340B Drug Program

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Agenda

• 340B Basics
• Proposed Changes
• 340B Audits
340B Basics

- Created in 1992 to provide discounts on outpatient prescription drugs to select safety net providers.
- Intent: to permit Covered Entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.
- Covered Entities receive the benefit of purchasing certain covered drugs at a price that has been set based on a pharmaceutical pricing agreement between the Secretary of Health and Human Services and the drug manufacturer.
340B Basics

• Covered Entities
  • Certain types of hospitals
    • DSH (11.75%)
    • Free Standing Cancer Center (11.75%)
    • Children's Hospitals (11.75%)
    • Sole Community (8.00%)
    • Rural Referral (8.00%)
    • Critical Access Hospitals
  • Federally Qualified Health Centers
  • Ryan White HIV/AIDS Program Grantees
  • Other Specialty Clinics
  • As of January 1, 2015, there were 11,530 registered Covered Entities

340B Basics

• Covered Entities
  • Parent site
  • Child sites – must be listed on HRSA's website or cannot participate
• 340B Registration/Enrollment
  • Register January 1 – 15, Eligible April 1
  • Register April 1 – 15, Eligible July 1
  • Register July 1 – 15, Eligible October 1
  • Register October 1 – 15, Eligible January 1
• 340B Database
  • Continually updated
  • Cannot participate unless on the 340B Database
  • Wholesalers will not ship discounted drugs unless it is an EXACT match to the 340B Database
340B Basics

- Enrollment/Recertification
  - Covered Entities must register, be enrolled, and comply with all 340B Program requirements.
  - Once enrolled, Covered Entities are assigned a 340B Identification Number that vendors must verify before allowing an entity to purchase discounted drugs.
  - Covered Entity profile must remain current and accurate.
  - Authorizing Official verifies continued eligibility.
    - If there is turnover in the Authorizing Official position, it is imperative that HRSA is notified.

340B Basics

- Eligible Drugs
  - FDA approved drugs
  - OTC drugs on prescription
  - Biological products that can be dispensed only by prescription

- Covered Entity must maintain purchasing and dispensing records

- Replenishment inventory system/virtual inventory
340B Basics

- Eligible Patients
  1. Covered Entity has established a relationship with the individual, such that the Covered Entity maintains records of the individual's health care.
  2. Individual receives health care services from a health care professional who is employed by or contracted with the Covered Entity, such that responsibility for care provided remains with the Covered Entity.
  3. Individual receives health care services or range of services from the Covered Entity which are generally services provided by that Covered Entity. Hospitals are exempt from this third requirement.

- Eligible Providers
  - The Covered Entity must maintain a roster of eligible providers. This roster must be updated periodically.

- Contract Pharmacies
  - Covered Entities can contract with outside pharmacies to dispense 340B drugs.
  - Covered Entities pay the Contract Pharmacies a dispensing fee.
  - After records are processed notifying the Covered Entity that eligible 340B drugs have been dispensed, the Covered Entity will replenish those drugs (bill to/ship to arrangements).
340B Basics

- **340B Vendor Software**
  - Sometimes referred to as “switch” software
  - Brings all information together - an eligible patient had an eligible health care service provided by an eligible provider with a prescription for an eligible drug.
  - This “flips the switch” to notify a pharmacist (whether internal or a contract pharmacy) that a prescription is 340B eligible.
  - Often, the vendors will note that they are “taking care of compliance” but what they are referring to is the switch, which is a small portion of the compliance required by HRSA for the 340B Program.

340B Basics

- **Diversion**
  - 340B drug is provided to someone who is not an Eligible Patient
  - Jeopardizes 340B eligibility
- **Duplicate Discounts**
  - Relates to 340B discounts plus Medicaid rebate
  - Need to carve in or carve out Medicaid patients
  - HRSA maintains based on NPI
- **GPO Exclusion: DSH, Children’s Hospitals, Free Standing Cancer Center cannot use Group Purchase Organization for purchasing covered 340B drugs**
340B Basics

- A HRSA audit may result in a Corrective Action Plan (CAP).
  - These are published and available for review by any organization on the HRSA website.
  - One of the requirements of a CAP could be to repay the vendors (pharmaceutical companies) for any discounts the Covered Entity received it was not entitled to (i.e. duplicate discounts or diversion of drugs).
  - This can be a long, drawn out process as the Covered Entity needs to determine how much is owed to each vendor and contact each vendor to coordinate the reimbursement.

340B Basics

- Other possible elements of a CAP
  - Periodic assessment of compliance
  - Internal monitoring and audit process
  - Education
  - Development/improvement of policies and procedures
  - Update 340B inventory management system
  - Correct/update 340B database – child entities
  - Others
  - 340B requirements include self-disclosure of material breaches.
**340B Basics**

- When an eligible entity voluntarily decides to enroll and participate in the 340B Program, it accepts responsibility for ensuring compliance with all provisions of the 340B Program, including all associated costs.
- Covered Entities are subject to audits by the federal government (HRSA) or by manufacturers.
- Failure to comply with 340B Program requirements may result in refunds to manufacturers or removal from the 340B Program.
- Covered Entity will be audited for all 340B requirements.

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**Proposed Changes**
Proposed Changes

• Mega-Guidance or Mega-Regs
• Published in the Federal Register on 8/28/15
  • http://federalregister.gov/a/2015-21246
  • “340B Drug Pricing Program Omnibus Guidance
• The Department of Health and Human Services “is proposing this omnibus guidance to provide increased clarity in the marketplace for all 340B Program stakeholders and strengthen HHS’ ability to administer the 340B Program effectively.”

Proposed Changes

• Patient Definition
  1. The individual received a health care service at a facility or clinic site which is registered for the 340B Program and listed on the public 340B database.
     a. Covered Entity is medically responsible for the care provided to the individual
     b. The use of telemedicine involving the issuance of a prescription by the Covered Entity provider is permitted
     c. An individual will not be considered a patient of the Covered Entity if the individual’s health care is provided by another health care organization that has an affiliation agreement with the Covered Entity, even if the Covered Entity has access to the affiliated organization’s records.
Proposed Changes

• Patient Definition

2. The individual receives a health care service provided by a Covered Entity provider who is either employed by the Covered Entity or who is an independent contractor for the Covered Entity, such that the Covered Entity may bill for services on behalf of the provider.
   a. Simply having privileges or credentials at a Covered Entity is not sufficient to demonstrate that an individual treated by that provider is a patient of the Covered Entity for 340B purposes.
   b. If a patient is referred from the Covered Entity for care at an outside provider and receives and Rx from that provider, the drug in question would not be 340B eligible.

Proposed Changes

• Patient Definition

3. An individual receives a drug is ordered or prescribed by the Covered Entity provider as a result of the service described in 2) in the previous slide.
   a. An individual would not be considered a patient of a Covered Entity whose only relationship to the individual is the dispensing or infusion of a drug. The dispensing of or infusion of a drug along, without a Covered Entity provider-to-patient encounter, does not qualify an individual as a patient for purposes of the 340B Program. However, if the Covered Entity infuses a drug and meets all other criteria as defined, an individual may be classified as a patient for 340B purposes.
Proposed Changes

• Patient Definition

4. The individual’s health care is consistent with scope of the Federal grant, project, designation or contract.
   a. A Covered Entity registered as one of the hospital covered entity categories is not subject to this limitation.

Proposed Changes

• Patient Definition

5. The individual’s drug is ordered or prescribed pursuant to a health care service that is classified as outpatient.
   a. An individual cannot be considered a patient of the entity furnishing outpatient drugs if his or her care is classified as inpatient.
   b. Basically, the health care service needs to be billed at an outpatient service. In other words, prescriptions given at the end of an inpatient stay are not 340B eligible.
   c. Clarification – the 340B Program does not serve as a general employee pharmacy benefit. Employees of a Covered Entity do not become eligible to receive 340B drugs solely by being employees, but by being an eligible outpatient.
Proposed Changes

• Patient Definition
  6. The individual’s patient records are accessible to the Covered Entity and demonstrate that the Covered Entity is responsible for care.
    a. Records need to demonstrate that the Covered Entity has a patient-to-provider relationship for the health care service.
    b. Covered Entity retains responsibility for care that results in every 340B drug ordered, dispensed, or prescribed to that individual.

Proposed Changes

• Self-disclosure protocol has removed the “material breach” terminology. Confusion as to whether all breaches need to be disclosed as the Proposed Guidance offers procedures to work with vendors for rebates when isolated instances of diversion and/or duplicate discounts are identified.
340B Audits

- Two Types of External Audits
  - HRSA Audits
  - Manufacturer Audits
340B Audits

- Manufacturer Audits
  - Manufacturer is to notify the Covered Entity of potential issues prior to contacting HRSA.
  - If the Covered Entity does not respond, or fails to acknowledge the violation, the Manufacturer will request permission from the Office of Pharmacy Affairs (OPA) to conduct an audit.
  - Manufacturer Audits are limited to assessing incidents of diversion or duplicate discounts.

- HRSA Audits
  - Entities are selected for audits based upon random and targeted processes, with a greater number of random selections coming from groups at higher risk of noncompliance.
  - Additional funding has been appropriated to HRSA to expand the number of audits being conducted.
  - “It is not a question of ‘if’ a Covered Entity will be audited, but ‘when’ a Covered Entity will be audited.”
340B Audits

• Management
• Enrollment
• Policy and Procedures Manual
• Human Resources
• Audits
• Contracts
• Orientation and Training
• Inventory
• Patient Eligibility
• Providers
• Compliance

HRSA wants to ensure that management is involved in the 340B Program and has an overall understanding of how it works.
340B Audits

- Enrollment
  - HRSA will ensure that the facility (parent and child sites) are included in the HRSA 340B database.
  - Need to determine who verifies the enrollment and that enrollment is verified on an annual basis.
  - The documentation related to the enrollment and annual verification must be maintained.
  - Medicare cost report will also be reviewed, primarily for DSH percentage if applicable.
    - If a Covered Entity is eligible based on DSH percentage and falls below the required percentage, the Covered Entity will be ineligible at the date the Medicare cost report is filed which shows the DSH percentage below the required percentage.

340B Audits

- Policy and Procedure Manual
  - HRSA will ask for the Policy and Procedure Manual
  - Manual should address:
    - 340B eligibility requirements
    - Enrollment
    - Recertification
    - Procurement of 340B drugs
    - Dispensing 340B drugs
    - Determining eligible patients
    - Training and development of staff
    - Ongoing compliance
    - Reporting of missing medication
    - When was the manual last updated and approved
340B Audits

• Human Resources
  • The Covered Entity should have job descriptions that include specific language for the 340B Program for positions that work with it.
  • All job descriptions should be reviewed annually and there should be evidence of that review.

340B Audits

• Audits
  • HRSA will inquire as to whether the Covered Entity conducts internal audits and what audit template is followed, if any.
  • HRSA will also inquire as to whether the Covered Entity is auditing the Contract Pharmacies.
  • There should be documentation of any audits conducted, whether completed internally or by a third party.
340B Audits

• Contracts
  • The Covered Entity must have a listing of all Contract Pharmacies and should be using a standard contract template. The template should include the 12 elements of compliance as defined by HRSA.
  • Contracts should include provisions for preventing duplicate discounts and diversion of drugs.
  • Contracts should also include provisions on documenting transactions and auditing requirements.
  • Determination of who signs contracts and when, contract reviews (at least annually), where are the contracts stored, etc.
  • The Covered Entity should evaluate Contract Pharmacies.

340B Audits

• Orientation and Training
  • HRSA will inquire as to whether there is an orientation program for the 340B Program and what type of form the training takes (formalized or one-on-one).
  • Determination of who conducts the 340B Program training and the trainer’s credentials.
  • Determination of the when the training occurs (upon employment and annually).
  • Determination of how changes in the 340B Program are communicated to staff.
  • Documentation of training conducted.
340B Audits

- Inventory
  - HRSA will review the 340B drug log and determine how drugs are received and inventoried.
  - Covered Entities need to ensure that 340B drugs are separated from non-340B drugs.
  - HRSA will inquire as to how often 340B drugs are inventoried and whether the Covered Entity can produce a current inventory of 340B drugs.
  - The Covered Entity should maintain a listing of 340B drug purchase orders, drug orders, and prescriptions.
  - Determination of purchasing, storing, dispensing and billing orphan drugs.
  - Replenishment system, inventory system, virtual inventory system.

- Patient Eligibility
  - Determination of how the Covered Entity enrolls patients into the 340B Program.
  - Determination of how eligible patients are identified for the 340B Program.
  - Determination of the method for admitting and discharging patients in and out of the 340B Program.
  - Determination of identification of inpatients versus outpatients of the Covered Entity.
  - Determination of the dates of service for the 340B patient.
  - Process for how a patient registers for a 340B prescription, how the medication is dispensed, how the patient is charged and billed, and how the medication is restocked.
340B Audits

• Providers
  • Determination of how providers are enrolled in the 340B Program.
  • The Covered Entity should provide a roster of providers eligible to write prescriptions for eligible drugs.
  • Determination of how often the provider roster is updated.

340B Audits

• Compliance
  • The Covered Entity should have a Corporate Compliance Plan in which the 340B Program is a specific component.
  • The Covered Entity should maintain auditable records demonstrating compliance with 340B Program requirements.
  • The Corporate Compliance Plan should have an internal audit plan adapted by the Compliance Officer that is conducted annually (the internal audit does not have to be conducted by internal personnel).
  • Audits should be conducted at least annually.
  • The Covered Entity should have a self-reporting policy in the event that a breach of a requirement would occur.
Questions?

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