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

- 340B and Part D

- 340B and Medicaid

- State Opportunities

- Issues to Watch
340B Overview – What is it?

- 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

- “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

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

- 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

- “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.
340B & Pharmacy Arrangements

- 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.
“Patients”

- 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

- **340B law does not require covered entities to pass on discounts to patients or 3rd 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

- **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

- 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

- 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

- **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
340B “Take Up”

- 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

- **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

Eligible Health Facilities
For 340B Pharmaceutical Discounts as of January 1, 2006

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

Source: NCSL. States and the 340B Drug Discount Program.
340B and State Partnerships

- 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

- 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”.
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)

West Virginia

- 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

West Virginia

- 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
Issues to Watch

- 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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