The Federal 340B Drug Discount Program: A Primer

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Preview

- 340B Program Overview
  - What is it
  - Who is eligible
  - Pricing/Discounts and Pharmacy Arrangements
  - Revenue/Savings Opportunities for Covered Entities
- 340B and Medicaid
- Impact of AMP Changes
- Issues to Watch

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340B Overview – What is it?

- Established by Congress in 1992
- Requires pharmaceutical manufacturers that contract with Medicaid to provide discounts on outpatient drugs purchased by "covered entities"
  - Generally, designated safety net providers that receive government funds for safety net mission
  - Outpatient drugs include physician-administered and patient prescription
- Administered by the Office of Pharmacy Affairs (OPA) in the Health Resources and Services Administration (HRSA)

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340B Overview

- "Covered entities" (CEs) include
  - Federally-qualified health centers (FQHCs) and "look-alikes"
  - Public and non-profit high-DSH hospitals that have indigent care contracts with state/local governments
    - DRA added Children's Hospitals, but inclusion not implemented to date
  - Ryan White CARE Act grantees
  - Title X Family Planning/STD clinics
  - TB and Black Lung Clinics
  - Urban Indian clinics
  - Homeless clinics

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340B Discounts and Pricing

- 340B "ceiling" price = rough Medicaid "net" price
  - AMP – mandatory unit rebate amount (URA) under SSA §1927(c)
- CEs 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
- "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

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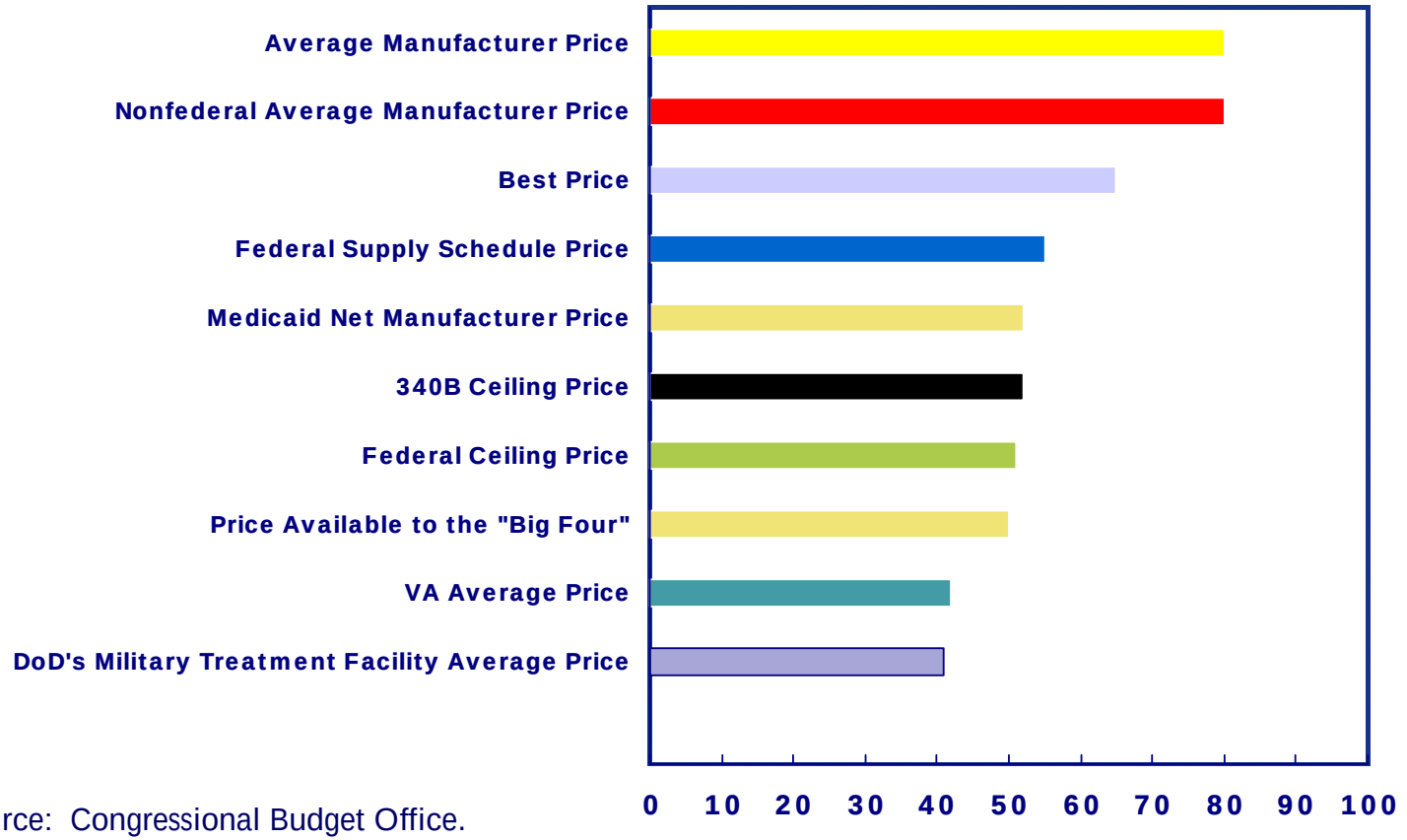
Estimated Prices Paid

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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Impact of AMP Changes

- OPA has flip-flopped on issue of whether DRA AMP changes will apply in 340B context
- Changes, including exclusion of prompt pay discounts, likely to raise 340B prices overall
- OPA January 2007 letter to manufacturers: calculate a separate 340B AMP based on pre-DRA guidance to set ceiling prices
- OPA May 2007 letter to manufacturers: you can calculate ceiling prices using the new AMP methodology "until further notice"
  - Promised more analysis and consideration

340B & Pharmacy Arrangements

- CEs have two options to dispense 340B drugs:
  - Use in-house (outpatient) pharmacies to purchase and dispense 340B drugs
  - Contract with 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 to non-CE patients
- "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
- Proposed HRSA rule would allow CEs to contract with multiple pharmacies

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"Patients"

- 340B drugs may only be dispensed to CE "patients"
- What makes a person a "patient"?
  - CE has relationship with individual such that it maintains a record of the individual's health care; *and*
  - Individual receives health care services 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)
  - An individual not a "patient" of the entity for purposes of 340B if the only health care service received from the covered entity is the dispensing of a drug or drugs for subsequent self- administration or administration in the home setting.
- Proposed Rule to tighten patient definition

340B Offers Savings/Revenues for Safety Net Providers

- 340B law does not require CEs to pass on discounts to patients or payers
- CEs that provide free or reduced price drugs to low-income patients can *save* money with 340B
- Covered entities that bill insurance or government payors for patients' drugs can *make* money by using 340B drugs
  - Medicaid reimbursement poses special issues

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340B and Medicaid

- 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

- 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
- Heinz reports – RI and WA state
- Impact of DRA and J-codes issues

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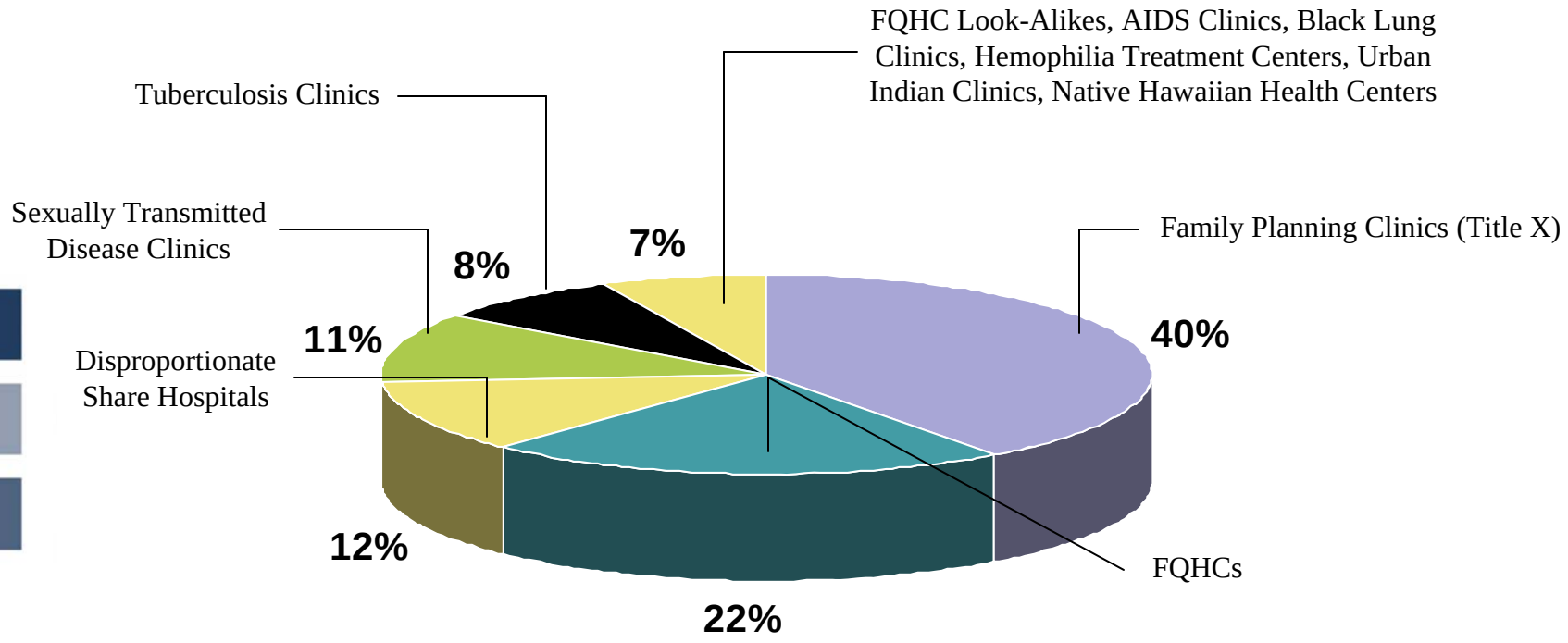
340B Participation

(As of January 2006)



- N = 12,469
- Covered entities purchased roughly $3.5 billion in drugs in 2003

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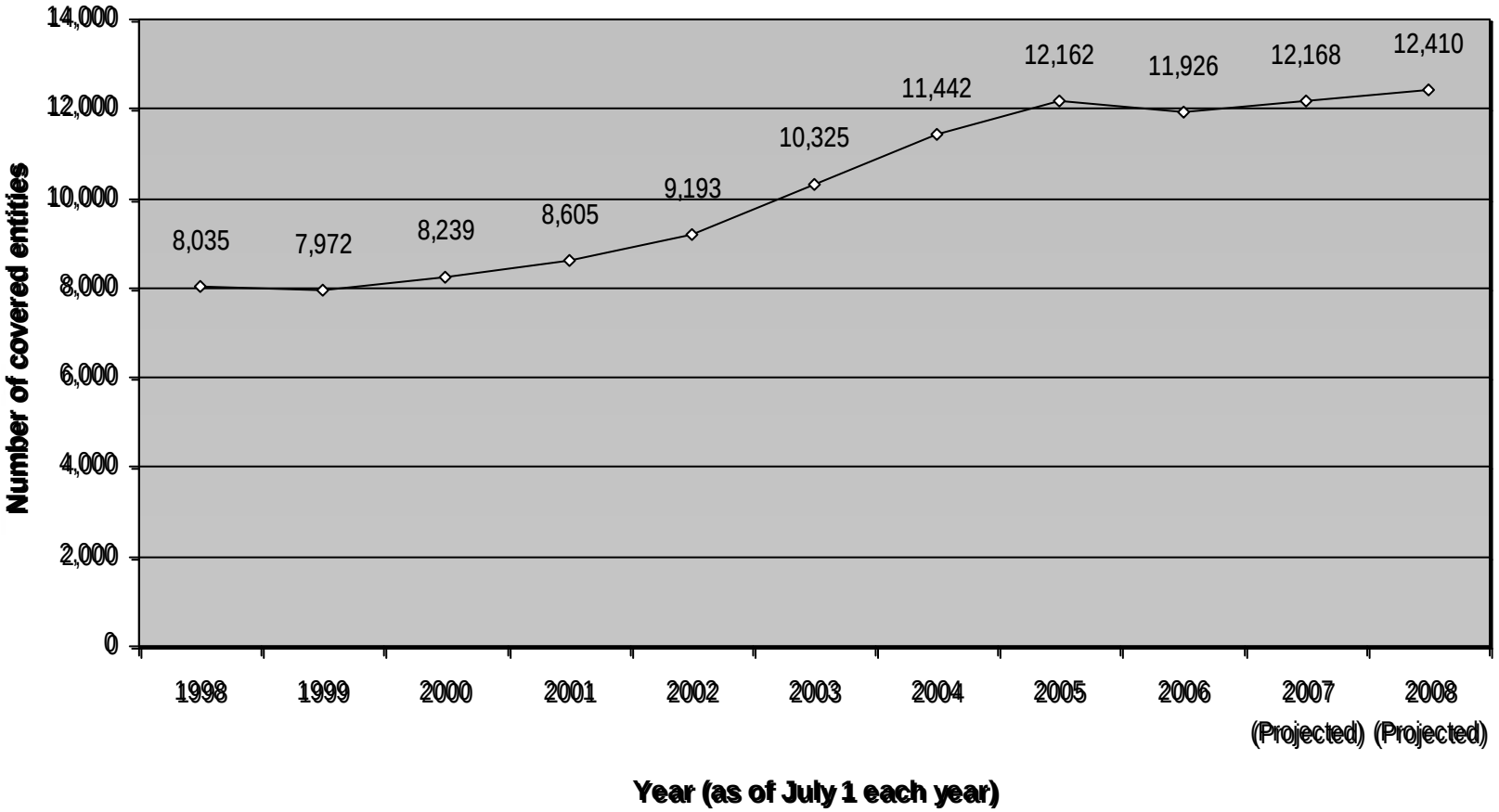
Growth in Participating CE Sites



Source: Presentation of Jimmy R. Mitchell, RPh, MPH, MS (July 17, 2006)

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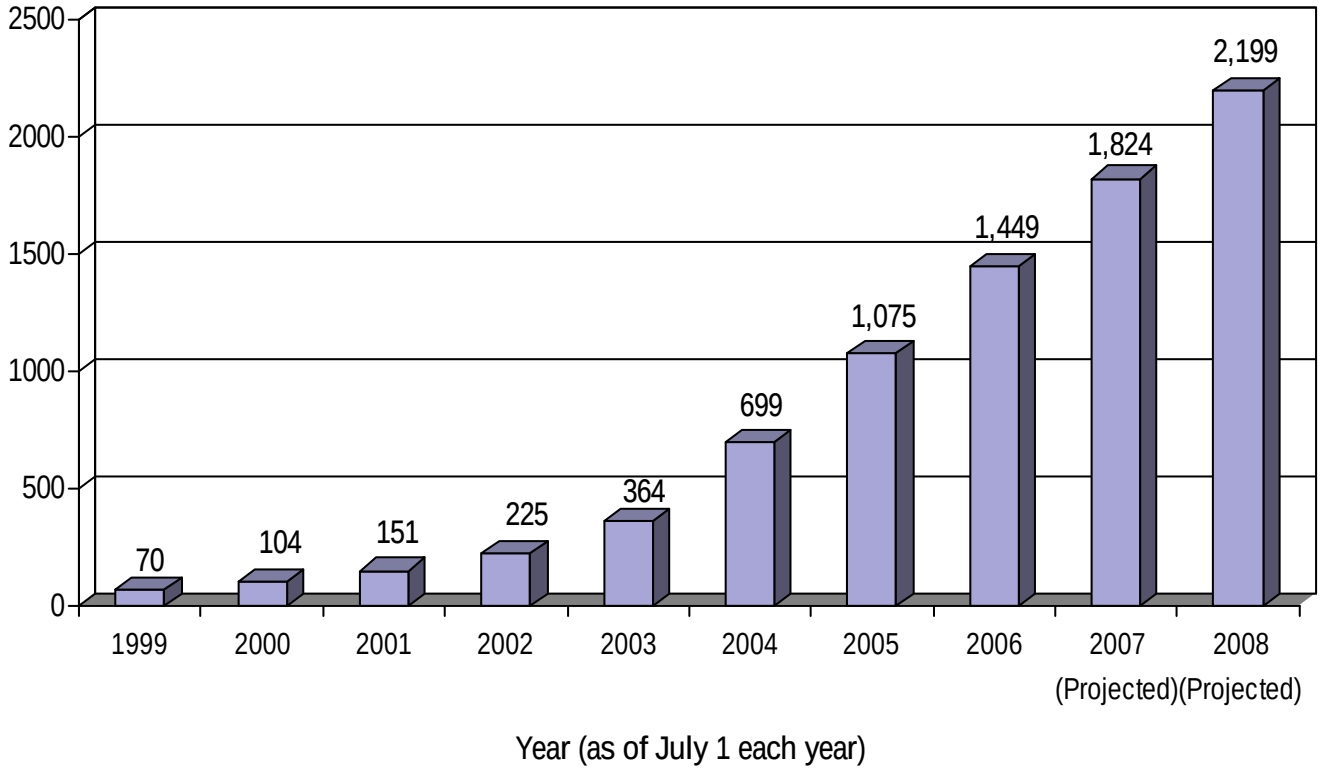
Growth in Contracted Pharmacy Arrangements



Source: Presentation of Jimmy R. Mitchell, RPh, MPH, MS (July 17, 2006)

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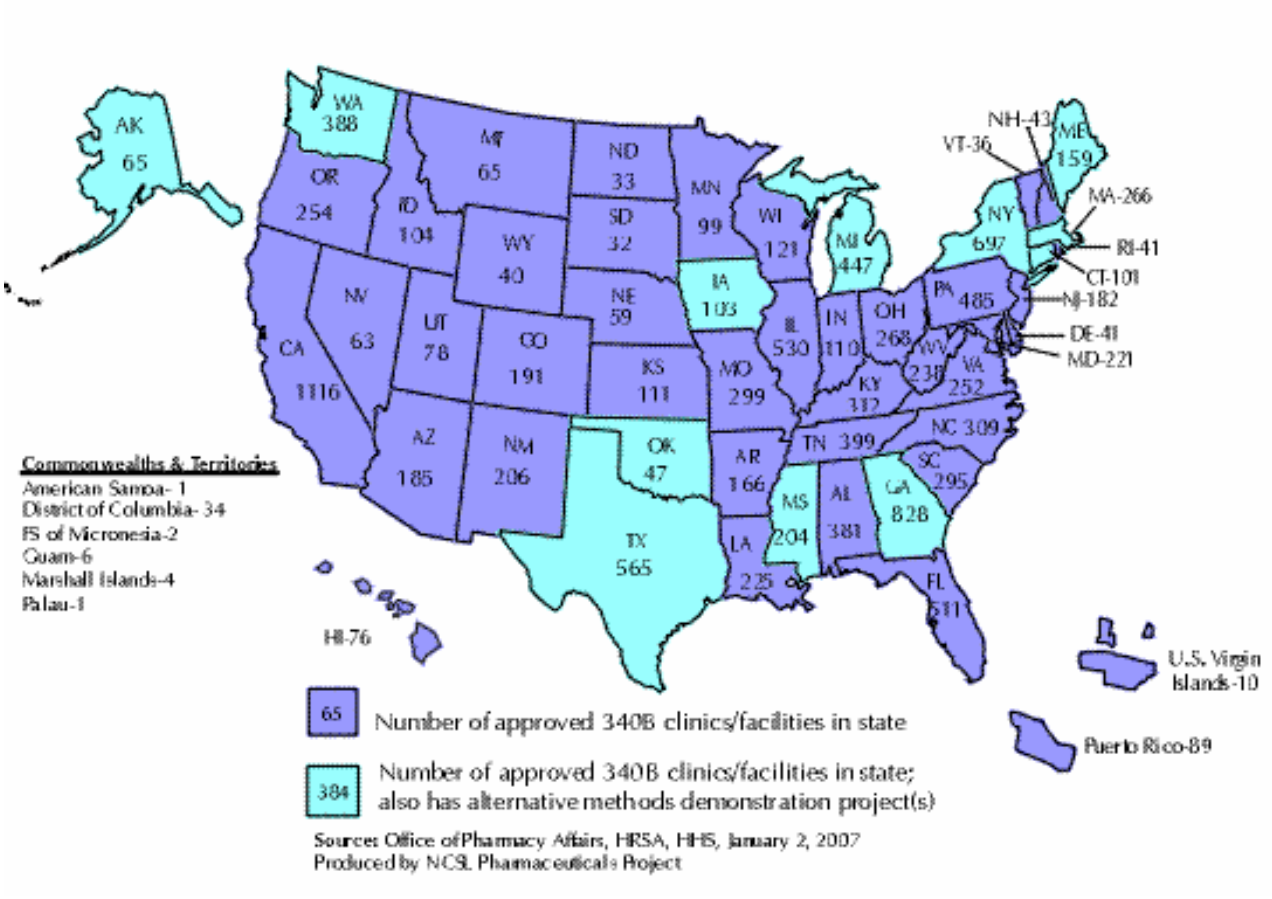
Eligible Health Facilities

For 340B Pharmaceutical Discounts as of January 2007



States with Highest Numbers

CA – 1116 • ID 1074 • GA 828 • NY 697

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

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340B and State Partnerships

- State and local government frequently working with CEs to reduce Rx drug costs for certain populations
- Opportunities for government savings on drugs:
  - 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 still qualify as patients of 340B covered entities

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Texas

- 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

- 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)

Source: Official California Legislative Information Web Site. http://www.leginfo.ca.gov/.

New York

- 2005 provision requires Medicaid program to purchase 340B drugs
  - State could not seek Medicaid rebate from manufacturers for 340B drugs
  - Reimbursement to CEs would be set at acquisition cost plus a dispensing fee
- Savings to State were anticipated
- State has not yet implemented the provision
  - Pricing trends in 340B and Medicaid may reduce States' 340B savings opportunities

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Current Issues: Pricing Integrity

- AMP and URA are confidential, so CEs and wholesalers can't assess appropriateness of manufacturer 340B pricing
- OIG Report 7/06 found that CEs are paying higher prices for 340B drugs in some cases than the statutory pricing scheme allows
- OPA has begun more active monitoring of 340B ceiling prices, with data-sharing with CMS on AMP and URA
- Seeking manufacturer voluntary submission of 340B ceiling prices to do comparisons

Current Issues: Diversion to Non-Patients

- Notice regarding proposed new "patient" definition recognizes proliferation of CE arrangements that may extend 340B pricing beyond traditional "patient" populations
  - DSH /CE employees with no clinical relationship
  - Patients of community physicians with privileges at DSH/CEs
  - Individuals receiving care management services only sponsored by CE

Issues to Watch

- Impact of AMP pricing changes
- New guidance on definition of “patient”
- New guidance on use of contract pharmacies
- Implementation of expansion to children’s hospitals
- Agency enforcement authority
- State expansion efforts
- Federal proposals to expand reach of 340B and authorize more rigorous enforcement

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Questions?

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