



# The Federal 340B Drug Discount Program: A Primer

Andrea G. Cohen

Manatt, Phelps & Phillips, LLP

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# Preview

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- 340B Program Overview
  - What is it
  - Who is eligible
  - Pricing/Discounts and Pharmacy Arrangements
  - Revenue/Savings Opportunities
- 340B and Part D
- 340B and Medicaid
- State Opportunities
- Issues to Watch



# 340B Overview – What is it?

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- Program established by Congress in 1992
- Requires pharmaceutical manufacturers that contract with the Medicaid program to provide discounts on outpatient drugs purchased by “covered entities,”
  - Generally, designated safety net providers that receive government funds
- Program “named” by section of the Public Health Service Act
  - Original statute also amended the Medicaid statute, Section 1927 of the Social Security Act



# 340B Overview

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- “Covered entities” include
  - Federally-qualified health centers (FQHCs) and “look-alikes”
  - Public and non-profit DSH hospitals that have indigent care contracts with state/local governments
    - DRA added Children’s Hospitals
  - Ryan White CARE Act grantees
  - Title X Family Planning/STD clinics
  - TB and Black Lung Clinics
  - Urban Indian clinics
  - Homeless clinics
  - Others



# 340B Overview

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- 340B Program administered by the Office of Pharmacy Affairs (OPA) in the Health Resources and Services Administration (HRSA)



# 340B Discounts and Pricing

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- 340B “ceiling” price = rough Medicaid “net” price (or AMP – mandatory rebate amount under SSA §1927(c))
  - Impact of Medicare Part D best price exemption
  - Impact of DRA Medicaid pricing changes
- Covered entities can negotiate prices lower than the “ceiling” price on their own or through a statutorily-chartered “Prime Vendor” program
  - Actual 340B prices may be significantly lower than Medicaid “net” price



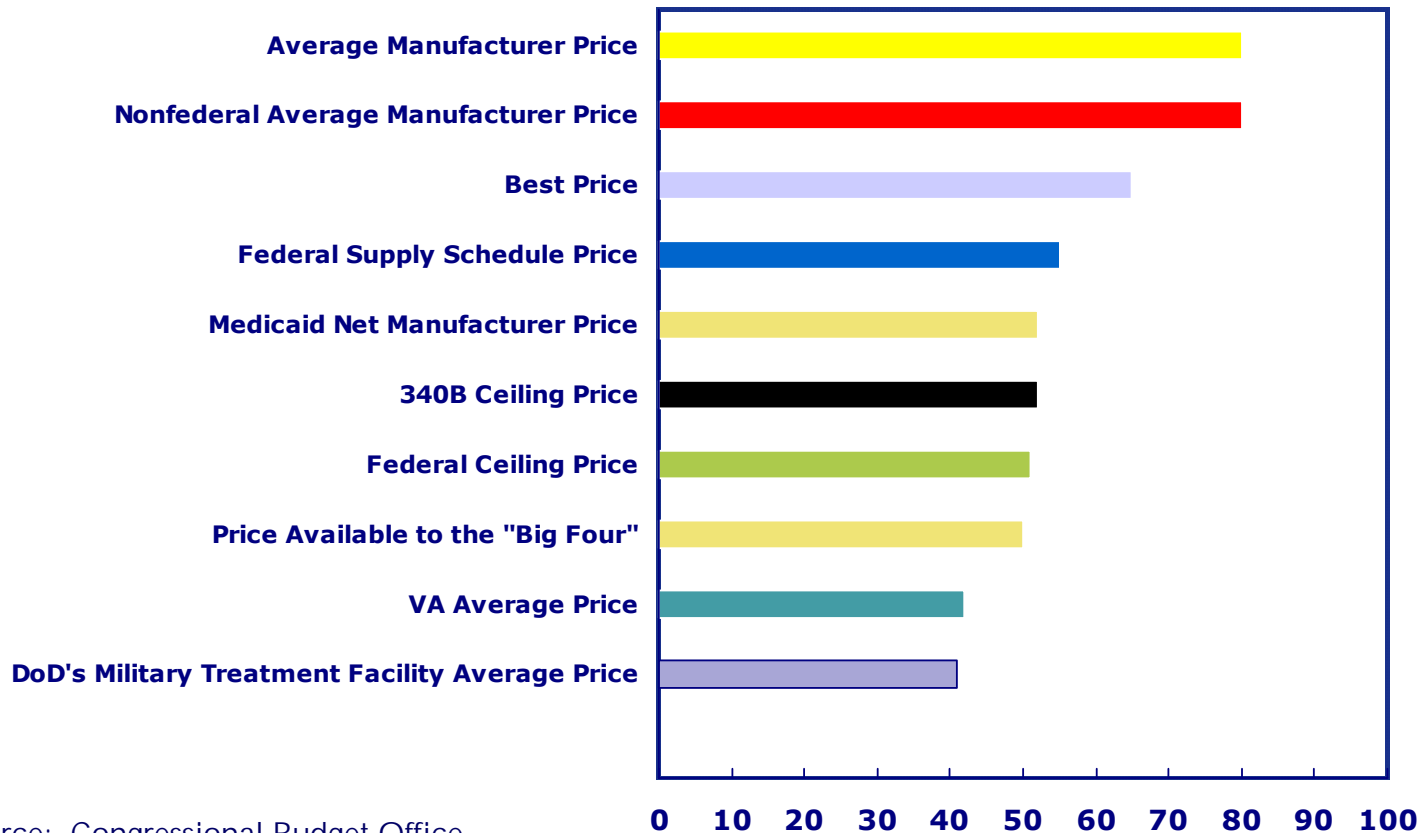
# 340B Discounts and Pricing

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- “Double rebates” not permitted
  - Manufacturers cannot be subject to 340B discount and Medicaid rebate on same drug
  - DSH hospitals not permitted to obtain 340B discount and use Group Purchasing Organization

# Estimated Prices Paid

to Manufacturers Relative to List Price, for Brand-Name Drugs Under Selected Federal Programs, 2003



Source: Congressional Budget Office.

Notes: In this analysis, the list price is the average wholesale price.

The "Big Four" are the four largest federal purchasers of pharmaceuticals: the Department of Veterans Affairs (VA), the Department of Defense (DoD), the Public Health Service, and the Coast Guard.

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# 340B & Pharmacy Arrangements

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- Covered entities can use in-house (outpatient) pharmacies to purchase and dispense 340B drugs
- If no in-house pharmacies, covered entities can contract with one outside pharmacy to act as dispensing agent
  - Covered entity “owns” the drugs, but has them shipped to contract pharmacy
  - Complex recordkeeping/tracking systems required to ensure discount drugs are not diverted
- “Alternative Methods Demonstration” authority allows HRSA to waive one contract pharmacy rule
  - Some covered entities use several contract pharmacies to dispense 340B drugs
  - Others have created networks to allow patients a choice of pharmacies

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# "Patients"

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- 340B drugs may only be dispensed by a covered entity to a "patient" of that covered entity
- What makes a person a "patient"?
  - Covered entity has relationship with individual such that it maintains a record of the individual's health care; *and*
  - Individual receives health care services/prescription from health care professional
    - Employed by the covered entity, *or*
    - Providing services under contractual, referral or other arrangement such that responsibility for care remains with covered entity; *and*
  - Services the individual receives are consistent with the covered entity's grant funding (does not apply to DSH hospitals)
- "Patient" definition causes significant confusion – lots of very gray areas
  - Examples

# 340B Offers Savings/Revenues for Safety Net Providers

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- *340B law does not require covered entities to pass on discounts to patients or 3<sup>rd</sup> party purchasers*
- Covered entities that provide free or reduced price/sliding scale drugs to low-income patients can *save* money by using 340B drugs
- Covered entities that bill insurance or government payors for patients' drugs can *make* money by using 340B drugs
  - Medicaid reimbursement poses special issues

# 340B and Part D: Payment Terms

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- Covered entities may dispense 340B drugs to patients who are enrolled in Part D plans
  - Reimbursement is negotiated by covered entity with Part D plan
  - CMS/HRSA have prepared a “model addendum” for Part D contracts for 340B covered entities
    - Entities/Part D plans not required to use the model addendum
    - Part D plans not required to contract with 340B covered entities, though encouraged
      - Interplay with “any willing provider” provision
    - Some Part D plans offer standard payment terms, others reduced reimbursement to 340B covered entities to capture benefit of 340B discount
      - In some cases, Part D plans may not know about the use of 340B drugs, e.g. in contract pharmacy scenario
- Payment negotiation issues increasingly contentious policy issue
  - Covered entities want CMS/HRSA to weigh in

# 340B and Part D: Copayment Assistance

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- Typically, many covered entities have missions/grants that require them to provide co-payment assistance or sliding scale fees for drugs to low-income patients
  - “low income” for covered entities may exceed Part D’s LIS levels
- When patients are enrolled in Part D, co-payment assistance provided by most covered entities (FQHCs, DSH hospitals, etc.) does NOT count toward TrOOP



# 340B and Part D: Copayment Assistance

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- Co-payment waivers subject to specific CMS/OIG rules to avoid anti-kickback concerns
  - Waivers can't be routine;
  - Indicia of need or inability to pay;
  - Not advertised
- Covered entities may need to consider new ways to advance mission for low-income patients enrolled in Part D who cannot afford copays



# 340B and Medicaid

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- General rule: drug may not be subject to both 340B discount and a Medicaid rebate
  - Known as “double dipping”
- State may elect to claim Medicaid rebate whenever possible
  - In that case, covered entities may not use 340B drugs for Medicaid patients
  - Exceptions where Medicaid reimburses for drugs under bundled per diem or per visit rate and rebate cannot be pursued

OR



# 340B and Medicaid

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- State may elect to forgo Medicaid rebate and reimburse for 340B drug at 340B acquisition cost + dispensing fee/admin fee
  - State must evaluate potential for budget savings
  - Weigh difficulty of pursuing rebates on the back end; value of supplemental rebates; state's up-front reimbursement rate, etc.
  - E.g., Massachusetts



# 340B "Take Up"

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- In January 2006, there were 12,469 Federal grantee covered entities
  - Family Planning Clinics (Title X) – 40%
  - FQHCs – 22%
  - Disproportionate Share Hospitals – 12%
  - Sexually Transmitted Disease Clinics – 11%
  - Tuberculosis Clinics – 8%
  - FQHC Look-Alikes, AIDS Clinics, Black Lung Clinics, Hemophilia Treatment Centers, Urban Indian Clinics, Native Hawaiian Health Centers – 7%



# 340B Growth Expected

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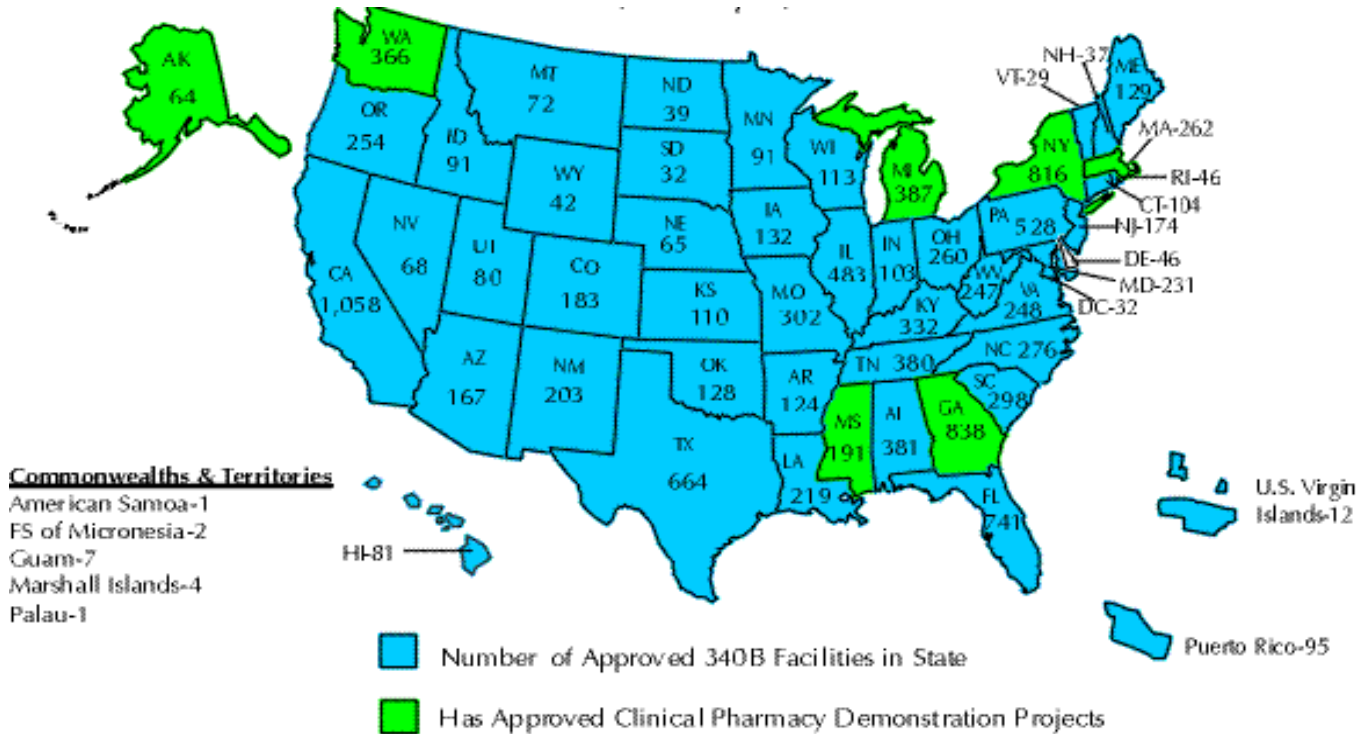
- All covered entities
  - 2005 (actual): 12,000+
  - 2007 (projected): 14,000
- Participating Hospitals (including DSHs)
  - 2005 (actual): 1200+
  - 2007 (projected): ~ 2000
- Contracted Pharmacy Arrangements
  - 2005 (actual): 1075
  - 2007 (projected): 1786

Source: Presentation by Jim Mitchell. "Office of Pharmacy Affairs Update." July 2005.

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# Eligible Health Facilities

For 340B Pharmaceutical Discounts as of January 1, 2006



Sources: Office of Pharmacy Affairs, HRSA, HHS, 2006.

States with Highest Numbers  
 CA – 1058 • GA – 838 • NY – 816 • TX - 664

Source: NCSL. States and the 340B Drug Discount Program.  
<http://www.ncsl.org/programs/health/drug340b.htm>





# 340B and State Partnerships

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- State and local government are increasingly partnering with 340B covered entities to reduce prescription drug costs for certain populations
- Opportunities for savings on drugs purchased by government programs for
  - Medicaid
  - State-financed health insurance other than Medicaid (immigrants; childless adults)
  - Prison populations
  - Mental health populations
  - Nursing home residents in publicly-owned facilities
  - State employees
- To take advantage of 340B prices, government-funded populations must be “patients” of 340B covered entities



# Texas

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- 2001 Legislation required University of Texas Medical Branch at Galveston to purchase drugs through 340B for inmates in UTMB managed care program
- One contracted pharmacy in Huntsville handles all 340B drug dispensing for inmates

Source: 1) Texas State Senate Legislation SB 347. 2) Presentation by Nancy Gast. "Texas Department of Criminal Justice (TDCJ) Managed Care 340B Pricing Initiative".

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# California

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- Recent legislation
  - Authorizes the Department of Corrections to set up a pilot project to provide drugs for inmates through 340B (AB 77; Signed into law 10/05)
    - California Performance Review recommends involving the University of California (a covered entity) as the primary provider of health services to California's inmate population
  - Requires State DOHS to develop a standard contract for private nonprofit hospitals to facilitate participation in 340B program (SB 708; Signed into law 9/05)

# West Virginia

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- Workgroup Established in 2003 with representation from Governor's office, State DHHS, Medicaid, Primary Care Association
  - Increase number of covered entities
  - Increase number of dispensing pharmacies
  - Prioritize contracts with independent pharmacies
  - Enhance coordination of care by forming 340B covered entity network
  - Increase programs that offer cost savings in prisons, Medicaid programs, etc.
- Pharmacy Cost Management Council Established through 2004 Law
  - Makes recommendations to the Governor and Legislature on drug prices, expanding 340B

Source: Presentation by Scott Brown and Phil Schenck. "West Virginia: The Health Care System and 340B". July 2005.

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# West Virginia

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- Launching large-scale educational effort to increase participation in 340B
  - Presentations to Governor's Cabinet, Pharmacy Cost Management Council, DHHS, Public hearings
  - Promotion through WV Primary Care Association
  - Discussions with Board of Pharmacy, Pharmacist's Association

Source: Presentation by Scott Brown and Phil Schenck. "West Virginia: The Health Care System and 340B". July 2005.

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# Issues to Watch

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- Enforcement of anti-diversion rules
- Enforcement of pricing rules
- Drug shortages
- New guidance on definition of “patient”
- New guidance on use of contract pharmacies
- Implementation of expansion to children’s hospitals
- OVERALL: Tensions between program expansion and heightened attention to program integrity issues
  - Providers
  - Manufacturers
  - Regulators



# Questions?

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Andrea G. Cohen

Counsel

Manatt, Phelps & Phillips, LLP

[acohen@manatt.com](mailto:acohen@manatt.com)

212-790-4562

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