associated outpatient Medicare costs and charges.

Meeting these criteria will qualify the “child” facility or clinic to be listed on the public 340B database and allowed to purchase and use 340B drugs for eligible patients. The agency is soliciting public comment on alternative approaches to demonstrate the eligibility of a “child” clinic or facility.

Definition of Patient

HRSA is proposing an updated definition of “patient.” The proposed guidance increases the number of conditions from three to six that must be met for someone to be considered a patient of a 340B-covered entity and eligible for discounted drugs.

1. The individual receives a healthcare service at a facility or clinic site that is registered for the 340B Program and listed on the public 340B database.
2. The individual receives a healthcare service provided by a covered entity provider who is either employed by the covered entity or is an independent contractor for the covered entity, such that the covered entity may bill for services on behalf of the provider.
3. An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the services described in the previous point.
4. The individual's healthcare is consistent with the healthcare service or range of services designated in the federal grant, project, designation, or contract.
5. The individual's drug is ordered or prescribed pursuant to a healthcare service that is classified as outpatient.
6. The individual's patient records are accessible to the covered entity and demonstrate that the covered entity is responsible for care.

The covered entity must also maintain records that will show that all the criteria “were met for every prescription or order resulting in a 340B drug being dispensed or accumulated through a replenishment model.”

A patient whose drugs qualify for a discount must receive services from a provider who is employed by a 340B member organization or can bill for services on the provider's behalf. In other words, simply having privileges or credentials with a 340B hospital would no longer be “sufficient to demonstrate that an individual treated by that privileged provider is a patient of the covered entity for 340B program purposes.”

Further, an individual would not be considered a 340B provider's patient if their care were to be provided by another organization that “has an affiliation arrangement with the covered entity, even if the covered entity has access to the affiliated organization's records.” Additionally, a referral to a non-340B facility from a 340B covered entity would not qualify for the 340B price discount.

HRSA also explicitly addresses how employees receiving drugs are handled by a covered entity. The guidance states that all employees of covered providers must also meet the definition of a patient in order to receive 340B discounted drugs. HRSA asserts that in arrangements in which a covered provider contracts with prescribing healthcare professionals to provide care to employees, the provider is acting as an insurance provider, not a healthcare provider.

There are two exceptions under which patients who do not meet all six requirements may receive 340B drugs:

- A patient who is enrolled in the Ryan White HIV/AIDS Program is considered a covered patient (*no change from current policy*).
- In a declared public health emergency, the covered entity may request temporary alternate criteria for determining patient eligibility. For the duration of the public health emergency, the covered entity must maintain auditable records to identify patients meeting the alternate criteria and the drugs that were dispensed.

Contract Pharmacy Agreements

In 1996, HRSA issued guidance recognizing the use of contract pharmacy arrangements to dispense 340B drugs on behalf of a covered entity. Additional guidance was issued in 2010 permitting a covered entity to use multiple contract pharmacies to access 340B drug pricing. Since that time, contract pharmacies have grown significantly to over 15,000 locations across the nation. With this increased growth comes increased risk of diversion or duplicative discounts. As a result, HRSA is proposing the following:

- A covered entity must register every contract pharmacy used. HRSA states that groups or networks of covered entities may not register or contract for pharmacy services on behalf of their individual covered entity members. A “parent”-covered entity registering their contract pharmacies may indicate which “child” sites plan to use these pharmacies.
- The contract pharmacy may only provide 340B drugs to patients of the covered entity after the contract pharmacy is registered in the public 340B database. Additionally, the contract pharmacy may not dispense 340B drugs on behalf of a covered entity on or after the date that the contract pharmacy is terminated.

A recent survey by the Office of the Inspector General and HRSA's own audits have identified gaps in audits of contract pharmacies by covered entities. As such, HRSA is proposing additional audits and quarterly review requirements for covered entities. Covered entities are ultimately responsible for contract pharmacy compliance with the 340B program. If a contract pharmacy is found in violation of 340B program requirements, HRSA reserves the right to remove the contract pharmacy from the 340B program.

Changes to the GPO Prohibition

Current law prohibits disproportionate share hospitals, children's hospitals, and freestanding cancer hospitals from purchasing outpatient prescription drugs from GPOs. Instead, these providers may purchase drugs directly from manufacturers or wholesalers at the 340B price. These covered entities may buy their outpatient drugs through the 340B prime vendor program and purchase drugs for inpatients through a traditional GPO. In all cases, the covered entity is required to maintain separate billing systems for 340B outpatient versus inpatient drugs. That is because outpatient drugs purchased at the 340B price or inpatient drugs purchased through a GPO cease to be "inpatient" or "outpatient" once they are inventoried.

The proposed guidance clarifies the following three situations that would not violate this requirement:

- A covered entity may use a GPO to purchase outpatient drugs for an off-site outpatient facility that does not participate in the 340B program and is not listed in the 340B database. The off-site facility must use a separate purchasing account from the "parent" entity and must ensure that GPO-purchased drugs are never provided to outpatients of the hospital or other "child" sites enrolled in the 340B program.
- If the Medicare Recovery Audit Contractor or other third party insurer changes the status of an inpatient to outpatient, any GPO-sourced drugs administered or dispensed while the individual was an inpatient would not be considered in violation of the prohibition.
- A hospital or other covered entity may purchase through a GPO when they are unable to access a drug either at the 340B price or the wholesale acquisition cost (WAC), and the purchase is necessary to prevent disruptions in patient care. In these instances, the covered entity must provide the drug name and manufacturer, and document the circumstances under which the drug could not be purchased at the 340B price or WAC.

HRSA notes that manufacturers and covered entities often work together within 30 days to identify and correct errors in GPO purchasing, and encourages greater adoption of this practice.

Further, any violation of the GPO prohibition would not automatically result in exclusion from the 340B program if the covered entity is able to demonstrate that the violation was an isolated error.

Other Key Provisions

Termination

Under the proposed guidance, covered entities removed from the 340B program may re-enroll after satisfactorily demonstrating compliance with statutory requirements and, if necessary, repaying any affected manufacturers. HRSA is soliciting comment on the type of information necessary from a covered entity to demonstrate compliance with the 340B program that would permit re-enrollment.

“Reasonable Cause” standard for a manufacturer-triggered audit

Manufacturers may audit a covered entity if they believe the entity is in violation of statutory prohibitions against duplicate discounts and diversion of 340B. HRSA is proposing a new “reasonable cause” standard in which a manufacturer must document to the agency that a reasonable person could conclude, based on reliable evidence, that a covered entity, its child sites, or contract pharmacies have violated 340B program requirements.

Reasonable cause may include:

1. Significant changes in quantities of specific drugs ordered by a covered entity without adequate explanation,
2. Significant deviations from national averages of inpatient or outpatient use of certain drugs without adequate explanation, or
3. Evidence of duplicate discounts provided by manufacturer or state Medicaid agencies.

Before undertaking an audit, a manufacturer would be required to submit an audit work plan for HRSA approval. If HHS approves the work plan and audit, a covered entity must provide records pertaining to compliance of the covered entity, child sites, and any related contract pharmacy with the prohibition against duplicate discounts and diversion. Failure by the covered entity to submit this documentation within 30 days of the request would be considered a violation of the 340B program.

Maintenance of auditable records

A covered entity is required to maintain auditable records demonstrating compliance with all 340B program requirements for itself, any child sites, and any contract pharmacy for a period of

at least five years from when a drug was ordered or prescribed, regardless of whether or not the entity remains in the 340B program.

Next Steps

ASHP and our partners in the stakeholder community will remain engaged with HRSA as they develop their final guidance. It will be important for the agency and other parts of the federal government to have the input of ASHP and its membership as it considers the impact on patients and healthcare organizations of their final guidance.

Pharmacists and other appropriate individuals in covered entities should carefully review their current 340B compliance procedures in light of this new guidance to ensure that they are either compliant or can become compliant with the newly proposed requirements of the 340B program.

ASHP will submit comments to HRSA on this guidance and will continue to work closely with other organizational partners and coalitions throughout the process.

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