

BKD Health Care

**340B
Prescription
for Success**

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This presentation should not be relied upon as legal advice.

Agenda

- 340B Overview
- 340B Compliance
- 340B Audits
- 340B Strategy
- 340B Legislative Update
- Questions

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“You can’t solve a problem on the same level it was created. You have to rise above it to the next level.”

Albert Einstein

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340B Drug Pricing Program (340B Program) Overview

- Federally mandated drug pricing program created in 1992
- 2017 marked the 25th anniversary of the program
- Part of Public Health Service Act, section 340B & Medicaid rebate program
 - Drug manufacturers must provide front-end discounts on covered outpatient drugs purchased by covered entities
- Provides discounts on outpatient drugs purchased by “safety net” providers for eligible patients
 - Intended to provide financial relief to facilities that provide care to medically underserved
- Average savings of 25 - 50% for eligible covered entities on outpatient drugs
- How are covered entities using 340B savings?

Provide discounts on drugs to patients



Expand services by provider to patients

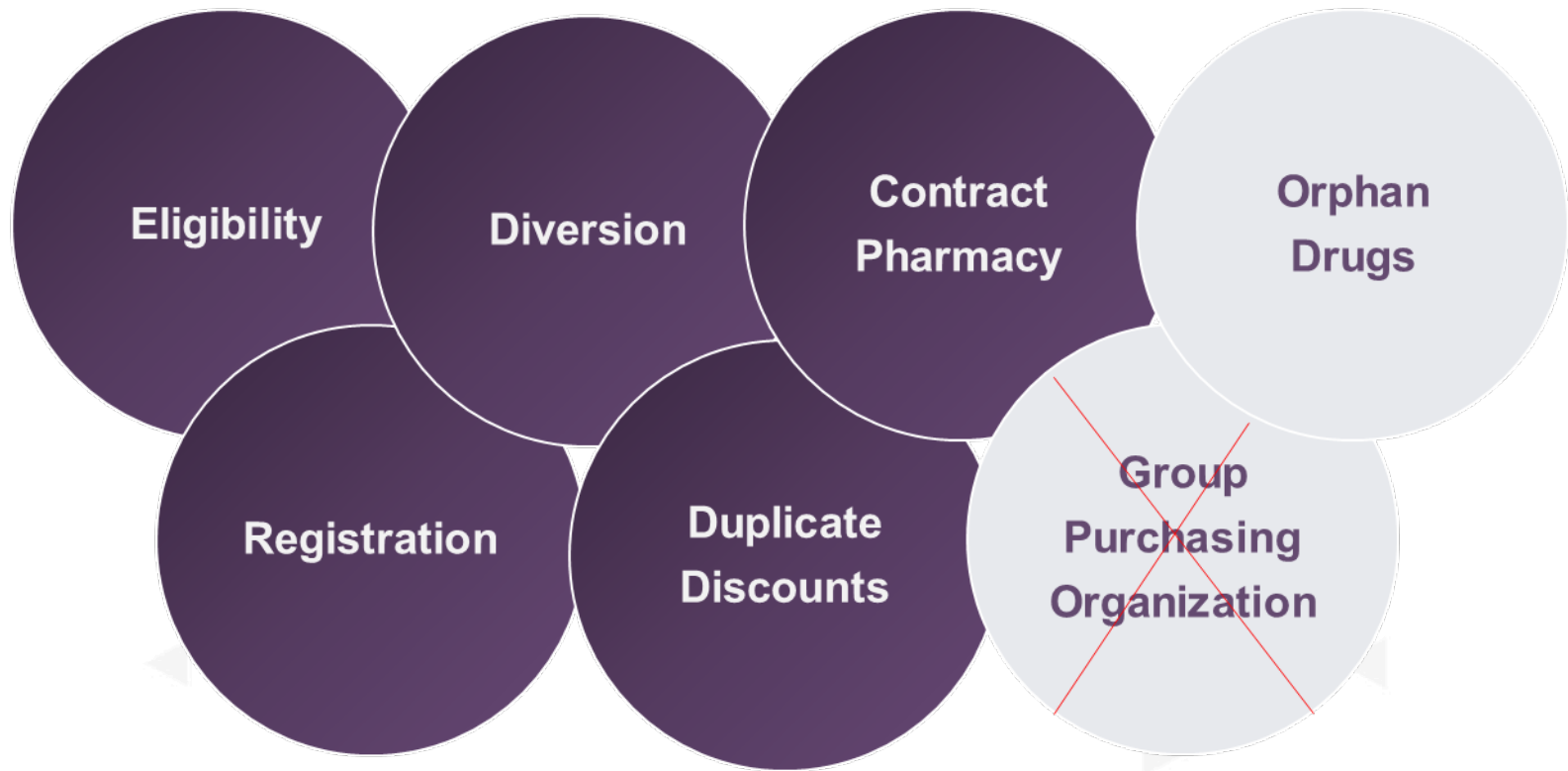


Provide services to more patients

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340B Compliance



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Eligibility

340B participation is limited to only certain non-profit and government affiliated hospitals.

- **Disproportionate Share Hospital (DSH) Hospitals** – traditional acute care hospitals that can demonstrate a DSH Adjustment Factor greater than 11.75% on the most recently filed Medicare Cost Report
- **Children’s Hospitals** – pediatric hospitals with a 3300-series Medicare provider number that can perform a DSH calculation based on worksheet S-3 and demonstrate a result greater than 11.75%
- **Sole Community Hospitals (SCH)** – hospitals with Sole Community designation that can demonstrate a DSH Adjustment Factor greater than 8.0% on the most recently filed Medicare Cost Report
- **Rural Referral Centers (RRC)** – hospitals with Rural Referral Center designation that can demonstrate a DSH Adjustment Factor greater than 8.0% on the most recently filed Medicare Cost Report
- **Critical Access Hospitals (CAHs)** - All CAHs, regardless of DSH values
- **Ryan White HIV/AIDS Program Grantees**
- **Specialized Clinics** – Black Lung Clinics, Hemophilia Diagnostic Treatment Centers, Title X Family Planning Clinics, Sexually Transmitted Disease Clinics, Tuberculosis Clinics
- **Community Health Centers** – Federally Qualified Health Centers, Federally Qualified Health Center Look-Alikes, Native Hawaiian Health Centers, Tribal/Urban Health Centers

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Registration

- 4 registration periods annually in the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs Information System (OPAIS) database
- Authorizing Official & Primary Contact must be different individuals and neither can be consultant
 - Both are required to create logins with 2 step authentication
- Only Authorizing Official can attest to changes, registrations, terminations and recertification
- Contract with local or state government
- Federal Grant Number or most recently filed Medicare cost report
- Medicaid Billing Number and National Provider Identifier if carving in Medicaid
- If participating in contract pharmacy, contract pharmacy must be registered in the database and there must be a written contract in place prior to registration.
- 340B OPAIS will house the statutorily mandated secure website to make 340B ceiling pricings available to providers

Recertification

- 340B covered entities must annually recertify their 340B eligibility
- Notifications are sent to Primary Contact & Authorizing Official
- Once recertification period begins the Authorizing Official only has access via their user accounts to attest their covered entity's compliance with 340B requirements & complete recertification
- Contacts listed in the 340B database must be accurate at all times to receive all notifications
- If covered entity fails to recertify, termination from program will occur

Diversion

Diversion

- Drugs can only be used on an outpatient basis for covered entity's patients as defined by HRSA
- Use for other individuals constitutes prohibited diversion
- Focus on defining **“patient”** & **“covered entity”**

What is **“covered entity”**?

- Where services are provided
- Physicians must be employed or under a contractual or other arrangement
- Entity should maintain a listing of approved 340B physicians

Medicaid Duplicate Discounts

- 340B laws prohibit application of both 340B price discount on front end and payment of pharmacy rebate to state Medicaid on back end for same drug claim
- General options for covered entities
 - **Carve-out** Medicaid - from 340B drug purchases
 - **Carve-in** Medicaid - requires verifying Medicaid exclusion file is accurate in 340B OPAIS
- Some states have been slow to establish and communicate Medicaid billing requirements and potential modifiers
- Transition to Medicaid managed care has created confusion
 - Covered entities should have mechanisms in place to identify Medicaid Managed Care Organization (MCO)
 - Contract pharmacies should not “Carve-in” Medicaid Fee for Service (FFS) and should review state guidance and consult with legal on Medicaid MCO

The responsibility for avoiding duplicate discount is on the covered entity

Medicaid Duplicate Discount - Medicaid Apexus Tool

Colorado Medicaid State Details (as of 07-FEB-18)

Retail

Drug Ingredient Cost
340B AAC Invoice

Professional Dispensing Fee
9.31

Required Claim Identifiers
SCC = "20" and BOCD = "08"

Professional Dispensing Fee (Max Range)
14.14

Provider or Facility Administered Drugs

Drug Ingredient Cost
340B AAC Invoice

Required Claim Identifiers
UD

Can Contract Pharmacies Dispense 340B Drugs
No - explicitly prohibited by state

Comments/Notes

Colorado	Current Quarter			Prior Quarter	
	% Carve-IN	Number of 340B CEs	Change from Prior Quarter	% Carve-IN	Number of 340B CEs
All Types	61%	115	-3%	62%	119

Colorado Medicaid Contacts

Technical Contact	Rebate Contact	Policy Contact
MAURY ANDERSON MBDaniels@magellanhealth.com 11013 WEST BROAD ST, SUITE 500 GLEN ALLEN, VA 23060 (804) 548 0336	FELICIA DIPAOLO FLDipaolo@magellanhealth.com 11013 WEST BROAD ST., SUITE 500 GLEN ALLEN, VA 23060 (804) 548 0338	TOM LEAHEY thomas.leahey@state.co.us 1570 GRANT STREET DENVER, CO 802031714 (303) 866 2617

- Recommendation – Engage in ongoing dialogue with Medicaid pharmacy directors of the states where you file claims—a “win-win” solution may be available

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Orphan Drugs

- These covered entity types must purchase all orphan drugs at non-340B pricing
 - Critical Access Hospitals
 - Sole Community Hospitals
 - Rural Referral Centers
 - Free-Standing Cancer Hospitals
- Manufacturers are not required to provide these covered entities orphan drugs under the 340B Program. A manufacturer may, at its sole discretion, offer discounts on orphan drugs to these hospitals
- 340B Like Pricing
- October 14, 2015 – U.S. District Court for District of Columbia ruled on Orphan Drug Interpretation
- HRSA lacks the authority to allow 340B pricing for orphan drugs used for common indications

Contract Pharmacy

- HRSA allows providers to enter into arrangements with multiple contract pharmacies to dispense 340B drugs to qualifying patients of providers
- Covered entity is responsible for compliance and must monitor contract pharmacies
- Monitor and self audit
 - Are the settings, eligibility requirements, rules and testing parameters effectively identifying 340B transactions and excluding ineligible transactions?
- HRSA recommends independent audits
- Child sites, outpatient clinics
- Retail pharmacy 340B software
- Brand vs. generic
- Do you periodically review your contract pharmacy arrangements?

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HRSA Audits

- HRSA has the authority to audit covered entities and audits began in 2012
- HRSA has conducted approximately 200 audits annually since 2015
- Results are publicly available
- Audits initially had a collaborative/educational tone but the tone has changed when HRSA began instituting punitive penalties to ensure compliance
- HRSA audits conducted by the Bizzell Group
- HRSA will continue to focus on contract pharmacy arrangements, diversion, duplicate discounts & 340B database records

Example Audit Findings

- Incorrect 340B OPAIS Database Record
- Entity did not provide contract pharmacy oversight
- Diversion
 - 340B drugs dispensed at contract pharmacy for prescriptions written at ineligible sites
 - 340B drug dispensed to inpatient; 340B drugs dispensed at contract pharmacies, not supported by a medical record
 - 340B drugs were not properly accumulated
- Duplicate Discounts
 - Inaccurate or incomplete information in the Medicaid Exclusion File.
 - Entity was billing Medicaid contrary to information included in the Medicaid Exclusion File

Preparing for HRSA Audit

- HRSA audits are designed to:
 - Obtain an understanding of the entity's policies, procedures, and drug distribution system;
 - Review the entity's eligibility status, including compliance with the Group Purchasing Organization (GPO) prohibition for certain entity types;
 - Review drug procurement and distribution to determine whether the entity provided 340B drugs to appropriate patients as defined by Section 340B(a)(5)(B) of the Public Health Service Act (PHSA); and
 - Determine whether the entity properly prevented duplicate discounts, as required by Section 340B(a)(5)(A) of the PHSA.

Preparing for HRSA Audit, continued

- HRSA audit work procedures will include:
 - Review of policies, procedures and processes that pertain to 340B
 - Verification of internal control in place to prevent diversion and duplicate discounts
 - Testing, on a sample basis, transactions that pertain to 340B drugs

Preparing for HRSA Audit, Data request

- Data request:
 - Policies and Procedures
 - Covered entity eligibility documentation
 - Listing of 340B eligible locations
 - Most recently filed Medicare Cost Report
 - Trial balance and crosswalk
 - Contract with state or local government
 - Provide 340B universe for previous 6 month period
 - Dispensations for previous 6 month period
 - Provider list
 - Purchasing for previous 6 month period
 - Contract pharmacy documentation
 - Self-disclosure documentation, if applicable
 - Medicaid billing documentation

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Preparing for HRSA Audit, Timeline

- Timeline
 - HRSA will send covered entity letter stating selection for audit
 - Pre-site visit conference call with Bizzell Group
 - Bizzell Group will spend 2 days on-site (45-60 days after receiving letter)
 - Report provided
 - Corrective action plan (CAP)

Preparing for HRSA Audit, On Site

- On Site Audit
 - Audit procedures include, at a minimum:
 - review of relevant policies and procedures and how they are operationalized;
 - verification of eligibility, including Group Purchasing Origination (GPO) and outpatient clinic eligibility;
 - verification of internal controls to prevent diversion and duplicate discounts, including how the covered entity defines whether a patient is considered inpatient or outpatient, HRSA Medicaid Exclusion File designations, and accuracy of covered entity's 340B OPAIS record;
 - review of 340B Program compliance at covered entity, outpatient or associated facilities, and contract pharmacies; and
 - testing of 340B drug transaction records on a sample basis.

Preparing for HRSA Audit, On Site Continued

- On Site Audit
 - Introductory meeting
 - Observe processes/systems
 - Outpatient site visits
 - Contract pharmacy visit
 - Inventory, dispensing, procurement
 - Analysis of samples
 - Follow up questions raised during audit
 - Exit conference
 - Results are not provided at the conclusion of the audit

Preparing for HRSA Audit, Post Audit

- Post Audit
 - No preliminary results provided by auditor at the conclusion of on-site audit, auditors findings are sent to Office of Pharmacy Affairs (OPA) for review and OPA finalizes
 - 3-6 months to receive final report
 - 30 days to challenge findings
 - 60 days to submit CAP
 - After corrective action plan approval, periodic CAP implementation updates
 - CE attests to completion of CAP
 - Audit closure

Manufacturer Audits

Manufacturer Audit Guidelines

May only conduct after showing of “reasonable cause”

Manufacturer inquiries to covered entity may help support “reasonable cause”

Important for covered entities to respond to manufacturer inquiries, failure to respond could result in audit

Details are not publicly available

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Consequences of Non-compliance

Repayment of
discount to
manufacturer

Removal
from
340B Program

Possible Civil
Monetary Penalties
for knowing &
intentional
violations

Potentially false
claim liability
(ripe for *qui tam*
actions?)

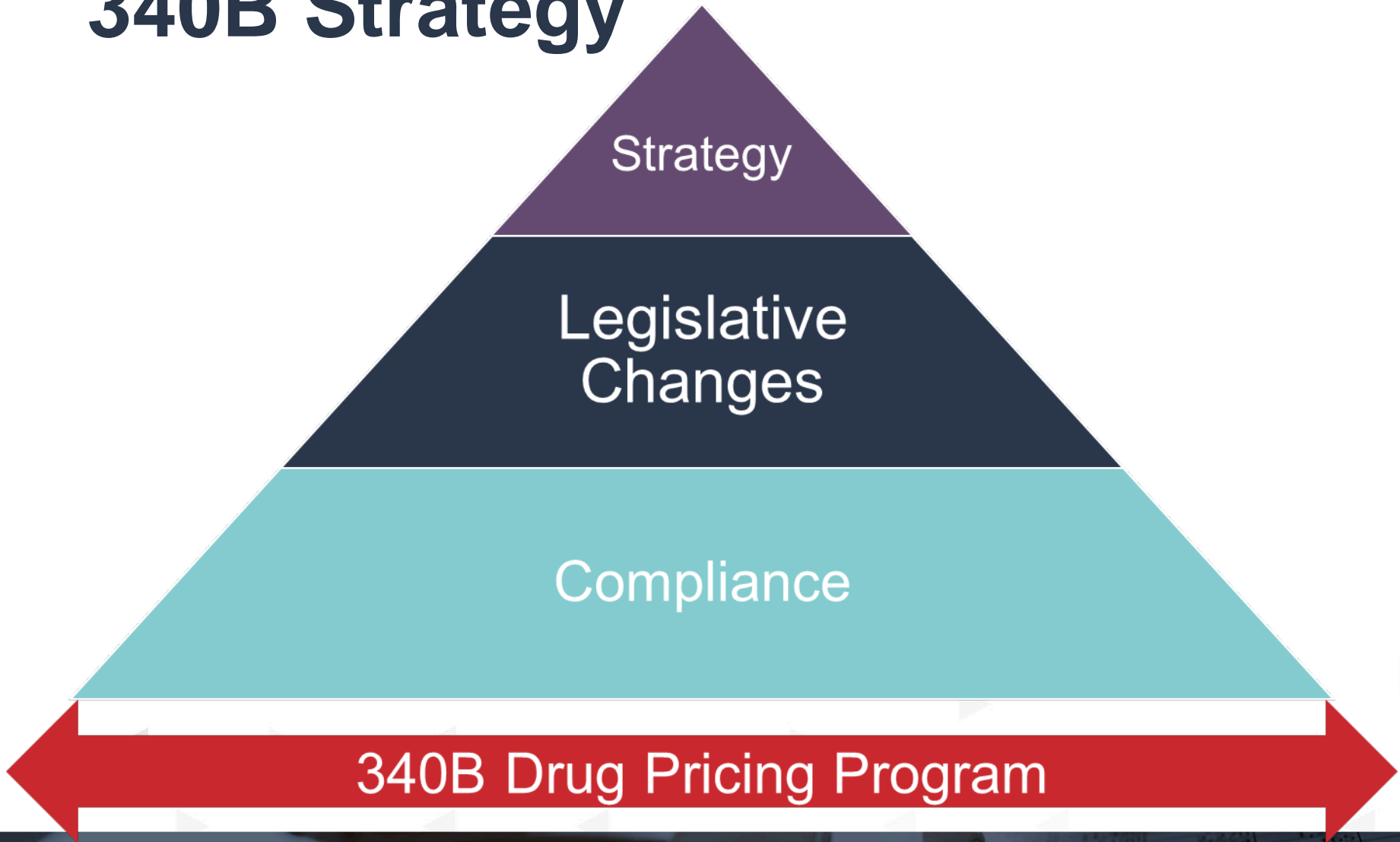
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340B Prime Vendor Program (PVP)

- Apexus operates as the current PVP and they perform services in accordance with HRSA policy
- Covered entities can enroll in the PVP which provides pricing lower than 340B for many drugs
- In addition to cost savings, the PVP
 - Communicates policy
 - Provides education
 - 340B University
 - 340B Frequently Asked Questions
 - 340B Tools

340B Strategy



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Replenishment Model



- Virtual inventory
- Receive discounts based on the drug utilization by covered outpatients
- Retrospective procurement is used to realize the discounts based on utilization
- Eligibility requirements should meet 340B patient definition



Figure obtained from [the 340B Prime Vendor Program](#)

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Replenishment Model, Continued

- 340B split billing software maintains converts the drug quantity administered in the IT data feed to the National Drug Code (NDC) wholesaler purchase quantity that is eligible to be replenished on the 340B account

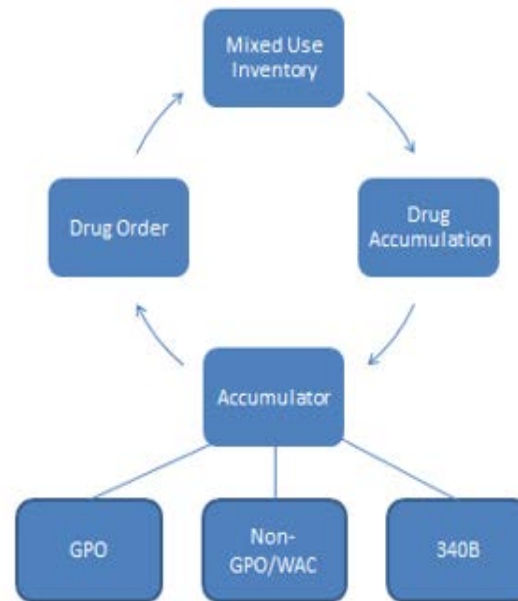


Figure obtained from [the 340B Prime Vendor Program](#)

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340B Software

- Accumulator maintenance
 - Crosswalk
 - Utilization data sources and queries
 - Purchasing trends
 - Rules and filters
 - Reports
 - Multiple contract pharmacy split-billing vendors
 - EHR billing conversions



340B Strategy - Approach

- 340B Team
- Policies and procedures
- Documented use of savings
- Internal monitoring
 - Medicaid BIN/PCN/Groups
 - Eligible locations
 - Contract pharmacy qualification parameters
- Internal audit
 - Mock audit procedures
 - Frequency and sample
- Independent external reviews
 - Operational
 - Compliance



340B Strategy - Opportunities

- Contract pharmacy arrangements
- Medicaid Carve-In
- Clinic conversions / Child sites
- Orphan Drugs
- Legislative changes
- Registration type
- Direct vendors
- Biosimilars



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Evolution of 340B

340B was started with the Public Health Services

Audit guidelines established.
Patient definition clarified.
Contract pharmacy process established

HRSA guidance on contract pharmacies allowing multiple relationships.
ACA expands eligibility to include 5 new entities

HRSA begins audits and Recertification process established

Federal judge invalidates HRSA's orphan drug regulation

1992

1994

1996

2000

2010

2011

2012

2013

2014

Guidance on outpatient clinics released by HRSA

Medicaid duplicate discount prohibition
Carve-in/Carve-out

Orphan drug exclusion

GPO prohibition guidance
HRSA issues final rule on orphan drug exclusion

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Legislative Updates 2017-2018

- Prohibit new enrollments in 340B for at least 2 years
- Increase transparency and strengthen reporting requirements to prevent abuse and ensure 340B savings are used to lower drug costs
 - Critical Access Hospitals, Rural Referral Centers, Sole Community Hospitals, Grantees, Prospective Payment System (PPS)-exempt Children's and Cancer Hospitals would be excluded from enrollment restrictions and new reporting requirements
- Provides authority for Department of Health and Human Services (HHS)
- Hold hospitals accountable for passing 340B savings from drugs to patients
- Block Medicare Part B cuts
- Orphan drug discounts
- Patient definition
- How should hospitals qualify for 340B
- Increasing DSH % to qualify
- User Fee
- 340B administrator changes

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OPPS Final Rule CY 2018

- On November 1, 2017, Centers for Medicare and Medicaid Services (CMS) released a Final Rule that reduces payment to certain 340B hospitals for separately payable Part B drugs without pass-through status (Status Indicator K) by nearly 30%.
 - Prior to January 1, 2018, these drugs are reimbursed at Average Sales Price + 6%. Effective January 1, 2018, the Final Rule reduces the payment rate to Average Sales Price minus 22.5%
 - The payment reduction will apply to 340B hospitals that are designated by Medicare as DSH, RRC, or **Urban** SCH
 - The payment reduction will not impact 340B hospitals that are designated by Medicare as CAH, **Rural** SCH, children's hospital and PPS-exempt cancer hospitals
- Hospitals that are subject to the reduced payment will be required to use modifier JG for all OP 340B drugs with status indicator K from Addendum B
- Hospitals that are subject to the reduced payment will be required to use modifier TB for all OP 340B drugs with status indicator G from Addendum B

OPPS Final Rule CY 2018, continued

Hospital Type (CMS Designation)	Status Indicator G Drugs (Pass-through)	Status Indicator K Drugs (Separately Payable)	Vaccine (Status Indicator F, L or M)	Status Indicator N (Packaged Drug)
Not Paid under OPPS				
Critical Access Hospital	TB, Optional	TB, Optional	N/A	TB or JG, Optional
Maryland Waiver Hospital	TB, Optional	TB, Optional	N/A	TB or JG, Optional
Non-Excepted Off-Campus	TB	TB	N/A	TB or JG, Optional
Paid under OPPS, Excepted from the 340B Payment Adjustment for 2018				
Children's Hospital	TB	TB	N/A	TB or JG, Optional
PPS-Exempt Cancer Hospital	TB	TB	N/A	TB or JG, Optional
Paid under the OPPS, Subject to the 340B Payment Adjustment				
Rural Sole Community Hospital	TB	TB	N/A	TB or JG, Optional
Disproportionate Share Hospital	TB	JG	N/A	TB or JG, Optional
Medicare Dependent Hospital	TB	JG	N/A	TB or JG, Optional
Rural Referral Center	TB	JG	N/A	TB or JG, Optional
Non-Rural Sole Community Hospital	TB	JG	N/A	TB or JG, Optional

Source: Medicare-FFS Program Billing 340B Modifiers under the Hospital Outpatient Prospective Payment System (OPPS) Frequently Asked Questions <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Billing-340B-Modifiers-under-Hospital-OPPS.pdf>

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OPPS Final Rule CY 2018, Final

- On November 13, 2017, the American Hospital Association (AHA), the Association of American Medical Colleges (AAMC), and America's Essential Hospitals filed a lawsuit against HHS to prevent the payment cuts
- December 27, 2018 – federal judge ruled that HHS “does not have the statutory authority” to reduce Medicare Part B drug reimbursement to hospitals participating in the 340B Program
- On May 6, 2019 – federal judge stated that HHS would have the “first crack at crafting appropriate remedial measures.” Request for status report of proposed remedies to be filed by August 5, 2019
- Reimbursement still effective for 2020
- CMS appealed decision for 2018 and 2019 and oral arguments were heard on November 8, 2019 in the DC Circuit Court of Appeals
 - We are still waiting on decision from courts

Energy & Commerce Report

- HRSA should have regulatory authority to administer & oversee 340B
 - Improve program integrity
 - Program requirements
 - Monitor & track use
 - Ensure low-income & uninsured directly benefit from 340B
- HRSA requires additional resources
- Independent audit requirements
- Reduce duplicate discounts paid for under Medicaid managed care
- HRSA should work toward ensuring that it audits covered entities & manufacturers at the same rate
- Intent of the 340B program
- 340B transparency
 - Ceiling prices
 - Disclose annual savings &/or revenue
- Monitor charity care provided by covered entities
- Reassess whether DSH is an appropriate measure for program eligibility or base on outpatient population metric

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Congressional Committee on Energy & Commerce Recent Inquiries

- Historical 340B Utilization Statistics
 - Analgesics, Antidepressants, Oncology treatment drugs, Antidiabetic agents, Antihyperlipidemic agents
 - Medicare, Medicaid, Commercial, Uninsured
 - Annual Savings from GPO Price
 - Number of Child Sites, Contract Pharmacies
- Charity Care Organization Provides – Dollars, %, & Patients
- How are 340B Savings Used for Vulnerable Populations
 - Additional Charity Care Programs Using 340B Savings?
- How do Uninsured & Underinsured Directly Benefit from 340B

2020 Outlook



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Questions?

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