# The 340B Mega-Wait Is Over- Now What? (More Waiting?)

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# What is the 340B Program?

- Federal drug discount program
- Limited to eligible and registered hospitals and federal grantees/programs ("covered entities")
- Limited to certain outpatient drugs ("covered outpatient drugs") dispensed to eligible patients of covered entities
- Administered by the Office of Pharmacy Affairs (OPA), Health Resources and Services Administration (HRSA)

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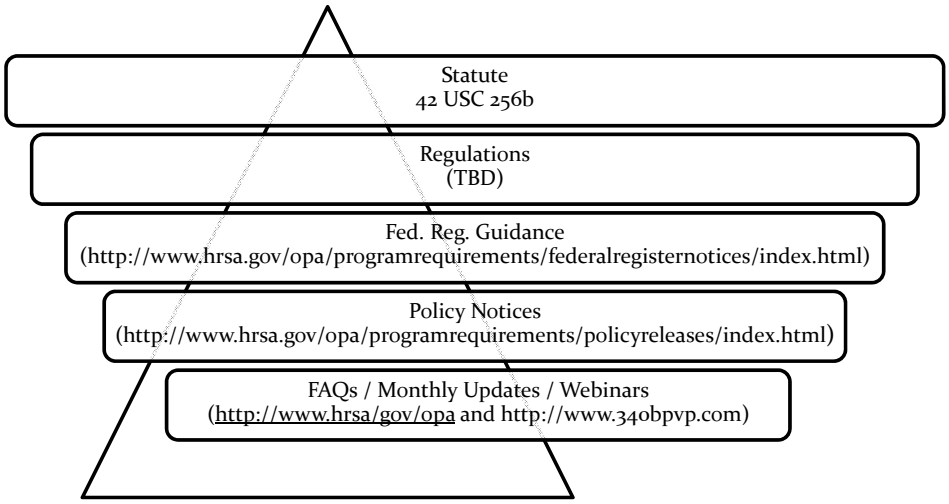
# Oversight of 340B

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# Why the Changes to 340B?

| 2010 | 2011 | 2012 | 2013 | 2015 | 2016 |
|---|---|---|---|---|---|
| • 340B program was significantly expanded with the passage of the Affordable Care Act and the concurrent release of additional federal guidance<br>• Additional expansion included provisions for contract pharmacy partnerships with retail pharmacies to help service their patients | • Expansion resulted in increased scrutiny from lawmakers and drug manufacturers<br>• 9/23/2011 GAO report and 11/9/2011 press release issued by Senator Chuck Grassley are critical of 340B program oversight | • In response to scrutiny regarding program oversight, OPA briefed the Senate Appropriations Committee in February 2012<br>• Plan to strengthen program to ensure compliance with existing requirements<br>• Created timetable for issuing new regulations that address compliance concerns | • Senate Appropriations Committee later reaffirms 340B's intent in July 2013<br>• Bipartisan letters of support are issued from over 100 lawmakers in August 2013 | • HRSA released omnibus guidance in August in an attempt to clarify existing policy and provide a framework for program audit & enforcement<br>• November 2015 OIG report analyzing the impact of reducing Medicare Part B payments for drugs purchased thru 340B program | • MedPAC recommends reduction to Part B drug payments to hospitals participating in the 340B program<br>• President's budget requests 340B program regulatory authority for HHS |

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# Why No Regulations?

- Historical Focus
  - Pre-2010- Education, Outreach, Expansion
  - Post-2010- Compliance, Oversight, Enforcement
- Statutory Authority
  - Very limited rulemaking authority
  - As shift in focus, moved to formalize requirements
- Orphan Drug Case

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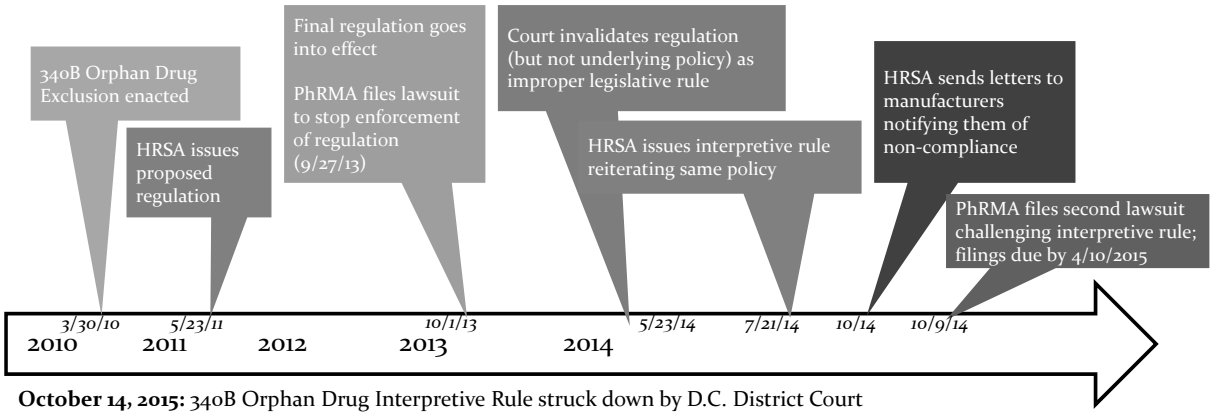
# Orphan Drugs




**October 14, 2015:** 340B Orphan Drug Interpretive Rule struck down by D.C. District Court

- The impact of this decision is that the orphan drug interpretive rule is invalid and all drugs designated as orphan drugs under standards established by the FDA are exempt from receiving 340B pricing as to 340B-covered entities subject to the orphan drug exclusion, regardless of the "use" for which the drug is prescribed.

Source: http://www.klgates.com/340b-orphan-drug-interpretive-rule-struck-down-by-dc-district-court-hhs-and-hrsa-lose-in-second-round-of-litigation-over-340b-orphan-drug-rules-10-22-2015/

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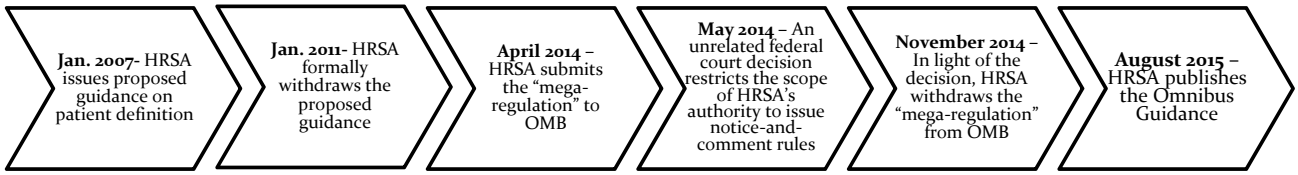
# Proposed Guidance

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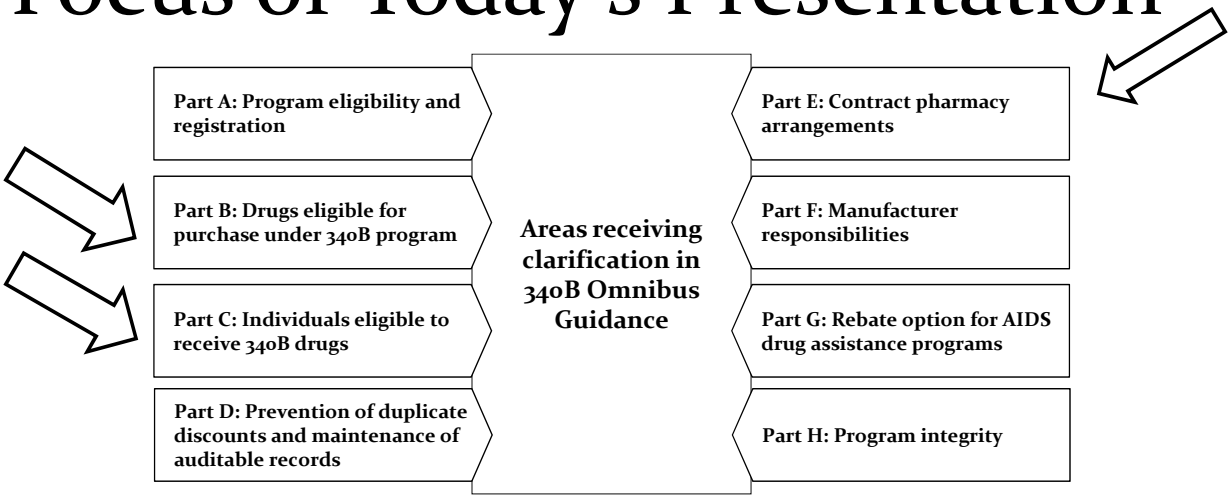
# Focus of Today's Presentation

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# Key Topics

- Patient Eligibility
- Drug Eligibility
- Contract Pharmacy

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# Patient Eligibility

- Current Definition of "Patient" (finalized in 1996)
  - The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care
  - 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
  - The individual receives a health care service or range of services from the covered entity that 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 (Does not apply to hospitals)

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# Patient Eligibility

- Proposed Definition of "Patient"
  1. The individual **receives a health care service at a covered entity site** that is registered for the 340B Program and listed on the public 340B Database
     - Individual that sees a physician in the physician's private practice, which is not listed on the 340B Database, would not be eligible to receive 340B drugs – including any referral or follow up care from the covered entity
  2. The individual receives a health care service from a health care provider who (i) is **employed** by the covered entity or (ii) is an **independent contractor** of the covered entity such that the covered entity may bill for services on behalf of the provider
     - Privileges or credentials at a covered entity are not sufficient
     - If a patient is referred from the covered entity to an outside provider, and receives a prescription from that outside provider, the prescription would not be 340B-eligible

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# Patient Eligibility

- Proposed Definition of "Patient" (cont.)
  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**
     - An individual will not be considered a patient of the covered entity if the only health care received by the individual from the covered entity is the infusion of a drug or the dispensing of a drug
     - Telemedicine is acceptable
  4. The individual is classified as an outpatient **when the drug is ordered or prescribed**
     - The patient's classification status is determined by how the services for the patient are billed to the insurer
     - An individual who is self-pay, uninsured or whose cost of care is covered by the covered entity will be considered a patient if the covered entity has clearly defined policies and procedures that it follows to classify such individuals consistently

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# Patient Eligibility

- Proposed Definition of "Patient" (cont.)
  5. The individual has a relationship with the covered entity such that the covered entity maintains access to **auditable health care records**
     - Records demonstrate that the covered entity has a **provider-to-patient relationship** and the **responsibility for care is with the covered entity**
  6. For grantees, the individual receives a health care service that is consistent with the covered entity's scope of grant, project or contract
     - Applies to each child site of the covered entity

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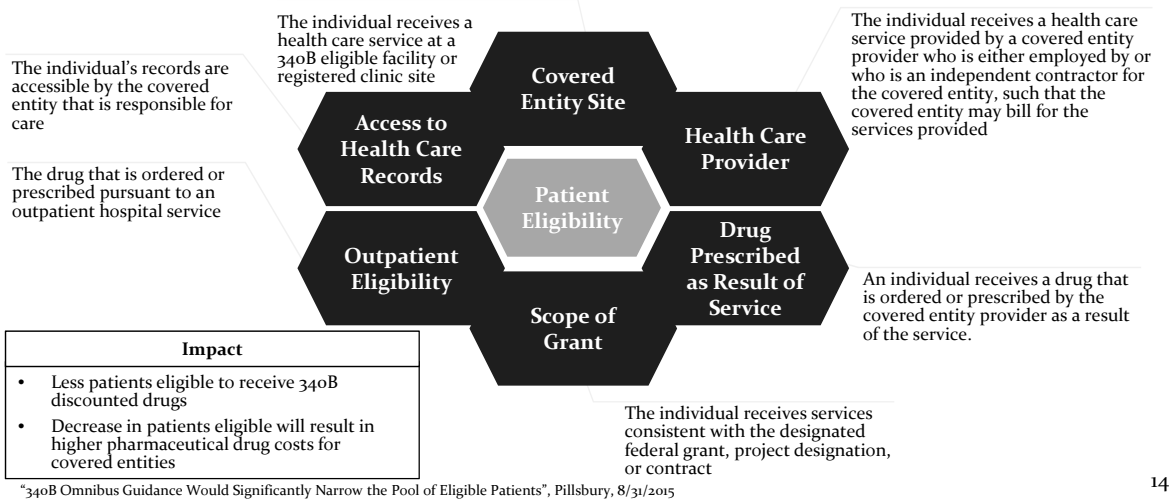
# Changes to Patient Eligibility

**Guidance moves from a 3-part test to a 6-part test on a per-prescription basis.**




| Impact |
|---|
| • Less patients eligible to receive 340B discounted drugs<br>• Decrease in patients eligible will result in higher pharmaceutical drug costs for covered entities |

"340B Omnibus Guidance Would Significantly Narrow the Pool of Eligible Patients", Pillsbury, 8/31/2015

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# Patient Eligibility

- Key Difference
  - Tightens the nexus between the covered entity and the prescription eligible for 340B drugs
- Practical Implications
  - Visits at private physician offices are not eligible
  - Use of physical inventories impractical
  - Limits on "340B-only" locations/inventories
  - Referred infusion services not eligible for 340B drugs
  - Employee/dependent status is irrelevant to eligibility determination

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# Drug Eligibility

- "Covered Outpatient Drug"
  - Defined by reference to Social Security Act § 1927(k)(2)
  - Generally includes:
    - FDA-approved prescription drugs
    - Over-the-counter (OTC) drugs written on a prescription
    - Biological products that can be dispensed only by a prescription (other than vaccines)
    - FDA-approved insulin
  - But, also includes a "limiting definition" at § 1927(k)(3) excluding drugs bundled for Medicaid payment

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# Drug Eligibility

- Current Guidance
  - Covered entity may interpret the definition of "covered outpatient drug" so long as it is: "defensible, consistently applied in all areas of the entity, documented in policy/procedures, and auditable." (Apexus FAQ 1355)

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# Drug Eligibility

- Proposed Guidance
  - Explicitly applies the "limiting definition," but only to Medicaid
  - Drugs that are part of a bundled payment for Medicaid reimbursement, and are billed to and paid for by Medicaid as part of bundled payment are excluded from definition of "covered outpatient drug"
- Practical Implications
  - May not be able to determine 340B eligibility at time of dispensing or billing
  - Creates risk of violation of GPO Prohibition for certain hospitals

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# Contract Pharmacy

- Covered entities may contract with third-party pharmacies to dispense 340B drugs
- Source of significant growth in 340B purchasing and focus of government/manufacturer oversight
- Current Guidance
  - Covered entity is responsible for contract pharmacy's compliance with 340B Program requirements
  - Contract pharmacies may not dispense 340B drugs to Medicaid patients unless HHS has approved a system to prevent duplicate discounts
  - Covered entity is expected to conduct audits of the contract pharmacy arrangement
- Proposed Guidance
  - Covered entity must conduct quarterly reviews and annual audits of each contract pharmacy location

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# Operational and Financial Takeaways

**Financial impact:** Infusion centers and contract pharmacy are typically large drivers of program savings. If the proposed changes go into effect as written, **what can organizations do to make up for the lost savings?**

**Sustainable margin opportunities** such as revenue cycle maximization, supply chain and pricing optimization, and clinical utilization evaluations

**Audit and monitoring:** Proposed guidelines included detailed expectations for audit and monitoring activities. Most entities perform routine auditing and monitoring, but many lack a formal, structured, and integrated plan.

Assess the possibility of **immediate corrective action** versus waiting until the guidance is released in final form:

- Audit and monitoring practices
- Error reporting procedures
- Develop a repository for program documentation
- Software and data infrastructure modifications

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# 340B Conference Takeaways

**1**

**Release of omnibus guidance**
- Expected release date is September 2016, however other factors suggest a possible extension
  - Election year
  - Heightened focus on budget
  - Avoidance of debate

**2**

**Anticipated HRSA enforcement in 2016**
- Outstanding Regulations:
  - Manufacturer Civil Monetary Penalties (CMP)
  - Ceiling Price Rules
  - Dispute Resolution
- Other Updates: 340B Pricing Website & Legislation (?)

**3**

**Online 340B pricing system**
- Will allow authorized users from covered entities the ability to view 340B ceiling prices for covered outpatient drugs.
- Will allow manufacturers to upload quarterly pricing data for their portfolio of covered outpatient drugs and validate their prices with the HRSA-verified 340B ceiling price

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# MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) has backed a proposal to reduce Part B drug payment rates for hospitals participating in the 340B Drug Pricing Program

- On January 16, 2016, MedPAC voted 14 to 3 to recommend a reduction in Part B drug payment rates to 340B hospitals by **10%** of the average sales price of the drugs
- Medicare would distribute uncompensated care payments made under the disproportionate share hospital program based on data from Schedule S-10 of the hospital's Medicare cost report
- This change would be phased in over **three** years
- The American Hospital Association estimates that this would redistribute the estimated **$300 million** in savings to hospitals providing uncompensated care services.
- Requires additional action by Congress in implement MedPAC recommendation

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Source: http://news.aha.org/article/160115-aha-critical-of-medpacs-misdirected-340b-payment-proposal
https://www.federalregister.gov/articles/2015/08/28/2015-21246/340b-drug-pricing-program-omnibus-guidance

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# Future 340B Landscape

**Pivoting in the marketplace**

… providers need to take advantage of the changes in the regulatory landscape and pivot in the marketplace.

**Compliance**

…the rules are complex and massive. Proceed with caution.

**Moving toward a new 340B Program landscape**

**Costs**

…new Omnibus Guidance may reduce program savings. New opportunities and funding streams need to be explored

**Providers and payers**

…how they define value, act as purchasers and respond to new incentives will set the stage.

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