



# CHOP

Tulsa, Oklahoma

340B Background for the  
Hematology/Oncology Specialist

A 340(B) GUIDE

April 9, 2011



**J. KEITH HANCHEY, R.Ph**  
Managing Director  
Navigant Consulting

NAVIGANT



# 340B Background Information



## **Public Health Services Act established 340B**

- **The 340B Drug Pricing Program was established through the Veterans Healthcare act of 1992 (Public Law 102-585). Section 340B of the Public Health Services Act provides discounts on outpatient drug purchases for eligible “covered entities” similar to the Medicaid discounts mandated by the federal government in 1990**
- **That means that if a manufacturer sells to any Medicaid program it must provide a 340B price.**
- **The program enables indigent care networks made up of disproportionate share hospitals, community health centers, clinics and other safety net providers to purchase outpatient pharmaceuticals at discounted pricing, thereby expanding access to care for low-income and vulnerable segments of the population.**

# The Covered Entities



## Initial Covered Entities

- Federally qualified health centers including Community Health Centers, Hemophilia Clinics, Sexually Transmitted Disease Clinics, Ryan White Clinics, Family Planning Clinics and American Indian and Hawaiian treatment centers, Tuberculosis Clinics and State operated Aids Drug Assistance programs.
- In February, 2006, stand alone Children Hospital were given 340B status under a provision of the Social Security Act amended by the Deficit Reduction Act
- Section 7101 of the Affordable Care Act expanded the definition of covered entities to:
  - Free Standing Cancer Centers
  - Critical Access Hospitals
  - Sole Community Hospitals
  - Rural Referral Centers

# The Covered Entities



Covered entities that qualify for 340B drug pricing include disproportionate share hospital (DSHs), federally qualified health centers (including community health centers, hemophilia clinics, sexually transmitted disease clinics, Ryan White clinics and American Indian and Hawaiian treatment centers); tuberculosis clinics and state-operated Aids drug assistance programs.

<http://www.hrsa.gov/opa/introduction.htm>

In February, 2006, Children's Hospital (stand alone) was given 340B status but the regulations were not completed until September, 2009.

Section 7101 of the Affordable Care Act expanded the definition of covered entities that are now eligible to participate in the 340B program. Under the provision Children's Hospitals, free standing cancer centers, critical access hospitals, sole community hospitals and rural referral centers are now eligible to participate in the program.

Note: Children's Hospitals had been previously enrolled under a provision of the Social Security Act (SSA) amended by the Deficit Reduction Act.



**A. The office of Pharmacy Affairs**

The 340B program is administered by the office of Pharmacy Affairs and is a division of HRSA. The Website is: <http://www.hrsa.gov/opa.htm>

**B. 340B Prime Vendor Program (PVP)**

As part of the original 340B legislation, the government was also required to establish prime vendor program. The PVP serves its participants in three roles:

1. Negotiating sub-340B pricing on pharmaceuticals
2. Establishing solutions and network that improve access to affordable medications.
3. Providing other value added products and services.
4. The program is a voluntary program of 340B covered entities. The program provides the only legal means for 340B eligible hospitals to conduct group purchasing and leverage their outpatient drug purchases to secure sub-340B discounts



Apexus manages the PVP and has done so since 2004. More information is available at: <http://www.340bpvp/faq.htm> or <http://www.apexus.org>

Chris Hatwig is the Executive Vice President.

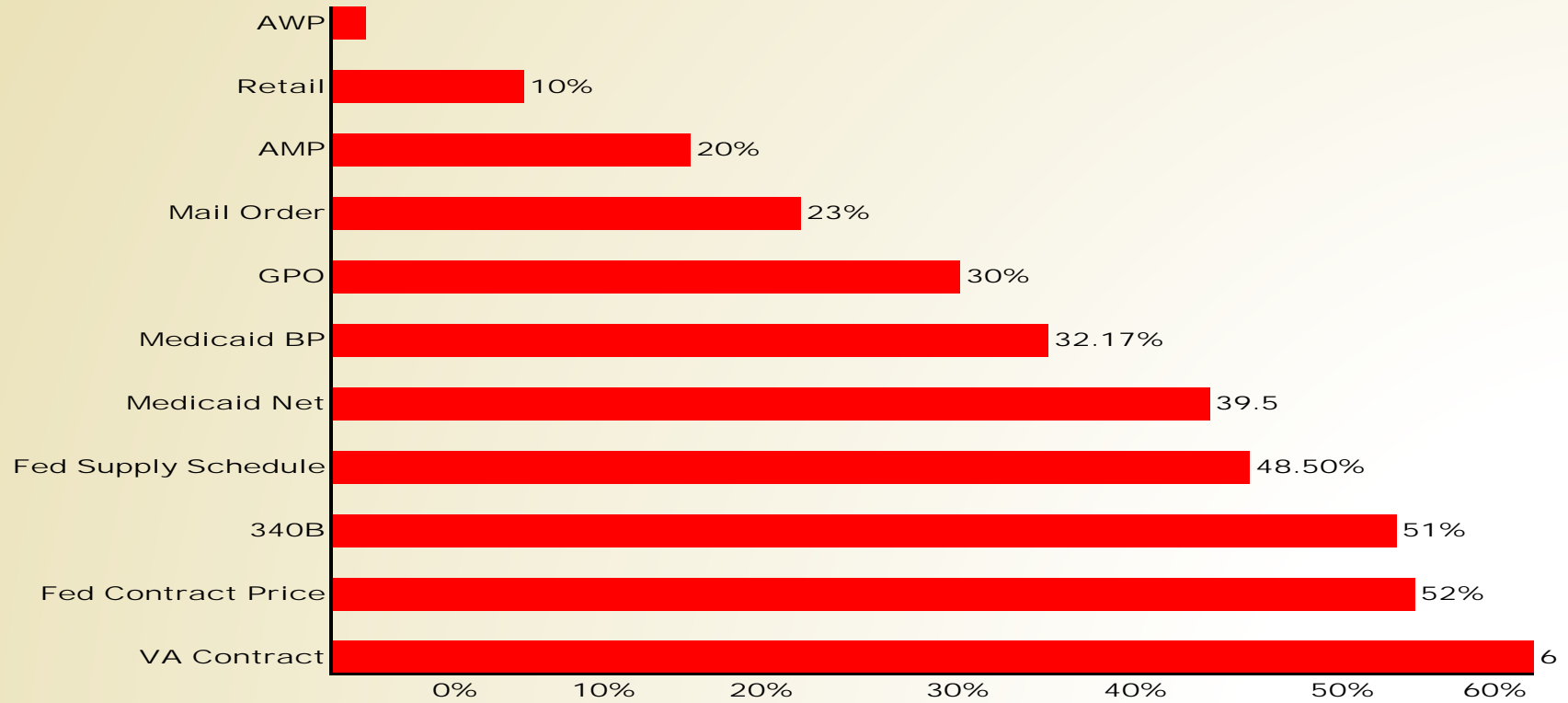
[Chatwig@apexus.org](mailto:Chatwig@apexus.org)

Ph: 972-910-6641

Address: 125 E. John Carpenter Frwy., Irving, Texas, 75062-2324



## Drug Class of Trade Discounts





Item Description	Generic Name	Unit Size	Unit Size UOM	GPO Price	340b Price	340b Savings Per Pckg
Jevtana 60MG/1.5ML JEVTANA KIT FOR INJ 60MG/1.5ML SDV 1/EA	CABAZITAXEL	60 MG		\$7,931.68	\$ 5,996.56	\$ 1,935.12
Campath 30MG/ML CAMPATH 30MG/ML 1ML SDV 3/PAC	ALEMTUZUMAB	30 MG		\$5,362.19	\$ 3,703.53	\$ 1,658.66
Campath 30MG/ML CAMPATH 30MG/ML 1ML SDV 3/PAC	ALEMTUZUMAB	30 MG		\$5,216.87	\$ 3,703.53	\$ 1,513.34
Neupogen 480 MCG/0.8 ML NEUPOGEN 480MCG/0.8ML SYR 10/PAC	FILGRASTIM	480 MCG		\$3,474.65	\$ 2,319.05	\$ 1,155.60
Vectibix 20MG/ML 400 MG VECTIBIX 20MG/ML 20ML SDV 1/EA	PANITUMUMAB	400 MG		\$3,370.58	\$ 2,571.48	\$ 799.10
Sandostatin Lar Depot 30 MG SANDOSTATIN LAR DEPOT 30MG KT 1/EA	OCTREOTIDE ACETATE	30 MG		\$3,268.08	\$ 1,368.45	\$ 1,899.63
Herceptin 440MG HERCEPTIN 440MG MDV W/DIL 1/EA	TRASTUZUMAB	440 MG		\$2,859.06	\$ 1,687.15	\$ 1,171.91
Rituxan 10 MG/ML 500 MG RITUXAN 10MG/ML 50ML SDV 1/EA	RITUXIMAB	500 MG		\$2,815.13	\$ 1,445.33	\$ 1,369.80
Ixemptra 45MG IXEMPRA KIT FOR INJ 45MG SDV 1/EA	IXABEPILONE	45 MG		\$2,765.89	\$ 2,124.91	\$ 640.98
Winrho Sdf 15000IU 3000 MCG WINRHO SDF15000IU/3000MCG LIQ 1/EA	RHO(D) IMMUNE GLOBULIN	3000 MCG		\$2,614.25	\$ 891.91	\$ 1,722.34
Alimta 500MG ALIMTA 500MG SDV PWD EL 1/EA	PEMETREXED	500 MG		\$2,520.71	\$ 1,641.29	\$ 879.42
Neulasta 6MG/0.6ML NEULASTA 6MG/0.6ML SYR 1/PAC	PEGFILGRASTIM	6 MG		\$2,515.61	\$ 1,841.88	\$ 673.73
Avastin 25MG/ML 400 MG AVASTIN 25MG/ML 16ML SDV 1/EA	BEVACIZUMAB	400 MG		\$2,244.42	\$ 1,749.03	\$ 495.39
Sandostatin Lar Depot 20 MG SANDOSTATIN LAR DEPOT 20MG KT 1/EA	OCTREOTIDE ACETATE	20 MG		\$2,144.48	\$ 911.85	\$ 1,232.63
Neupogen 300 MCG/0.5 ML NEUPOGEN 300MCG/0.5ML SYR 10/PAC	FILGRASTIM	300 MCG		\$2,141.19	\$ 1,436.97	\$ 704.22
Eloxatin 5MG/ML 100 MG ELOXATIN 5MG/ML 20ML SDV 1/EA	OXALIPLATIN	100 MG		\$2,020.85	\$ 1,160.70	\$ 860.15
Treanda 100MG TREANDA 100MG LYO SDV PWD 1/EA	BENDAMUSTINE HCL	100 MG		\$1,800.00	\$ 1,372.35	\$ 427.65
Faslodex 50MG/ML 250 MG FASLODEX 50MG/ML 5ML SYR AZ 2/PAC	FULVESTRANT	250 MG		\$1,613.52	\$ 1,230.87	\$ 382.65
OXALIPLATIN 5MG/ML 20ML SDV SAN 1/EA	OXALIPLATIN	100 MG		\$1,604.10	\$ 1,065.26	\$ 538.84
Taxotere 80MG TAXOTERE ONE-VIAL 80MG/4ML SDV 1/EA	DOCETAXEL	80 MG		\$1,539.97	\$ 733.12	\$ 806.85



## A. Manufacturer's Requirements

- **Manufacturer's that participate in the Medicaid Drug Program are required to also participate in the 340B program.**
- **There are over 22,000 sku's of eligible 340B items.**
- **The price on 340B items change quarterly and the distribution of these items are done by wholesale distributors.**
- **The 340B drugs must be replaced by covered entities NDC to NDC.**
- **If a pharmacy does not settle their replacements of 340B drugs quarterly there is potential risk in that an item will not be available the following quarter.**



## B. Program Prohibitions

- 1) Diversion is defined as providing 340B discounted priced drugs to individuals who are not patients of the eligible covered entities.
- 2) Duplicate Discounts refers to accessing the 340B discounts plus the Medicaid rebate on the same drug prescription. If a covered entity is dispensing their 340B drugs to Medicaid patients, the prescription must be submitted at 340B acquisition cost plus a dispensing fee. State Medicaid is bond to segregate 340B eligible prescriptions so as not receive a rebate on the NDC dispensed. That is referred to as “double dipping” and is prohibited covered entities must report Medicaid billing status.  
See: <http://www.hrsa.gov/opa/Medicaidexclusion.htm>

Some state Medicaid programs segregate the 340B volume and apply a greater dispensing fee to the provider but the prescription cost to Medicaid is still less cost than a non-340B prescription Louisiana has a dispensing fee of \$7.75 for 340B providers.



- 3) **GPO Exclusion rule refers to the regulation that states that if a covered entity participates they must buy all of their outpatient drugs for qualified patients through their 340B account exclusively even if the 340B price is higher than a GPO contracted price. That situation does exist on a small number of occasions.**

**Covered entities that participate in the 340-B program must be “all in” which means they must buy everything at 340B or at WAC.**



## C. Terms and Definitions

### 1. Qualified Patient

- a) A patient who is eligible to receive a prescription or have a drug administered eligible for is 340B drug use, is an outpatient who receives a professional service from the covered entity.
- b) The cover entity has an established relationships with the individual
  - i. The covered entity owns and maintains the medical/health record of the individual's healthcare.
- c) The individual receives a healthcare service from a healthcare professional who is either employed, contracted or provides healthcare under some contractual arrangement.



**d) The prescription is filled by the covered entity pharmacy or at a contract pharmacy affiliated with the covered entity. As a contract pharmacy you must be aware of some other tests to be absolutely compliant with the regulations. A simple test to apply:**

- 1. Outpatient Services**
- 2. Rx proximal to visit**
- 3. Covered entity owns medical record**
- 4. Same provider number for outpatient area**
- 5. Same tax id number**



Some nuances to be aware is that a surgery center located on a hospital campus that is a JV between the hospital and a physician group would fail the test. The JV would have a separate tax id and separate provider numbers. See [http://hrsa.gov/opa/patient\\_definition.htm](http://hrsa.gov/opa/patient_definition.htm)

## 2. Contract Pharmacy Ratios 1:1 vs. 1:many

In April, 2010, the 340B regulations changed to allow a single covered entity to establish relationships with multiple pharmacies.

Reference: <http://edocket.access.gpo.gov/2010/pdf/2010-4755.pdf> See Appendix C

The summary of the change in regulation changes the ratio of the number of contracted 340B pharmacies that can provide service to a single covered entity from 1:1 to 1:many. The increased number of contracted pharmacies to a single covered entity, allows the most vulnerable patient populations more affordable access to drugs.



# The Contract Pharmacy Issues



### **III. The Contract Pharmacy**

#### **A. The Regulations**


**It is important to understand the regulation published in 1966 that describes a summary of contract Pharmacy requirements. Refer to: Federal Register, August 23, 1966, Vol. 61, No. 165, Page 43555.**

**Summary of Guidelines include:**

- a) A “ship to bill to” procedure may be used in which the covered entity purchases the drug; the distributor or manufacturer bills the covered entity for the drug purchased, but ships the drug directly to the contract pharmacy. The inventory can be replenished “virtually” or a separate inventory can be maintained.**
- b) The contractor will provide all Pharmacy Services**
- c) The covered entity health care provider will inform the patient of his or her freedom of choice to choose a pharmacy provider.**
- d) The contractor may provide the covered entity services, other than pharmacy.**



- e) **The contractor and the covered entity will adhere to all Federal, State and local laws and requirements.**
- f) **The contractor will provide the covered entity with reports consistent with customary business practices.**
- g) **The contractor with the assistance of the covered entity will establish and maintain a tracking system suitable to prevent diversion of section 340B discount drugs to individuals who are not patients of the covered entity. Customary business records may be used for this purpose. The covered entity will establish a process for periodic random (sample) comparison of its prescribing records with the contractors dispensing records to detect potential irregularities.**
- h) **The covered entity and the contract pharmacy will develop a system to verify patient eligibility.**
- i) **Both parties will not use drugs purchased under section 340B to dispense Medicaid prescription unless the contract pharmacy and the state Medicaid agency have established an arrangement to prevent duplicate discounting.**
- j) **Both parties understand that they are subject to audits, by the office of Pharmacy Affairs and participating manufacturers, of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against delicates Medicaid rebates and 340B discounts.**



# Medical Oncologists Use of 340B

# Specialty Pharmacy



- “ Stay Close to the Drugs”
- Closed Pharmacy Dispensing
- Potential Additional Revenue  
++ Several Models

# Navigant Contact



J. Keith Hanchey, R.Ph  
Managing Director  
2001 Ross Ave., Ste. 3155  
Dallas, Texas 75201  
Direct: 214-712-1526  
Mobile: 214-695-9066  
[Keith.Hanchey@navigant.com](mailto:Keith.Hanchey@navigant.com)