340B Drug Discount Program

Stated Purpose:

"The 340B Program enables covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

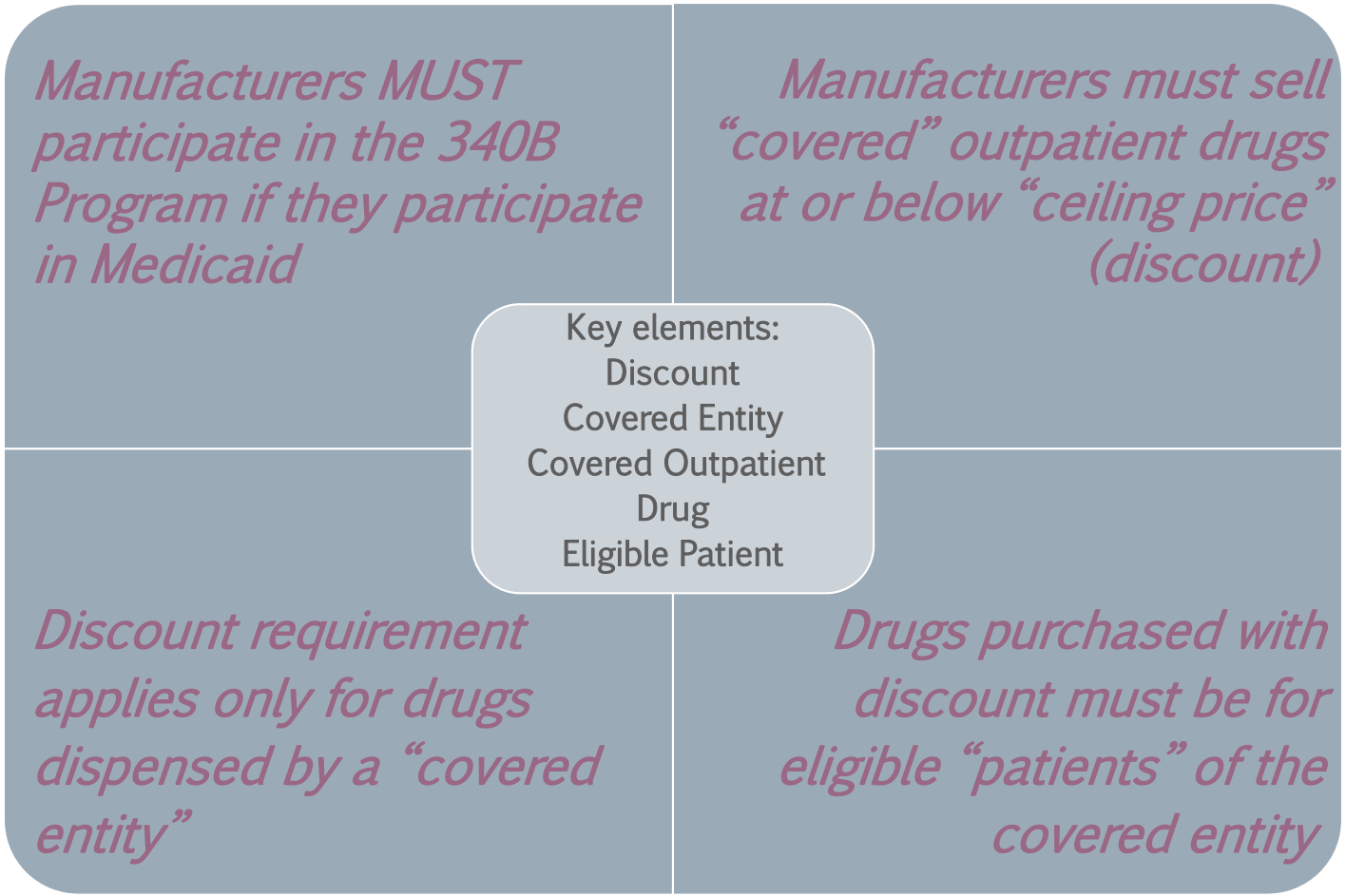
Background

In 1992, Congress passed a law, adding Sec. 340B to the Public Health Service Act, creating a new program intended to support hospitals serving a disproportionate share of indigent patients.

The 340b program is administered by the US Dept. of Health and Human Services (HHS), specifically through the Office of Pharmacy Affairs at the Health Resources and Services Administration.

The program is administered through rulemaking and various forms of guidance, although HRSA's ability to issue rules for this program has been challenged, and remains in question.

340b is a voluntary program, *BUT…*



The Discount and How It's Calculated

The discount, also known as the "ceiling price" is set by statute = Ceiling price = AMP – URA

- Average Manufacturers Price = the average price wholesalers pay manufacturers for sale to retail pharmacies
- Unit Rebate Amount = statutory basic rebate (23.1% of AMP*) + additional rebates (when/if quarterly AMP increases grow faster than CPI-Urban).

Aggressive price increases can result in a URA that equals 100% of AMP, such that a ceiling price calculated at AMP minus URA can equal zero (or less).

When the ceiling price is at or below zero, manufacturers must charge the covered entity a penny ("Penny Pricing") for each "unit"

Note: The discount does not flow to the patient. The patient is charged the full ASP+6 price, paid by the patient's insurance with the patient responsible for the 20% copay on the full price. This means the full discount goes to the bottom line of the hospital. The more patients they dispense 340b drugs to, the more money flows to their bottom line. >> Key parameters to monitor – is the individual a patient of the hospital in name only? Is the patient receiving inpatient or outpatient services?

The discount does not flow from the manufacturer to a government entity before reaching the covered entity. So there are far fewer rules and regulations than there would be on funds dispensed from the US Treasury. This is a taxpayer to taxpayer transfer.

*17% for clotting factors and exclusively pediatric indication drugs and 13% for non-innovator drugs.

"Covered Entities" -- Generally

- Any *outpatient* hospital that
  - is a non-profit with formal governmental powers, or
  - *has a contract with state or local government (very broad),* or
  - is owned/operated by state or local government;
  - is a critical access hospital (CAH)

The hospital must also meet disproportionate share hospital (DSH) thresholds

- Disproportionate Share Hospitals; Cancer; Children's – must have DSH adjustment > 11.75%
- Rural Referral Centers and Sole Community Hospitals – must have DSH adjustment ≥ 8%

The hospital also may not buy its outpatient drugs through a GPO.

Complex Eligibility, BUT –

All "Covered Entities" are listed on a Database. Manufacturers simply check the list.

New regulations promulgated in Jan 2017 require that covered entities be "in compliance with the duplicate discount and diversion prohibitions,"

- This change may give manufacturers recourse when they are not able to recover duplicate discounts.

Who is a Patient of a Covered Entity?

Guidance pulled by Trump

CURRENT

1) The Covered entity/hospital must have an established relationship with a patient – ie, ***maintains the patient's health records;*** and
2) The patient must get their healthcare services from a provider employed by that hospital (or has a contract to provide services) that has ***responsibility for the patient's care;*** and
3) The patient's care is ***consistent with*** the services that hospital provides (except for disproportionate share hospitals (DSH);

PROPOSED/FUTURE

1) The patient's care must be provided by a hospital employee or someone for whom the hospital can bill for their services;
    1) Provider cannot simply have privileges at the hospital.
2) The patient's outpatient drugs are prescribed specifically ***as a result of that provider's services;***
3) The services are ***consistent with*** that facilities services;
4) The outpatient drug(s) is prescribed or ordered pursuant to a health care service that is ***classified as outpatient***.
5) ***Patient records are accessible*** to the covered entity and demonstrate that the covered entity is *responsible for care*.

These additional parameters were meant to prevent doctors with privileges at the outpatient hospital from simply sending their patients there for the 340b discounted drugs;

Who is *NOT* a Patient of a Covered Entity?

Guidance pulled by Trump

Current exclusion:

· Patients whose *only healthcare service* is the dispensing of a drug(s) are not considered patients of a 340b entity – ie, for subsequent self-administration, inpatient or home setting administration

Proposed:

· Patients receiving physician-administered *drugs as their only service* in a covered entity would not be considered patients;

· *Patients of clinicians w/ "privileges"* (as opposed to employment or contractual relationships) at a covered entity may not be considered patients;

· RESPONSIBILITY FOR CARE may be key question in determining whether individual is a "patient" of a covered entity.

These additional parameters were meant to prevent doctors with privileges at the outpatient hospital from simply sending their patients there for the 340b discounted drugs.

Manufacturer Responsibilities

- When a
  - "covered entity"
  - requests 340B discount
  - on a covered outpatient drug,
- Manufacturer must
  - Sell that drug
  - At or below the "ceiling price"

New regulations promulgated in Jan 2017 require that covered entities be "in compliance with the duplicate discount and diversion prohibitions,"

- This change may give manufacturers recourse when they are not able to recover duplicate discounts.

- "Covered entities" are listed in a database – if it isn't there, it isn't a covered entity and is NOT entitled to 340B discount;
- New Civil Monetary Penalties (CMPs) for manufacturers that fail to provide 340B discounted drug to covered entities.

Requirements and Constraints on Covered Entities

- Must register with HRSA and ***ensure that they appear on database***;
- Must ***request discount at the time drug is ordered***;
- May NOT receive Medicaid rebate on 340B discounted drugs. Covered entities can dispense to Medicaid patients, but **may not get both the discount and the *rebate*** (double dipping);
- May NOT dispense 340B discount drug that is not for a covered entity patient (diversion) – this includes 340B drug to inpatients, and to any entity or person outside definition of "patient" – i.e., ***no "diversion"***
- NO requirement that covered entities use savings to provide care to indigent or under insured patients -- no constraints at all;
- BUT . . . Manufacturer recourse is limited to audit, referral to HRSA (no clear process) . . . Can be costly, time-consuming, and uncertain.
- BIO exploring advocating for manufacturer access to "claims level data" as part of State Medicaid rebate invoicing.

340B Program Evolution Beyond Its Purpose

ACA and other legislative changes have grown the 340B program exponentially

1. 20,000 covered entities – up from 8,000 in 1998;
2. 340B discounted drugs were originally a marginal consideration (4-6% of sales) – Now, 340B sales can exceed 25% of manufacturer sales volume;
3. Covered entities have consolidated with other hospitals, and incorporated physician office specialties with high-cost drugs (e.g., oncology practices)
4. A hospital outpatient department can build an off site facility (known as a "Child site") and qualify to receive 340b discounts at that facility, for those patients, (if child site is on outpatient department's Medicare cost report)
5. Contract Pharmacy Arrangements -- the Covered Entity no longer has to dispense 340b drugs through its own pharmacy; it can contract to have drugs dispensed through one or more retail pharmacies, so long as it retains legal title.

Growing Awareness of Potential 340B Problems

- Audits
  - Covered entity audits focus on drug diversion and duplicate discounts
    - Diversion = drug not going to true entity patients or to patients in the wrong setting of care (e.g., inpatient
    - Duplicate discount – the hospital is taking both a 340b discount and a Medicaid rebate
  - Increasing manufacturer audits and inquiries
    - New Civil Monetary Penalties (CMPs) for manufacturers
    - High variability possible – Highest cost/highest utilization products are ripest for "gaming" by both manufacturers and covered entities

Some, including the OIG, MedPAC have concerns:

(i) Do manufacturers charge more for drugs to afford all the 340B discounts they have to provide?

(ii) Public Policy –

  (i) What if patient's 20% copay actually exceeds the acquisition cost?

  (ii) Savings not passed on to patients

  (iii) Savings not passed on to Medicare [PROPOSED RULE CHANGES THIS]

Pursuing Changes to "Fix" the 340B Program – Contract Pharmacy Arrangements

Contract Pharmacy Arrangements Moving Forward – ***WHY IS THIS IMPORTANT?***

- Substantial room for growth in 340b channel, e.g., specialty pharmacy arrangements;
- Growing number of pharmacies, consultants, software vendors, health plans focused on maximizing 340b revenue;
  - Limited regulatory oversight
  - 3rd party vendors emerging to help covered entities leverage contract pharmacy arrangements
- Original hospitals that 340b was designed to help:
  - Have very low levels of contract pharmacy arrangements
  - Have 340b purchases that are steady, rather than growing, over time
  - If high 340b growth is due to new covered entities – are they "gaming" the program?
- Despite very high rates of non-compliance found through HRSA audits, there is still limited regulation in contract pharmacy – ie, lack of records, transparency, diversion.

340B, the New Administration, and ACA Repeal/Replace – What's at Stake?

- Several key changes in 340B (e.g., penny pricing affirmation, CMPs) were finalized under ACA statutory authority;
- If the new Congress repeals the ACA in its entirety, the specific statutory authority for the regulations disappears;
- Alternatively, Congress could disapprove or reject the HRSA rule, even if the ACA were not repealed, given that the new Administration can reject regulations submitted within the last 60 days of a legislative session of Congress during the final year of a President's term. Even if they don't pull it, they have enforcement discretion.

ACTION ITEMS

- We will closely monitor the impact of the ACA repeal initiative(s) and the rejection of regulations;
- HRSA has already promised another guidance on the particular components of a ceiling price reporting system, including defining terms like package size and case package size;
- 340B growth will likely continue absent legislative or regulatory changes to align breadth and scope of program with its original intent
  - Complex issues in light of Administration's statements about reducing/containing drug prices