



WHAT IS 340B?

SCOTT MILNER PHARMD, MBA

The slide features a light gray background with a white rectangular area in the center. The title 'WHAT IS 340B?' is centered in a large, dark serif font. Below the title, the name 'SCOTT MILNER PHARMD, MBA' is centered in a smaller, dark sans-serif font. To the right of the text area is a vertical rectangular graphic with a gold-colored grid pattern.



DISCLOSURE

- No conflicts of interest to disclose

The slide has a light gray background. At the top, the word 'DISCLOSURE' is centered in a large, dark serif font. Below this, a single bullet point is centered, stating '• No conflicts of interest to disclose' in a dark sans-serif font.

OBJECTIVES

- At the end of this presentation we should be able to:
 - Describe the origin of the 340b drug pricing program
 - Explain government divisions that oversee the 340b program
 - Define “carve-in” and “carve-out”
 - Explain what it takes to have an eligible patient

340B ORIGINS¹

- Medicaid Drug Rebate Program in 1990
- Required manufacturers to provide rebates for medication purchases
- Hospital prices increased in excess of normal rates
- Public Law 102-585, section 340b of the Public Health Service Act under the Veterans Health Care Act in 1992
- Clarifications/expansions have occurred (1994, 2003, 2005, 2010)

340B ORIGINS^{1,4}

- “U.S. federal government program created in 1992 that requires drug manufacturers to provide outpatient drugs to eligible health care organizations”
- “...requires drug manufacturers to provide outpatient drugs to eligible organizations/covered entities at significantly reduced prices”
- “...enables covered entities to stretch scarce federal resources as far as possible, reaching more patients and providing more comprehensive services”

-HRSA/OPA Website⁴

340B ORIGINS¹

- Created in 1992
- Drug manufacturers provide front-end discounts to covered entities
- The program promotes
 - Access to affordable medications
 - Efficient business practices
 - Outcomes-driven pharmacy services
 - Quality assurance

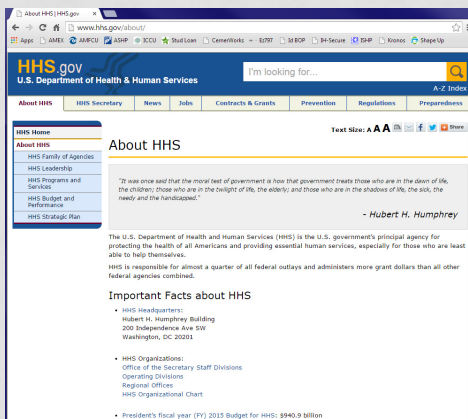
340B PROGRAM INTENT AND PURPOSE²

- The intent of the program is to permit covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” (HRSA)



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)³

- The Government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.



HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)⁴

- An agency of the HHS and is the primary Federal agency for improving access to health care... to people who are geographically isolated, economically or medically vulnerable.



OFFICE OF PHARMACY AFFAIRS (OPA)⁵



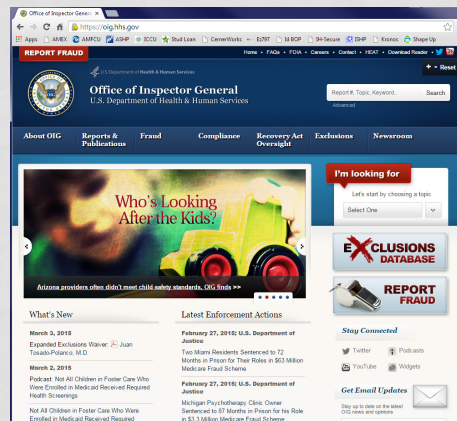
- The OPA is responsible for administering the 340B program.
- They have three primary functions:
 - 1) administer the 340B program
 - 2) develop innovative pharmacy delivery models and provide technical assistance
 - 3) act as a federal resource for pharmacy issues

OFFICE OF PHARMACY AFFAIRS (OPA)⁵

- They provide:
 - General information about the program
 - Database of covered entities
 - Charts and reports relating to program participation
 - Legal resources
 - Registration forms for health centers with contract pharmacies
 - Information on contract pharmacy services
 - Information on patient safety and clinical pharmacy services
 - Glossary of pharmacy terms

OFFICE OF THE INSPECTOR GENERAL (OIG)⁶

- An independent and objective oversight unit of the HHS to carry out the mission of promoting economy, efficiency and effectiveness through the elimination of waste, abuse and fraud.



OFFICE OF THE INSPECTOR GENERAL (OIG)⁶

- Conduct/supervise audits, inspections, investigations,
- Identify weaknesses
- Detects wrongdoers and abusers of HHS programs
- Keeps the Secretary and the Congress informed about problems and deficiencies in the administration of HHS programs

GOVERNMENT ACCOUNTABILITY OFFICE (GAO)⁷

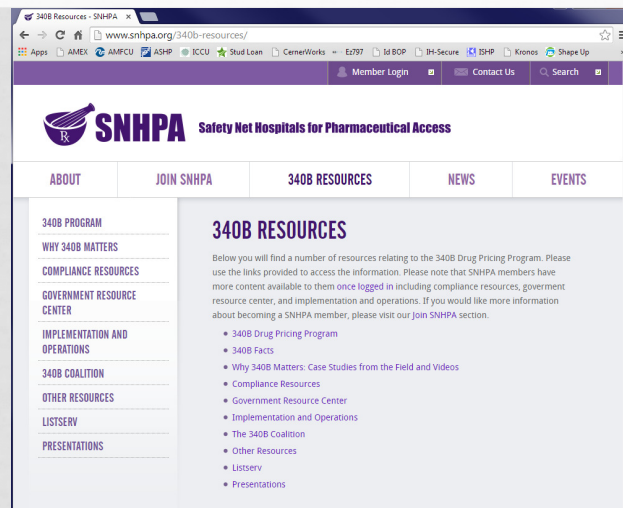
- An independent, nonpartisan agency that works for Congress. GAO investigates how the federal government spends taxpayer dollars.



SAFETY NET HOSPITALS FOR PHARMACEUTICAL ACCESS (SNHPA)⁸

- Nonprofit organization of nonprofit hospitals and health systems in the U.S. that participate in the 340B program. Work to maintain the affordability and accessibility of pharmaceutical care for the nation's poor and underserved populations.
- Advocate and resource for those providers who serve their communities through participation in the program.

SAFETY NET HOSPITALS FOR PHARMACEUTICAL ACCESS (SNHPA)⁹



PRIME VENDOR PROGRAM (PVP) ^{1, 10}

- The government was required to establish a Prime Vendor Program (PVP) to provide additional discounts (sub-ceiling) on outpatient drugs and other pharmacy related items as well as other value-added services for participating 340B entities.

PRIME VENDOR PROGRAM (PVP) ¹⁰

- Apexus
 - Negotiates sub-ceiling 340B pricing on branded and generic pharmaceuticals
 - Establishes distribution solutions and networks that improve access to affordable medications
 - Provides other value-added pharmacy related products and services to its participants



PRIME VENDOR PROGRAM (PVP) ¹⁰

- Apexus bids to be the PVP
- Surveys sent to CE to ensure satisfaction

**Please tell us which of the following tools you have most recently used.
Please select all that apply.**

- 340B Independent Audit RFP Checklist
- All Entities 340B Compliance Self-Assessment Vendors
- All Entities Self-Reporting Non-Compliance
- Minimize WAC Exposure
- DSH Comprehensive 340B Policy and Procedure Manual
- Other (please specify)

POP QUIZ

- Of all the mentioned government entities mentioned, which department provides the greatest insight to operating a 340b program?
 - HHS
 - HRSA/OPA
 - OIG
 - GAO

PATIENT DEFINITION ^{1,5}

- An individual is a “patient” of a covered entity only if:
 - Established relationship
 - Seen by employed or contracted health care professional
 - Services provided are consistent with the services of the provider
- Discounted drugs may be administered only to patients of a covered entity.
- According to HRSA, an individual is not considered a patient if the only service provided to the individual is the dispensing of drugs.

PATIENT DEFINITION ^{1,5}

Qualify

- Patient sees employed provider in the hospital clinic, prescription for infusions to be given in IV Therapy

Not-Qualify

- Patient fills prescription from a provider in a neighboring town in your contract pharmacy

ELIGIBLE COVERED ENTITIES⁵

Hospitals

- Children's Hospitals
- Critical Access Hospitals
- Disproportionate Share Hospitals
- Free Standing Cancer Hospitals
- Rural Referral Centers
- Sole Community Hospitals



ELIGIBLE COVERED ENTITIES⁵

- Children's Hospital (PEDS): Non-profit serves patients under 19 with a DSH Adjustment Percentage > 11.75%
- Critical Access Hospital (CAH): Maintain no more than 25 inpatient beds, located in a rural area or be treated as rural with 24-hr emergency care services. (10 mile requirement)

ELIGIBLE COVERED ENTITIES⁵

- Disproportionate Share Hospital (DSH): Serve a significantly disproportionate number of low-income patients. DSH Adjustment Percentage > 11.75%
- Free-Standing Cancer Hospital (CAN): Non-profit entities that are financially and administratively independent. DSH Adjustment Percentage > 11.75%

ELIGIBLE COVERED ENTITIES

- Rural Referral Centers (RRC): Medicare participating acute care hospital located in a rural area, 275+ beds, at least 50% of Medicare patients are referred, etc.
- Sole Community Hospitals (SCH): Provide short-term, acute care, are not CAH, at least 35 miles from other like hospitals

OTHER ELIGIBLE COVERED ENTITIES

Health Centers

- Federally Qualified Health Centers
- Federally Qualified Health Center Look-Alikes
- Native Hawaiian Health Centers
- Tribal / Urban Indian Health Centers

Specialized Clinics

- Black Lung Clinics
- Comprehensive Hemophilia Diagnostic Treatment Centers
- Title X Family Planning Clinics
- Sexually Transmitted Disease Clinics
- Tuberculosis Clinics

HIV/AIDS Program Grantees

Ryan White HIV/AIDS Program Grantees

CHILD SITES ^{2,5}

- Eligible Clinics, Surgery Centers and Other Outpatient Facilities
 - To be eligible a hospital outpatient unit must be listed on a reimbursable line of the Medicare cost report
 - Offsite units must be registered under the covered entity
 - Units are considered off site if they have a separate address.
 - On site units (within the four walls) don't have to be registered, but can be
 - If a unit is moving off site or has the potential to move, it should be registered before it moves and a change form used when it moves
 - Use 340B drugs for patients that meet the Patient Definition

OPA DATABASE^{5,11}

HRSA Office of Pharmacy Affairs
340B Database

Home Search Register Change Request Reports/Files

Page size: 25 450 items in 18 pages

340B ID	Entity Type	Entity Name	Sub Name	Address	City	State	Start Date	Term Date	Exp Date
CAH131391-00	CAH	BOUNDARY COMMUNITY HOSPITAL		6640 KANKRSU STREET	BONNERS FERRY	ID	09/09/2010		09/08/2014
CAH131393-00	CAH	ONEIDA COUNTY HOSPITAL		150 NORTH 200 WEST	MALAD	ID	09/28/2010		03/13/2015
CAH131394-00	CAH	Power County Hospital District		510 Roosevelt ST	American Falls	ID	07/01/2013		09/08/2014
CAH131394-01	CAH	Power County Hospital District	Power County Family Clinic	502 Tyhee	American Falls	ID	07/01/2013		09/08/2014
CAH131397-00	CAH	Weiser Valley Hospital District dba Weiser Memorial Hospital		645 East 5th Street	Weiser	ID	07/01/2013		09/20/2014
CAH131397-01	CAH	Weiser Valley Hospital District dba Weiser Memorial Hospital	Weiser Memorial Hospital Clinic (Dental Clinic)	360 East Liberty Street	Weiser	ID	07/01/2013		09/20/2014
CAH131398-00	CAH	CASCADE MEDICAL CENTER		402 OLD STATE HIGHWAY	CASCADE	ID	10/01/2014		09/08/2014
CAH131399-00	CAH	CARBON MEMORIAL HOSPITAL		300 SOUTH 3RD WEST	SODA SPRINGS	ID	04/01/2011		09/08/2014
CAH131310-00	CAH	St Luke's Jeroma, LLC		709 NORTH LINCOLN AVE	JEROME	ID	09/30/2010		11/14/2014
CAH131310-01	CAH	St Luke's Jeroma, LLC	JEROME FAMILY CLINIC	132 5TH AVE WEST	JEROME	ID	09/30/2010		11/14/2014
CAH131310-02	CAH	St Luke's Jeroma, LLC	FIFTH AVENUE CLINIC	115 5TH AVE WEST	JEROME	ID	09/30/2010		11/14/2014
CAH131312-00	CAH	ST. LUKE'S MCCALL, LTD		1000 State Street	MCCALL	ID	01/01/2013		11/14/2014
CAH131312-01	CAH	ST. LUKE'S MCCALL, LTD	MCCALL ORTHO SURGERY CLINIC	200 FOREST ST	MCCALL	ID	04/01/2014		11/14/2014

<http://opanel.hrsa.gov/340B/Views/CoveredEntity/CESearch>

GPO Prohibition ¹²

- Disproportionate Share Hospitals
- Children's Hospitals
- Free-Standing Cancer Hospitals

Orphan Drug Exclusion ¹³

- Critical Access Hospitals
- Free-Standing Cancer Hospitals
- Sole Community Hospitals
- Rural Referral Centers

GPO PROHIBITION ¹²

- Prohibits DSH, PED, and CAN hospitals from obtaining covered outpatient drugs through group purchasing organizations.

340B Drug Pricing Program

- [Home](#)
- [Eligibility & Registration](#)
- [340B Implementation](#)
- [Program Requirements](#)
- [Medicaid Exclusion](#)
- [Orphan Drug Exclusion](#)
- [340B Peer-to-Peer](#)
- [Program Integrity](#)
- [Manufacturers](#)
- [340B Database](#)
- [FAQs](#)

FAQs

HRSA and its contracted 340B Prime Vendor Program (PVP) are the only sources of information related to the 340B Program that are verified and endorsed by HRSA. The responsibility to ensure compliance with 340B Program requirements remains with covered entities and manufacturers that participate. Information received from vendors, consultants and other third parties cannot be assumed to be compliant with HRSA policy. Therefore we recommend all information and guidance received from outside parties is verified by HRSA or the PVP.

- General
- 340B Program Eligibility
- 340B Implementation
- GPO Prohibition**
- Patient Definition
- Contract Pharmacy
- Annual Recertification
- Medicaid and 340B
- Orphan Drugs

Our hospital isn't subject to the GPO prohibition. Does the GPO Policy Release impact our hospital?

[View Answer](#)

The GPO prohibition applies to all disproportionate share hospitals, children's hospitals, and freestanding cancer hospitals enrolled in the 340B Program. The GPO Policy Release does not apply to entities registered as any other type of covered entity.

SPLITTERS/ ACCOUNTS



WAC

- Wholesale Acquisition Cost



GPO

- Group Purchasing Organization (Regular)



340b

- 340b

ORPHAN DRUG EXCLUSION ¹³

- Entities subject to the Orphan Drug Exclusion may not use 340B purchased drugs for patients with the orphan indication.

Orphan Drug Designation List

The following Orphan Drug Designation List was updated and developed using the methodology referenced below and should be used to govern the quarter **April 1 - June 30, 2015** (see "About the Orphan Drug List").

[Orphan Drug List Governing April 1 - June 30, 2015 spreadsheet](#) (XLS - 279 KB)

[Orphan Drug List Governing April 1 - June 30, 2015](#) (PDF - 1 MB)

Archived List

[Archived Orphan Drug List Governing January 1 - March 31, 2015 spreadsheet](#) (XLS - 249 KB)

[Archived Orphan Drug List Governing January 1 - March 31, 2015](#) (PDF - 1.74 MB)

[Archived Orphan Drug List Governing October 1 - December 31, 2014 spreadsheet](#) (XLS - 267 KB)

[Archive Orphan Drug List Governing October 1 - December 31, 2014](#) (PDF - 972 KB)

[Archived Orphan Drug List Governing July 1 - September 30, 2014 spreadsheet](#) (XLS - 250 KB)

[Archived Orphan Drug List Governing July 1 - September 30, 2014](#) (PDF - 1.596 KB)

ORPHAN DRUG EXAMPLE ¹⁶

- Order for patient to receive 600 mg RITUXimab
 - For Hodgkins lymphoma
 - Patient has private insurance
 - Contracted MD
 - IV Therapy in hospital

2618	rituximab	Rituxan	3/12/2002	Treatment of immune thrombocytopenic purpura
2619	rituximab	Rituxan	2/14/2006	Treatment of patients with anti-neutrophil cytoplasmic antibody-associated vasculitis (Wegener's Granulomatosis, Microscopic Polyangiitis, and Churg-Strauss Syndrome)
2620	rituximab	Rituxan	1/29/2004	Treatment of chronic lymphocytic leukemia
2621	rituximab	Rituxan	6/13/1994	Treatment of non-Hodgkin's B-cell lymphoma
2622	rituximab	Rituxan(R); Mabthera(R)	2/23/2015	Treatment of pemphigus vulgaris.

GPO Prohibition ¹²	Orphan Drug Exclusion ¹³
<ul style="list-style-type: none">• Disproportionate Share Hospitals• Children's Hospitals• Free-Standing Cancer Hospitals	<ul style="list-style-type: none">• Critical Access Hospitals• Free-Standing Cancer Hospitals• Sole Community Hospitals• Rural Referral Centers

COVERED OUTPATIENT DRUGS ¹²

Covered	Not Covered
<ul style="list-style-type: none">• FDA-approved prescription drugs• OTC drugs WITH a prescription• Biological Products• FDA-approved Insulin	<ul style="list-style-type: none">• Vaccines• Inpatient Drugs• Drug not directly reimbursed• Product where FDA doesn't require NDC

MEDICAID BEST PRICE ¹²

- The lowest manufacturer price paid for a drug by any purchaser (some exceptions).
- A drug's reported best price is required to reflect all discounts, rebates, and other pricing adjustments.

340B PRICING ^{9,10,12}

- HRSA Estimates 20% to 50% Savings on Covered Drugs
 - Maximum price calculated using the Medicaid rebate formula
 - Discount of 23.1% off average manufacturer's price (AMP) for most brand name drugs
 - Discount of 17.1% for brand name drugs exclusively approved for pediatric use
 - 13% discount for generic drugs and OTCs
 - Additional discount on brand name drugs if the manufacturer's best price is lower
 - Penny Pricing
 - Prime Vendor Pricing

PENNY PRICE ¹²

- The price that results when the calculation for a 340B price yields zero.
- 340B Ceiling Price = [(AMP)-(URA)] * Drug Package Size

AMP=Average Manufacturer Price
 URA=Unit Rebate Amount



<http://www.freakykids.com/news/penny-photos/7631>

PENNY PRICE ¹⁴

DEPARTMENT OF HEALTH & HUMAN SERVICES
 Health Resources and Services Administration
 Healthcare System Bureau
 Office of Pharmacy Affairs



Date: November 21, 2011

340B DRUG PRICING PROGRAM NOTICE
 Release No. 2011-2

CLARIFICATION OF PENNY PRICING POLICY

This policy release is being issued to clarify HRSA's long-standing policy with regards to 340B ceiling prices that are zero prices, known as the "penny pricing" policy, under the 340B Drug Pricing Program (340B Program).

Background

Section 602 of Public Law 102-585, the "Veterans Health Care Act of 1992," enacted section 340B of the Public Health Service Act, "Limitation on Prices of Drugs Purchased by Covered Entities." Manufacturers who participate in Medicaid are required to enter into an agreement with the Secretary under which the manufacturer must agree to charge a price that will not exceed the amount determined under a statutory pricing formula when selling covered outpatient drugs to particular covered entities listed in the statute.

340B Pricing

In order to calculate the 340B ceiling price, the Unit Rebate Amount (URA) is subtracted from the Average Manufacturer Price (AMP) for the smallest unit of measure, which is then multiplied by the drug package size. The following formula is used for calculating 340B ceiling prices:

$$340B \text{ Ceiling Price} = [(AMP) - (URA)] * \text{Drug Package Size}$$

Under the Medicaid Drug Rebate Program, the Centers for Medicare and Medicaid Services (CMS) indexes quarterly AMPs to the rate of inflation (Consumer Price Index adjusted for inflation-urban). Section 1927(c)(2)(A) of the Social Security Act provides that if the AMP increases at a rate faster than inflation, the manufacturer pays an additional rebate amount which is reflected in an increased URA. Historically, because of the basic rebate and the inflation factor, Section 1927(c)(2)(A) could increase the rebate amount manufacturers must pay to the States, and result in negative 340B prices. Now, based on the provision in section 1927(c)(2)(D) of the Social Security Act that limits the unit rebate amount to 100% of the AMP, effective January 1, 2010, an increase in the basic rebate and inflation factor would not result in a negative 340B price, but could result in a zero 340B price.

PRIME VENDOR PROGRAM (PVP)

- The government was required to establish a prime vendor program (PVP) to provide additional discounts (sub-ceiling) on outpatient drugs and other pharmacy related items as well as other value-added services for participating 340B entities.

PRIME VENDOR PROGRAM (PVP) ¹⁰

- Apexus
 - Negotiates sub-ceiling 340B pricing on branded and generic pharmaceuticals
 - Establishes distribution solutions and networks that improve access to affordable medications
 - Provides other value-added pharmacy related products and services to its participants



DRUG PRICING ^{10,12}

SUB-WAC

- Order covered outpatient drugs in situations that would require the entity to purchase at WAC pricing.
 - Negotiated without regard to 340B pricing
 - Use of Sub-WAC is GPO Prohibition compliant

SUB-340b

- Pricing that is negotiated with branded and/or generic manufacturers offering pricing less than the 340B price.
 - Negotiated by Apexus

RESPONSIBILITY ¹²

- The covered entity has total responsibility for compliance. Main tenants of compliance include:
 1. Diversion
 2. Duplicate Discount
 3. GPO Exclusion (where applicable)
 4. Orphan Drug Exclusion (where applicable)



DIVERSION ¹²

- The use of 340b purchased drug for ineligible patients



http://www.sagepub.com/blog/featurement_141988_VQ2649714

DUPLICATE DISCOUNT¹²

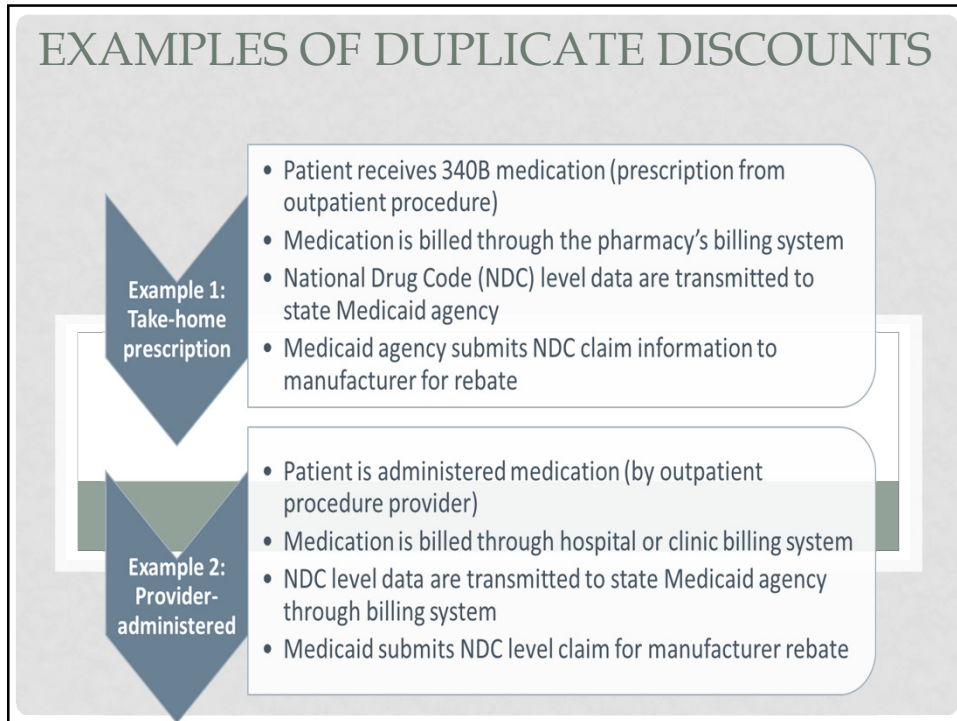
- Idaho could obtain Medicaid rebates for a drug that a covered entity bought through the 340B program.
 - Carve In: include Medicaid patients
 - Carve Out: do not include Medicaid patients



<http://wamerboutique.com/delicious-pieces-of-pie-wallpaper/>



<http://pumpkin.com/probably-the-best-pumpkin-carving-you-will-ever-see/>



CARVE IN VS CARVE OUT¹²

- Carve In: Purchase drugs for Medicaid patients at the 340B price
- Carve Out: Do not purchase drugs for Medicaid patients at the 340B price

**The state of Utah carves IN, Idaho however is currently carve OUT.

WHY CARVE-OUT OR CARVE-IN ?

- Reasons to Carve-In
 - Large patient population
 - Opportunity to receive significant discounts on pricing for large patient volumes
 - Significant revenue realization to the entity
 - Medications are not individually paid by Medicaid
 - Medicaid is not trying to get rebates
 - Required by Medicaid (some states)
 - Prevent buying Medicaid drugs on WAC
 - Want to lose money?
- Reasons to Carve-Out
 - Required by Medicaid
 - Evidence of duplicate discount
 - Contract Pharmacy

TWO WAYS TO REALIZE 340B SAVINGS¹²

1. Services to Outpatients
 - a) Physician/Clinic Administered Drugs
 - b) Mixed Use areas (OR/ER)
 - c) Infusion Centers
2. Discharge Services (340B drugs can be used for discharge prescriptions to the extent that the drugs are for outpatient use.)
 - a) Contract Pharmacy
 - b) Entity Owned Pharmacy

CONTRACT PHARMACY¹²

- A covered entity contracts with a pharmacy to distribute the covered entity's drugs on the covered entity's behalf.
 - Reduced readmissions
 - Continuity of care
 - Offset losses
 - Patient satisfaction

CONTRACT PHARMACY¹²

- Written Contract
 - CE must register as a contract pharmacy entity with OPA
 - CE must buy, maintain title, and assume pricing responsibility
 - CE is responsible for ensuring compliance with 340B requirements

TO PARTICIPATE, A CE MUST...¹²

- Ensure capability to maintain compliance with program requirements
- Register as a Covered Entity
- Recertify with HRSA annually

REGISTRATION^{11,12}

- OPA updates the database for NEW entities four times/year and requires a minimum of one month to process the application.
- Must be government owned
- Non-profit with government contract



REGISTRATION PERIODS ¹¹

- July 1-15 for October 1 start
- October 1-15 for January 1 start
- January 1-15 for April 1 start
- April 1-15 for July 1 start



ANNUAL RECERTIFICATION¹¹

- Website information must be kept current
- Must be completed by AO (Authorizing Official) (CEO, CFO, ETC.)
- Must designate a primary contact (DOP)
- Includes attestation of compliance, eligibility etc.

AUTHORIZING OFFICIAL (AO) ¹²

- Authorizing Official: Ultimately responsible for ensuring the entity's compliance with 340B program requirements. Any changes to an entity's 340B database record require AO approval.



THREATS TO THE 340B PROGRAM...

- AIR340B (Alliance for Integrity and Reform of 340B)
- Big pharmaceutical companies
- Concern that health systems are making discounted medicines available at regular prices to patients with health insurance and then pocketing the difference...

MANUFACTURERS AND 340B¹²

- Manufacturers must participate in the 340B program or their drugs cannot be covered by Medicaid
- Prices to covered entities for outpatient drugs are to be capped at a deeply-discounted ceiling price
 - Manufacturer must agree to charge a price that will not exceed the amount determined under statute (ceiling price) when selling covered outpatient drugs to 340B covered entities
 - Ceiling price is calculated by subtracting the Unit Rebate Amount (URA) from the Average Manufacturer Price (AMP). The formal calculation is: [340B Ceiling Price = Quarterly AMP – URA]

AUDIT TIME MIXED USE ¹⁵

- Determine patients that received 340b medications (i.e. use software, or manual processes)
- Make sure you eliminate 340b drug to patients:
 - Being treated for orphan drug indication
 - Medicaid (if carve-out)

*Ideal to show what drug went to each patient

**Need to make sure you work with your distributor to have a separate PHS account for 340b pricing and processing

AUDIT TIME-CONTRACT PHARMACY¹⁵

- Obtain list of all claims processed
- Confirm claim relates to hospital care
- Ensure Provider eligibility
- If unable to reverse claims, disclose and correct**

RC	NU	FI	FIR	AT	LAST	RIBR	FILL	Q	WRITTEN	SUBMITTED	DIS	PROV	CE	PROV	PRESCRIBER	NI	BEE	RIBER	NDP	DRUG	NM	OR	RE	IPENSE	DE	ME	M	PLAN
0							17Apr13		17Apr13		17Apr13	1198641423	029532305	Kavali	Dwara	22				PROAIR	HFA	AER	P		8.5	GM	6.4	
0							17Apr13		17Apr13		17Apr13	1198641423	029532305	Kavali	Dwara	22				PROAIR	HFA	AER	P		8.5	GM	6.4	
0							17Apr13		17Apr13		17Apr13	1198641423	029532305	Kavali	Dwara	22				PROAIR	HFA	AER	P		8.5	GM	6.4	
0							17Apr13		17Apr13		17Apr13	1198641423	029532305	Kavali	Dwara	22				PROAIR	HFA	AER	P		8.5	GM	6.4	
0							17Apr13		17Apr13		17Apr13	1198641423	029532305	Kavali	Dwara	22				PROAIR	HFA	AER	P		8.5	GM	6.4	
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0							05Aug13		04Aug13		05Aug13	1198641423	0780790147	Larvy	Caraballo	01				08MG			P		60		281.5	
0							05Aug13		04Aug13		05Aug13	1198641423	0780790147	Larvy	Caraballo	01				08MG			P		60		281.5	
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0							05Aug13		04Aug13		05Aug13	1198641423	0780790147	Larvy	Caraballo	01				08MG			P		60		281.5	
0							05Aug13		04Aug13		05Aug13	1198641423	0780790147	Larvy	Caraballo	01				08MG			P		60		281.5	
0							05Aug13		04Aug13		05Aug13	1198641423	0780790147	Larvy	Caraballo	01				08MG			P		60		281.5	
0							05Aug13		04Aug13		05Aug13	1198641423	0780790147	Larvy	Caraballo	01				08MG			P		60		281.5	

AUDIT TIME-CONTRACT PHARMACY¹⁵

- Disclosure to the OPA

CDR Krista Pedley, Director
 Office of Pharmacy Affairs (OPA)
 Healthcare Systems Bureau
 Health Resources and Services Administration
 5600 Fishers Lane, Parklawn Building, Room 10C-03
 Rockville, MD 20857

Re [REDACTED] Participation in the 340B Contract Pharmacy Program

Dear Commander Krista Pedley:

[REDACTED] is a [REDACTED] in [REDACTED]. [REDACTED] is part of [REDACTED], a not-for-profit healthcare organization operating multiple hospitals across [REDACTED]. [REDACTED] has been enrolled as a [REDACTED] 340B covered entity in the 340B Drug Purchasing Program ("340B Program") since April 1, 2013.

AUDIT TIME-CONTRACT PHARMACY¹⁵

- Disclosure to drug manufacturers
- Determined to send out letters, wait for response
- Second send out demonstrates “due-diligence”

ASTRA/ZENECA PHARMACEUTICAL
 1800 Concord Pike
 P.O. Box 1537
 Wilmington, DE 19850-5437

Re: [REDACTED] Purchases of Certain Drugs for Use in its Contract Pharmacy Program

Dear ASTRA/ZENECA PHARMACEUTICAL,

[REDACTED] a not-for-profit healthcare organization operating multiple hospitals across [REDACTED] has been enrolled as a [REDACTED] 340B covered entity in the 340B Drug Purchasing Program (“340B Program”) since April 2013.

Row Labels	Sum of \$ Impact
SANOFI U.S. LLC	[REDACTED]
ELI LILLY AND COMPANY	[REDACTED]
MERCK SHARP & DOHME	[REDACTED]
GLAXOSMITHKLINE PHARM	[REDACTED]
ASTRA/ZENECA PHARMACEUT	[REDACTED]
NOVO NORDISK PHARMA	[REDACTED]
ABBVIE	[REDACTED]
BOEHRINGER INGELHEIM	[REDACTED]
CORNERSTONE THERAPEUTICS	[REDACTED]
DAIICHI SANKYO INC	[REDACTED]
TEVA PHARMACEUTICALS @	[REDACTED]
NOVARTIS PHARMACEUTICALS	[REDACTED]
JOM PHARMACEUTICAL	[REDACTED]
ER SQUIBB & SONS LLC	[REDACTED]

AUDIT TIME-CONTRACT PHARMACY¹⁵

- Determine weaknesses (software/no-software, vendor, provider list, dates of eligibility etc...)
- Address prior to turning back on and notify OPA

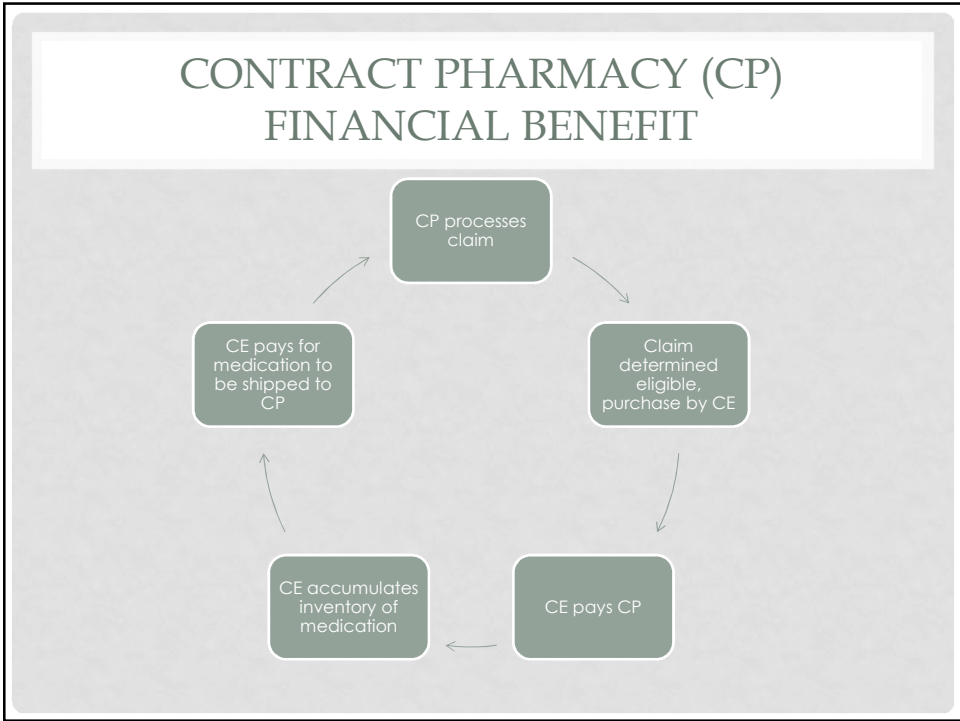
[REDACTED]
 Administrator & 340B Authorizing Official
 [REDACTED]

Dear [REDACTED]

Thank you for your letter dated July 9 regarding the [REDACTED] (340B ID: [REDACTED]) participation in the 340B Drug Pricing Program (340B Program) and non-compliance issues reported to the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA).

HRSA appreciates your stated efforts to comply with the 340B Program requirements. Based upon the information provided in your letter, we consider this matter closed. The OPA may request assurance of your compliance with 340B Program requirements in the future.

Received [REDACTED]



MIXED USE FINANCIAL BENEFIT

- Drug vertigotron (Typsy) administered in IV Therapy
 - WAC cost \$1100
 - GPO Price \$975
 - 340b cost \$575
- Patient billed cost + markup/handling fee of GPO price
- Determined after patient was eligible for 340b price

**Savings to department

- Employee cost (initial)
- Charity Prescriptions (more ideal)

HOW CAN THIS HELP?

- Cost to provide service (employee's)
 - Diabetes clinic
 - Anticoagulation Service (inpatient/outpatient)
 - Discharge prescription (bedside delivery)
- Charity Care
 - Prescription Vouchers**
 - Use to offset care written off

**Not just for the financial benefit

HOW CAN I LEARN MORE? ¹⁰

- 340b University (free registration)
- 340b Winter Coalition Conference

The screenshot shows the 340B Prime Vendor Program website. The main navigation bar includes links for Home, Partnering, 340B University, Resource Center, News, About Us, Register, and Event Calendar. The page is titled "340B University" and features a banner with a woman holding a book. Below the banner, there is a section titled "You Are Invited To Attend 340B University" which describes the program as an in-depth educational program for PVP participants and other stakeholders. It lists several upcoming sessions: March 26, 2015 (The Hilton San Diego Bayfront Hotel) and April 25, 2015 (Workshop limited to Family Planning and Title X entities, Alexandria, VA). On the left side of the page, there is a section for the "11th Annual 340B Coalition Winter Conference" held from February 4-6, 2015 at the Hyatt Regency Embarcadero in San Francisco, CA. The description of the conference highlights opportunities for hands-on implementation, compliance training, and networking with industry representatives and government officials.

HOW CAN I LEARN MORE? ¹²



- Enable all pharmacy members to understand 340b benefits and implications
- Be able to prove benefit to administration, and HRSA in the future

QUESTION 1

1. The 340b program name comes from
 - A: Number of covered entities allowed to participate
 - B: Patent number of a prescription claim process
 - C: Section of law from 1992

QUESTION 2

- To Carve In patients for eligible 340b purchases, you would:
 - A: Include patients being treated for orphan drug indications
 - B: Include patients with private insurance
 - C: Make sure OPA registration would indicate that you will include Medicaid patients for eligible 340b drug purchases

QUESTION 3

- Which of the following medications would qualify for 340b purchases (eligible patient):
 - A: Medications administered while inpatient
 - B: Medications administered under orphan drug indication
 - C: Non-Medicaid patient being treated with a medication being used for an indication not on the orphan drug indication list, in an outpatient area
 - D: Vaccines for outpatient use

QUESTION 4

- True / False

To start a 340b program you should trust software vendors to audit data feeds and trust they will support you if there are any diversion/duplicate discounts

REFERENCES

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14. "Clarification of Penny Price" Published 2/2011. Web. Accessed 3 Mar. 2015
15. Sample Hospital Audit Findings 2/2014
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