340B State of Play
A Webinar in Three Parts

Part I: A Guide to the Omnibus Guidance

October 1, 2015

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Webinar Schedule

- I. A Guide to the 340B Omnibus Guidance
  - 340B Background
  - Guide to the Guidance

- II. Stakeholder Response to the 340B Ceiling Price and Manufacturer CMP Proposed Rule
  - Thursday, Oct. 8, 2005
  - 12:00pm – 1:30pm EST

- III. The Path Ahead: The Potential Impact of Regulations, Guidance, Program-Related Litigation, and Possible Legislative Changes
  - Thursday, Oct. 15, 2005
  - 12:00pm – 1:30pm EST
Agenda Items

- 340B Program & Omnibus Guidance Overview
- Tracking the “Patient” Definition
- Eligibility Standards
- GPO Prohibition
- Covered Drug Definition
- Duplicate Discounts
- Contract Pharmacy Policy
- Compliance Requirements
  - Covered Entity Requirements
  - Replenishment, Credit & Rebills
  - Manufacturer Requirements
  - Limited Distribution Networks
  - Repayments
  - Audits
340B Program History
The 340B Drug Pricing Program was created by the Veterans Health Care Act and instituted in 1992 as part of a legislative effort to support access to prescription medicines for medically underserved populations by reducing outpatient drug costs for safety net providers and their patients.

At the time of its creation, the 340B legislation envisioned about 90 hospitals that cared for a disproportionate share of indigent patients would qualify.

In the early years after its creation, the 340B program remained relatively small, but has grown steadily, and in recent years significantly, with current costs of over $10 billion.

Regulatory changes, such as the expansion to cover contract pharmacies in 1996 and the ACA expansion in 2010, have led to skyrocketing 340B participation and most recently, increasing regulation.
Total Costs of Program Drug Discounts

Estimated Costs Per Year

- Billions Per Year

- 2004
- 2010
- 2016 (projected)
HRSA Oversight of the 340B Program

- The Program is overseen by the Office of Pharmacy Affairs (“OPA”) within the Health Resources and Services Agency (“HRSA”) within HHS
- The statute gives little regulatory or enforcement authority to HRSA and makes no provisions for appropriate enforcement resources
- The combination of these factors led to little to no enforcement of the Program between its creation and recent regulatory efforts – allowing significant risk of abuse
- In 2011, a GAO report found that “HRSA’s oversight is inadequate to ensure participants’ compliance with 340B Program requirements . . . because it primarily relies on covered entities’ and manufacturers’ self-policing”
HRSA Regulatory Activity Since 340B Program Creation

- HRSA issued over 20 policy documents in the first 20 years of the program, covering topics from the “patient” definition and outpatient hospital facilities to the potential for duplicate discounts, ceiling price calculations, and audit guidelines.

- In the last five years, as a result of the sharp increase in 340B program participation and expansion of the program through the ACA, HRSA increased its regulatory activities, issuing additional notices of policy and proposed rulemakings on critical topics.

- **2013-2014:** Orphan Drug “Rulemaking” and subsequent ongoing litigation.

- **June 17, 2015:** HHS issues proposed 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation
  - Significant comments submitted, question of reopening comment period

- **August 28, 2015:** HHS issues proposed 340 Drug Pricing Program Omnibus Guidance
  - Comments due October 27th
340B Drug Pricing Program
Omnibus Guidance
Guidance Overview

- Originally intended to be a rulemaking, but instead issued as Proposed Guidance following a district court holding that HRSA lacked statutory authority to regulate outside certain topics.
- Consolidates and updates previous guidance issued and implements a number of new program integrity requirements added by the ACA.
- Informed by HRSA audits.
- Has the potential to reduce scope of the 340B Program because of interpretation of “patient” and “covered outpatient drug” and new diversion controls.
- Not a regulation, so no economic analysis, but changes could have a significant impact on some participants.
- Not clear whether any current arrangements will be “grandfathered” or whether participants will have time to come into compliance.
Tracking the “Patient” Definition

1996-2015
1996 Guidance Definition

- **Three Part Test**
  - 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 the 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 lookalike status has been provided to the entity
  - Disproportionate share hospitals are exempt from this requirement
In 2007, HRSA proposed a new “patient” definition intended to clarify the types of encounters that qualified for the 340B drug discount.

**Moved to a set criteria under which “patient” status would be determined:**

- (1) Relationship of the Covered Entity to treated individual + Covered Entity had ownership, control, maintenance, and possession of individual’s health care records + documentation of services that resulted in use of/prescription of 340B drugs.
- (2) The individual received outpatient health care services that resulted in use/prescription of 340B drugs from a health care provider who was employed by or contracted to the Covered Entity. The individual could be referred for follow up care so long as ongoing responsibility for health care services remained with the covered entity; and
- (3) The outpatient health care services the individual received 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 lookalike 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.

HRSA abandoned the new “patient” definition in response to industry feedback.
An individual will be considered a patient of a Covered Entity, on a prescription-by-prescription or order-by-order basis, if all of the following conditions are met:

- (1) The individual receives a health care service at a facility or clinic site which is registered for the 340B Program and listed on the public 340B database

**Who Is NOT a Patient:**
- An individual who sees a physician in his or her private practice which is not listed on the public 340B database or any other non-340B site of a Covered Entity, even as follow-up to care at a registered site
- An individual whose health care is provided by another health care organization that has an affiliation arrangement with the Covered Entity, even if the Covered Entity has access to the affiliated organization’s records. Access to an individual’s records by a Covered Entity, by itself, does not make the individual a patient of that Covered Entity

- The use of telemedicine is permitted, as long as the practice is authorized under State or Federal law and the drug purchase otherwise complies with the 340B Program
(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.

- **Who Is NOT a Patient:**
  - Individuals treated by a health care provider who simply has credentials or privileges at a Covered Entity
  - If a patient is referred from the Covered Entity for care at an outside provider and receives a prescription from that provider, the drug prescribed will not be eligible for a 340B discount

- Faculty practice arrangements and established residency, internship, and volunteer health care provider programs are acceptable covered entity relationships so long as the Covered Entity may bill on behalf of the provider.

- When a referred patient returns to the Covered Entity for ongoing medical care, subsequent prescriptions written by the Covered Entity’s providers may be eligible for 340B discounts.
(3) An individual receives a drug that is ordered or prescribed by the Covered Entity provider as a result of the service described in (2)

- **Who Is NOT a Patient:**
  - An individual whose only relationship to the provider is the dispensing or infusion of a drug is not a “patient”

(4) The individual’s health care is consistent with scope of the Federal grant, project, designation, or contract

- **Who Is NOT a Patient:**
  - The dispensing of or infusion of a drug alone, without a Covered Entity provider-to-patient encounter, does not qualify an individual as a patient for purposes of the 340B Program
(5) The individual’s drug is ordered or prescribed pursuant to a health care service that is classified as outpatient

- **Who Is NOT a Patient:**
  - An inpatient of a Covered Entity who receives prescriptions to be taken on an outpatient basis following discharge

- Determined by how the service is billed to the payor

- Patients who are self-pay, uninsured, or whose costs of care are covered by the Covered Entity are a “patient” if the Covered Entity has clearly defined policies

(6) The individual has a relationship with the Covered Entity such that the Covered Entity maintains access to auditable health care records which demonstrate that the Covered Entity has a provider-to-patient relationship, and that the responsibility for care is with the Covered Entity
New Patient Definition

- Patient status will be a highly fact specific determination made on a prescription-by-prescription basis
  - Is there a sufficient internal auditing mechanism within Covered Entities to determine patient eligibility?
  - Can patient eligibility be challenged? How? By whom?
- Must a Covered Entity actually bill as a condition precedent or need it only have the power to bill?
- No eligibility for infusions only, but can an employed physician review and rewrite and thus create patient status?
- Can prescriptions written for a patient of a Covered Entity at the time of discharge be covered? What about refills? What if the insurer requires prescriptions be billed as part of inpatient stay?
- Limited exceptions to the “patient” definition for ADAP enrollees and for drugs dispensed during public health emergencies
Eligibility Standards

Non-Hospital & Hospital
Eligibility Requirements for Covered Entities

- Non-hospital Covered Entities described in sections 340B(a)(4)(A) through (K) of the PHSA include entities that receive certain Federal grants, Federal contracts, Federal designations, or establish Federal projects are eligible
  - Non-hospital Covered Entities include Federally-qualified health centers, Urban Indian Health Centers, Ryan White HIV/AIDS Program grantees, and specialized clinics such as Black Lung Clinics

- Six Types of Hospitals are Eligible:
  - Children’s Hospitals that are excluded from the Medicare prospective payment system
  - Free-standing Cancer Hospitals that are excluded from the Medicare prospective payment system
  - Disproportionate Share Hospitals (“DSH Hospitals”)
  - Critical Access Hospitals (“CAHs”)
  - Rural Referral Centers
  - Sole Community Hospitals
**Hospital Requirements**

- **Government Nexus Requirement**: All six types of hospitals must meet one of the following three criteria:
  - (1) Solely government owned or solely government operated
  - (2) Be formally granted governmental powers, or
    - Must be a formal power usually exercised by the State or local government
  - (3) Be under contract with a state or local government

- **Disproportionate Share Requirement**: all hospitals but CAHs must meet
  - For Children’s Hospitals, Free-Standing Cancer Hospitals, and DSHs must have a disproportionate share adjustment percentage greater than 11.75
    - Or qualify as a “Pickle” Hospital
  - Rural Referral Centers and Sole Community Hospitals must have a disproportionate share adjustment percentage equal to or greater than 8.0
Hospital Requirements

- HRSA will review the most recently filed Medicare cost report to confirm compliance with DSH percentage requirements.
- For Children’s Hospitals, a statement from a qualified independent auditor is required.
- Covered Entities may only register quarterly during specified registration periods.
- Registration must be made by an authorized individual who can attest that the Covered Entity meets the eligibility criteria and can comply with requirements.
- If a Contract Pharmacy will be used to dispense 340B Drugs to Medicaid beneficiaries, a written agreement with pharmacy, Medicaid agency or MCO describing a system to prevent duplicate discount must be provided to HRSA for review before listing on the database.
GPO Prohibition
DSH Hospitals, Children’s Hospitals, and Free-standing Cancer Hospitals cannot “obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement”

- GPOs can be used to obtain inpatient drugs or non-covered outpatient drugs

Exceptions to the GPO Prohibition

- (1) An off-site outpatient clinic of a hospital Covered Entity if such clinic is located at a separate physical address from the parent site, does not participate in the 340B Program, and is not listed in the 340B database, and purchases drugs through a separate account from the parent site
- (2) A drug purchased through a GPO that was provided to an inpatient who, upon subsequent review, is designated as an outpatient for payment purposes; and
- (3) A hospital that can only obtain a covered outpatient drug through a GPO must document its attempts to purchase the drug at the 340B price and report the circumstances to HHS
GPO Prohibition

- Challenge for Covered Entities in tracking usage of 340B Program drugs in mixed-use clinical settings
- Compliance with the GPO prohibition is a condition of eligibility and Covered Entities can be removed for violations
  - Isolated error may only require corrective action plan
- Violations require offer of repayment of 340B discount to affected Manufacturers for any covered outpatient drug purchase made after the date of the first GPO prohibition violation
- What should Manufacturers do if offered such repayment?
Covered Outpatient Drug
Omnibus Guidance & Preview to the Proposed Rule
“Covered Outpatient Drug” Definition

- “Covered Outpatient Drug” Definition: Section 340B(b)(2)(A) defines “covered outpatient drug” as the definition in section 1927(k) of the Social Security Act
  - This definition is included in the “Definitions” Section of the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation

- This definition is limited by excluding any drug or biologic provided as part of, or incident to, and in the same setting as certain other services

- HRSA states in the Guidance, that this exclusion only applies when the drug is “bundled for payment under Medicaid as part of a service in the settings described in the limiting definition”

- HRSA seems to be suggesting that a drug would be disqualified from the 340B Program only if the drug was billed to Medicaid as a bundle. Drugs billed to any other third-party in a bundle may still qualify

  - Some 340B stakeholders had previously understood this exclusion to apply to all drugs that would be bundled for payment under Medicaid, assuming that as the definition is borrowed from the Medicaid statute, it is the way that Medicaid would treat the drug that should control
Prohibition Against Duplicate Discounts
Manufacturers must participate in both the Medicaid Drug Rebate Program and the 340B Program

Section 340B(a)(5)(A)(i) of the PHS Act prohibits discounts where the State obtains a Medicaid rebate for a fee-for-service (“FFS”) patient or where the Covered Entity has “carved in” Medicaid managed care organization (“MCO”) patients, for a drug that was discounted under the 340B Program.

Guidance creates a number of responsibilities for Covered Entities to ensure compliance with the duplicate discount prohibition:

1. Elect whether it will dispense 340B drugs to Medicaid FFS patients and bill to the State or whether it will purchase through other mechanisms
   - If the Covered Entity “carves-in” (using 340B program drug discounts for Medicaid patients) it must provide its Medicaid billing number or NPI to HHS for inclusion on the Medicaid Exclusion File.
   - For MCO patients, Covered Entities can make a separate determination about carving-in or carving-out.
   - HRSA is seeking comments regarding an alternative mechanism to supplement the Medicaid Exclusion File for MCO patients to allow Covered Entities flexibility but prevent duplicate discounts.

2. Notify HRSA if the Covered Entity chooses to change its use of 340B Drugs for FFS or MCO patients
   - Can be submitted at any time but is only effective quarterly.
(3) Unless otherwise noted in the public 340B database, contract pharmacies will not dispense 340B drugs for Medicaid FFS or MCO patients

- If a Covered Entity wishes to use a contract pharmacy to dispense 340B drugs for its Medicaid FFS or MCO patients, it must provide HRSA with a written agreement with the contract pharmacy and State Medicaid Agency or MCO that describes a system to prevent duplicate discounts
  - Once approved, the contract pharmacy would be identified in the 340B database as dispensing 340B drugs for Medicaid FFS and/or MCO patients

(4) A Covered Entity may be found in violation of the duplicate discount prohibition if the information provided to HRSA did not reflect the Covered Entity’s actual billing practices

- The Covered Entity would be required to repay rebate amounts to Manufacturers if the duplicate discounts occurred as a result of inaccurate information
Contract Pharmacy Policy
Contract Pharmacies

- **Proposed Guidance** allows a Covered Entity to contract with one or more contract pharmacies, regardless of the availability of an in-house pharmacy, on behalf of itself and/or its child sites
  - Child sites may contract directly with a pharmacy
  - Groups or networks of Covered Entities cannot register or contract for pharmacy services on behalf of their individual Covered Entity members
  - Only the Covered Entity can submit a contract pharmacy registration and related information to HRSA

- **Requirement of a written contract between the Covered Entity and contract pharmacy**
  - Must list all locations of a single pharmacy company that the Covered Entity plans to use and all child sites that plan to use the contract pharmacies in order to be listed in the 340B database
  - No specification of what terms should be in the written agreement just that it should “set forth the requirements contained in the Proposed Guidance,” which should mean – prevention of diversion, duplicate discounts
A Covered Entity is expected to conduct quarterly reviews and annual independent audits of each contract pharmacy location.

- The records of such reviews and audits are among the records that can be audited by HRSA and Manufacturers.
- Any violations observed should be corrected, disclosed to HRSA, and Covered Entities are subject to applicable penalties of diversion or duplicate discounts.

The effect of required oversight of contract pharmacies by Covered Entities may serve to limit the number of contract pharmacy relationships Covered Entities enter into.
Compliance Requirements

Covered Entities & Manufacturers
Compliance Requirements For Covered Entities

- **Registration in 340B Database**
  - May enroll quarterly. Enrollment must be by an authorized official of the Covered Entity
  - Larger entities containing Covered Entities are **not** eligible to register

- **Regularly Review and Update Information in the 340B Database**
  - If loss of eligibility occurs, the Covered Entity is required to immediately update the database, cease purchasing 340B drugs, and is liable to refund the Manufacturer for any purchases occurring after loss of eligibility

- **Annual Recertification Process**

- **Auditable Records**: must permit HHS and a Manufacturer with a PPA to audit its records that pertain to the Covered Entity’s 340B eligibility compliance
  - Must maintain auditable records for itself, any child site, and any contract pharmacy for 5 years from the date the 340B drug was ordered or prescribed
Replenishment Models

- Are acceptable and do not constitute diversion if Covered Entities only order 340B drugs based on actual prior usage for eligible patients of that Covered Entity as defined by the Guidance
  - Hospital pharmacies would be required to account for dispensed drugs for inventory replenishment as inpatient, outpatient 340B eligible, or outpatient non-eligible drugs
  - May only replenish drugs by ordering from the appropriate account
  - Adequate records must be maintained demonstrating methods used in replenishment models comply with the GPO prohibition, and auditable records that establish segregation (either physical or virtual) of inventory
  - Diversion may occur if a Covered Entity improperly accumulates or tallies 340B drug inventory, or if the recorded number of 340B drugs does not match the actual number in inventory
Credit and Rebill

- **Preamble states that Covered Entities are responsible for requesting 340B pricing at the time of the original purchase**
- Guidance appears to allow Covered Entities to look back and attempt to re-characterize prior purchases as 340B eligible and obtain 340B pricing for prior transactions by stating that if a Covered Entity wishes to re-characterize a previous purchase as 340B, they should:
  - (1) First notify Manufacturers and
  - (2) Ensure all processes are fully transparent with a clear audit trail that reflects the actual timing and facts underlying a transaction
- Covered Entities subject to the GPO Prohibition must be able to establish that re-characterized purchases were not initially made through a GPO Agreement
- Encourage credit and rebill within 30 days, but the Guidance does not address how far back Covered Entities may re-characterize purchases or whether such re-characterization might have a pricing impact or impose penalties
Compliance Requirements for Manufacturers

- Enter into a PPA and offer covered outpatient drugs at statutory price
- Update PPA with new products
- Maintain Auditable Records
  - 5 year standard
  - Must provide to HHS upon request
  - Permit HHS audits
- Annual Review and Update 340B Database Information
  - Not clear what the certification requirement will be
- Limited Distribution Plans
- Issue Refunds and Credits for instances of overcharging
Limited Distribution Plans

- Limited Distribution Plans
  - Requires Manufacturers that use restricted distribution networks of specialty pharmacies to make the 340B price available to Covered Entities in a non-discriminatory manner
    - Must submit details of the plan to HRSA with an explanation of the rationale used before implementation, an assurance of non-discrimination, and a plan for notifying Covered Entities and wholesalers about the plan
    - Plan will be published on the 340B website
    - Not clear if HRSA must approve the limited distribution plan
  - Provisions would apply wherever a limited distribution plan is used (not only where limited distribution is required)
Manufacturer Refunds and Credits

- **Refunds and Credits to Covered Entities**
  - Required to issue refunds to Covered Entities in the event of an overcharge by the Manufacturer
    - May arise either from a routine restatement of AMP or best price, or exceptional circumstances such as erroneous or intentional overcharging of Covered Entities
    - Must submit to HRSA the 340B price recalculation information and an explanation of why the overcharge occurred, how the refund will be calculated, and to whom the refunds will be issued
Refunds and Credits

- **90 Day Requirement**
  - Manufacturer must issue a refund or credit within 90 days of the determination by the Manufacturer or HHS that an overcharge has occurred – this is at best impractical, at worst, impossible
  - If the Covered Entity does not cash the check within 90 days of receipt of the refund and the repayment amount is undisputed, the Covered Entity has waived their right to the refund

- **Refund Calculation** = (Sale price – Correct 340B price) x the # of units
  - No other calculations can be used, including aggregating purchases, de minimis amounts, or netting purchases – in other words, no offsets
Repayments to Manufacturers

- Under certain circumstances, Manufacturers may be entitled to repayments from Covered Entities (e.g., GPO prohibition violations, duplicate discounts, instances of diversion, ordering 340B drugs when ineligible, etc.)

- Manufacturers have the discretion to accept or decline payments based on their own business practices or request that repayments be processed through a credit/rebill process
  - Discretion is subject compliance with the federal anti-kickback statute
  - Manufacturers should consider the potential impact of such decisions on price reporting requirements under the MDRP
Audits

Manufacturer Audit of a Covered Entity
- A Manufacturer is authorized to audit Covered Entities for compliance with two eligibility requirements only:
  - (1) Prohibition against duplicate discounts
  - (2) Prohibition against diversion
- Standard: “reasonable cause”
  - Preamble states reasonable cause occurs when “a reasonable person could conclude, based on reliable evidence, that a Covered Entity and/or its child sites or contract pharmacies may have violated” one or both of the prohibitions
- Proposed Steps
  - (1) Must notify Covered Entity in writing of suspected violation and attempt to resolve for at least 30 days
  - (2) Manufacturer then submits an audit work plan to HHS with documentation of reasonable cause and attempts to negotiate a solution
  - (3) HHS reviews the work plan and may request changes
  - (4) Audit is conducted at Manufacturer expense
  - (5) Manufacturer submits a final audit report to the Covered Entity, which has 30 days to respond
  - (6) Manufacturer submits copies of the final audit report and Covered Entity responses to HHS, which may refer findings to OIG or other federal agencies
Audits

- **HHS Audit of Manufacturer**
  - **Proposed Steps**
    - HHS notifies the Manufacturer of its intent to conduct an audit
    - Following audit, HHS provides notice of its findings to the Manufacturer, which has 30 days to object in writing and provide supporting documentation
    - Following HHS’s review of this material (no deadline), HHS issues its final findings and a requests a corrective action plan to address them
    - Manufacturer has 30 days to submit a corrective action plan and HHS would then determine whether the corrective action plan is sufficient (again, HHS has no deadline)
  - If there is a determination that the Manufacturer no longer meets the requirements of the 340B program, HHS will provide the Manufacturer with notice and hearing
  - **Wholesaler Issue**
    - A Manufacturer is required to provide requested documents on its own behalf and on behalf of “any wholesaler or organization which performs 340B program requirements on its behalf”

- **HHS Audit of a Covered Entity**
  - Parallel provisions to HHS audit of Manufacturers, including notice and hearing
  - Includes ability to audit child sites and contract pharmacies
  - Failure of a Covered Entity to correct compliance issues may result in termination
Questions?

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Future Webinars
Upcoming Sessions

- **Stakeholder Response to the 340B Ceiling Price and Manufacturer CMP Proposed Rule**
  - Thursday, Oct. 8, 2005
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- **The Path Ahead: The Potential Impact of Regulations, Guidance, Program-Related Litigation, and Possible Legislative Changes**
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