An Introduction to and Updated Regarding the 340B Federal Drug Discount Program

Chris Roberson, JD, MPH
INDIANA HEMOPHILIA & THROMBOSIS CENTER, INC.

helping patients thrive
Raphael Health Center
Eskenezi Health
340B Federal Drug Discount Program
The Medicaid rebate program requires drug companies to enter into a rebate agreement with the Secretary of the Department of Health and Human Services (HHS) as a precondition for coverage of their drugs by Medicaid and Medicare Part B.

Section 340B of the Public Health Service Act (1992) requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign an agreement with the Secretary of Health and Human Services. This agreement limits the price manufacturers may charge certain covered entities for covered outpatient drugs.

The resulting program is called the 340B Drug Pricing Program.

The program is administered by the Office of Pharmacy Affairs (OPA), a part of the federal Health Resources and Services Administration (HRSA)/Department of Health and Human Services.
Under the program, a manufacturer must pay rebates to state Medicaid programs for “covered outpatient drugs,” as defined in the Medicaid rebate statute. The rebate amount for a brand name covered outpatient drug is based in part on the manufacturer’s “best price” for that drug.

In 1992, Congress extended to safety-net providers the same kind of relief from high drug costs that Congress provided to the Medicaid program with the Medicaid rebate law. In particular, Congress enacted Section 340B of the Public Health Service Act (created under Section 602 of the Veterans Health Care Act of 1992).

According to congressional report language, the purpose of the 340B program is to enable covered entities “to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”
How the 340B program works

1. Manufacturer provides 340B discounted drugs to eligible hospitals and clinics
2. 340B Hospitals and clinics dispense medications to eligible patients
3. Reimbursement from insurance companies provides revenue to 340B Hospitals and clinics
Overview

- **340B in context**
  - State and national statistics
  - Who supports and opposes the program

- **340B eligibility, rules and regulations**
  - General eligibility and requirements
  - Medicaid – generally, and Indiana
    - Indiana’s 340B covered entity community

- **340B compliance**
  - HRSA Audits
  - Compliance Preparedness
Indiana’s Covered Entities

As of 9/25/2017

- Critical Access Hospital, 61, 8%
- Community Health Center, 149, 20%
- Disproportionate Share Hospital, 433, 57%
- STD, 46, 6%
- TB, 2, 0%
- SCH, 11, 1%
- RRC, 11, 1%
- HV, 2, 0%
- Family Planning Clinic, 34, 5%
- FQHCLA, 1, 0%
- Hemophilia Treatment Center, 1, 0%
- Ryan White, 5, 1%
National Covered Entities

As of 9/25/2017
Financial Scope of the Program

- In 2015, HRSA estimated that covered entities saved approximately $6 billion\(^1\)
- Estimated to account, for 2-5% of the national drug spend\(^2,3\)

1. 82 Fed. Reg. 1210, 1227 (Jan 5, 2017)
Who (generally) supports and opposes 340B?

- Covered Entities
- 340B Health
  - Member organizations
- Patients

- PHARMA
  - AIR340B - Alliance for Integrity and Reform of 340B
- Medicaid?
WHO IS ELIGIBLE TO PARTICIPATE IN THE 340B PROGRAM?
The definition of "covered entities" includes six categories of hospitals:

1. Disproportionate share hospitals (DSHs),
2. Children’s hospitals,
3. Cancer hospitals exempt from the Medicare prospective payment system,
4. Sole community hospitals,
5. Rural referral centers, and
6. Critical access hospitals (CAHs).
The definition of "covered entities" includes six categories of hospitals:
1. Disproportionate share hospitals (DSHs),
2. Children's hospitals,
3. Cancer hospitals exempt from the Medicare prospective payment system,
4. Sole community hospitals,
5. Rural referral centers, and
6. Critical access hospitals (CAHs).
There are also eleven categories of non-hospital covered entities that are eligible based on receiving federal funding.

1. Federally qualified health centers (FQHCs),
2. FQHC “look-alikes”,
3. State-operated AIDS drug assistance programs,
4. Ryan White Comprehensive AIDS Resources Emergency (CARE) Act clinics,
5. Tuberculosis clinics,
6. Black lung centers,
7. Family planning clinics,
8. Sexually transmitted disease clinics,
9. Hemophilia treatment centers,
10. Title X public housing primary care clinics; homeless clinics, and
11. Urban Indian clinics; and Native Hawaiian health centers.
There are also eleven categories of non-hospital covered entities that are eligible based on receiving federal funding.

1. Federally qualified health centers (FQHCs),
2. FQHC “look-alikes”,
3. State-operated AIDS drug assistance programs,
4. Ryan White Comprehensive AIDS Resources Emergency (CARE) Act clinics,
5. Tuberculosis clinics,
6. Black lung centers,
7. Family planning clinics,
8. Sexually transmitted disease clinics,
9. Hemophilia treatment centers,
10. Title X public housing primary care clinics; homeless clinics, and
11. Urban Indian clinics; and Native Hawaiian health centers.
Registration

- https://340bregistration.hrsa.gov/login

- Covered entities must recertify their eligibility every year and notify the Office of Pharmacy Affairs whenever there is a change in their eligibility.
340B PROGRAM REGULATIONS & REQUIREMENTS
Program Requirements

- Keep 340B OPAIS Information accurate and up to date
- Recertify eligibly each year
- Prevent diversion to ineligible patients
  - Patient definition (for covered services only)
  - Outpatient only
- Duplicate Discount Prohibition
- Maintain auditable records
Prevent diversion to ineligible patients

An individual is a “patient” of a covered entity only if:

1. the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual’s health care; and

2. 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 responsibility for the care provided remains with the covered entity; and

3. the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding has been provided.
For drugs dispensed or administered to Medicaid recipients on a fee-for-service (FFS) basis, the law prohibits using 340B for Medicaid drugs that are subject to rebates, unless the covered entity complies with certain requirements.

- Covered entities must first decide whether they will use 340B drugs for their Medicaid patients (i.e., carve in).
- The rules for carving in differ depending on whether a contract pharmacy is used.
- To carve in drugs dispensed or administered at a registered outpatient, an entity must inform OPA of its decision to carve in and ensure that the numbers it uses to bill 340B drugs to Medicaid (i.e., national provider identifier (NPI) and/or state-specific billing numbers) are listed in OPA’s Medicaid exclusion file database.
- Some states impose additional notification requirements, such as requiring the use of a modifier on 340B claims. In most states, entities can elect to purchase their Medicaid covered outpatient drugs outside the 340B program (i.e., carving out).
All pharmacy benefits were carved out of Medicaid Managed Care and run through Traditional Medicaid (Fee For Service) from 2010-2015.

Beginning in 2015, pharmacy benefits were added back into the Managed Care Organization contracts and therefore the state needed to identify a process for MCOs to identify 340B claims.

- The ACA expanded Medicaid Rebates to MCOs.
Best Practices to ensure compliance with the duplicate discount prohibition

- Add contractual language with the MCOs explicitly stating that Covered Entity will be using 340B medication for MCO beneficiaries, and contractually requiring the MCO not include these dispensations in any rebate request data provided to or on behalf of the state
- Register a separate NPI number on the Medicaid Exclusion File that is used exclusively for Medicaid MCO beneficiaries
- Utilize a modifier to identify claims as 340B
CMS Rules

Covered Outpatient Drug Rule
▪ Required states to reimburse retail-dispensed drugs covered by fee-for-service (FFS) Medicaid at Actual Acquisition Cost (AAC) and to submit for CMS approval a State Plan Amendment (SPA) describing the state’s AAC reimbursement policy.

Medicaid Managed Care Rule
▪ Directed states to develop mechanisms capable of ensuring that Medicaid rebates are not collected on 340B drugs billed to Medicaid MCOs.

81 Fed. Reg. 5170 (Feb. 1, 2016)
81 Fed. Reg. 27497 (May 6, 2016); 340B Exclusion - § 438.3 (s)(3)
Indiana Medicaid’s Informal Proposal(s)

Summer/Fall 2016

• Indiana Medicaid staff publicly discussed the concept of prohibiting the use of 340B for MCOs to prevent duplicate discounts and maximize state rebates as part of required SPA

Winter 2016/2017

• Indiana Medicaid staff discuss the following proposals:
  1. Prohibit 340B for MCO
  2. Allow 340B, but require AAC billing
Efforts to engage a coalition of 340B entities throughout the state

- Initial call of a few CEs convened by Washington law firm
- Participants in the initial call contacted state trade associations (Primary Care, Hospital, etc.) and other individual CEs
- Meeting with FSSA Secretary, Medicaid Director, Medicaid Director of Pharmacy and approximately 15 CEs, followed by a letter from CEs describing our collective position
Position of Indiana’s 340B CEs

- The COPD only applies to Fee For Service Medicaid.
- A mandatory carve-out approach would undermine the 340B program’s purpose.
- Prohibiting the use of 340B, or requiring that CEs carve-in at the 340B acquisition price for MCOs would be financially devastating to Indiana’s safety net providers.
- Directing MCOs’ reimbursement methodology would contravene CMS’ Managed Care Regulation.

1. Except under certain circumstances, the State may not direct the MCO's, expenditures under the contract.
- 42 CFR 438.6 - Special contract provisions related to payment. Subsection C.
Final State Plan Amendment

- **What Medicaid said:**
  - Addresses requirements of COPD only
  - Does not direct any changes regarding 340B policy or reimbursement for MCOs

- **Indiana CEs offered to work alongside members of the Agency to serve as a task force for formulating 340B billing and payment policy.**
  - FSSA’s Response:
    
    “The Agency is appreciative of the new proposals and offer of assistance from the coalition, but respectfully declines to participate in further activities involving 340B drugs with members of the coalition at this time.”

- **What the SPA says:**
  - Drugs acquired through the 340B drug pricing program and dispensed by 340B contract pharmacies are not covered
  - References a section of the previously approved State Plan, which was modified to read “A CE billing for physician administered drugs purchased through the 340B program is reimbursed at the CE’s actual acquisition cost.”

Scrutiny of the 340B Program

- Congressional Hearing tomorrow October 11, 2017
- 20 CEs Received letters\(^1\) to provide testimony and/or information related to:
  - Number of drugs purchased through the program
    - By drug class
    - By payer (including uninsured)
    - Amount of savings compared to GPO pricing
  - Amount of charity care (amount and number of patients receiving)
  - How savings are used to care for vulnerable populations
  - How savings are shared with contract pharmacies

---

Conclusions

- The 340B Program can help safety net providers expand services to vulnerable patients

- The Program has grown significantly over the past decade, and with that growth has come increased scrutiny of:
  - What covered entities do with revenue generated from the sale of 340B drugs (i.e. how much charity care they provide), and
  - Compliance with program requirements

- **Current or future entities participating in the program must:**
  - Ensure full compliance with all 340B rules and requirements, and
  - Quantify and qualify the expanded programs and services provided to vulnerable patients as a result of participation in the program
Resources for more information

www.340bpvp.com

www.340bhealth.org/

https://www.hrsa.gov/opa/index.html
Additional Questions?

Chris Roberson, JD, MPH
Director of Compliance and Community Programs
Indiana Hemophilia & Thrombosis Center, Inc.
8326 Naab Road
Indianapolis, Indiana 46260
Phone: 317-871-0011
crobertson@ihtc.org