Pharmacy Drugs Analysis

1 - Prescription Drugs and Over-the-Counter (OTC) Drugs:

Prescription drugs are

- Prescribed by a doctor
- Bought at a pharmacy
- Prescribed for and intended to be used by one person
- Regulated by FDA through the New Drug Application (NDA) process.

OTC drugs are

- Drugs that do NOT require a doctor's prescription
- Bought off-the-shelf in stores
- Regulated by FDA through OTC Drug monographs. OTC drug monographs are a kind of "recipe book" covering acceptable ingredients, doses, formulations, and labeling.

2 – Food and Drug Administration (FDA) - FDA Orange Book

The Orange Book

- The publication ***Approved Drug Products with Therapeutic Equivalence Evaluations*** (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act Bought at a pharmacy
- https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm
- https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf

3 - What are Brand Name and Generic Drugs?

A Brand Name Drug is a medicine that's discovered , developed and marketed by a pharmaceutical company. Once a new drug is discovered, the company files for a patent to protect against other companies making copies and selling the drug. At this point the drug has two names: a generic name that's the drug's common scientific name and a brand name to make it stand out in the marketplace. This is true of prescription drugs as well as over-the-counter drugs. An example is the pain reliever Tylenol

- The brand name is **Tylenol**
- Generic name is **Acetaminophen**.

Generic drugs have the same active ingredients as brand name drugs already approved by the Food and Drug Administration (FDA). Generics only become available after the patent expires on a brand name drug. Patent periods may last up to 20 years on some drugs. The same company that makes the brand name drug may also produce the generic version. Or, a different company might produce it.

- Pfizer – **Viagra**(sildenafil) will allow generic manufacturer **Teva** to manufacture and sell generic **Viagra** in December 2017 in **USA.**
- Generic **Viagra** has been available in Canada since 2012 and **Europe** since 2013.

The Similarities

- According to the FDA, to substitute a generic for a brand name drug:
- It must contain the same active ingredients (the chemical substance that makes the drug work).
- It must have the same dosage strength (the amount of active ingredients, for example 20 mg or 40 mg).
- It must be the same dosage form (that is, it needs to be available in the same form as the original—for example, as a liquid, pill, etc.).
- It must have the same route of administration (the way the medication is introduced into the body).
- It must deliver similar amounts of the drug to the bloodstream (that is, it needs to deliver a comparable amount of the drug into the blood stream within a similar time period as the brand name drug).

The Differences

- It must contain the same active ingredients (the chemical substance that makes the drug work).
- It must have the same dosage strength (the amount of active ingredients, for example 20 mg or 40 mg).
- It must be the same dosage form (that is, it needs to be available in the same form as the original—for example, as a liquid, pill, etc.).
- It must have the same route of administration (the way the medication is introduced into the body).
- It must deliver similar amounts of the drug to the bloodstream (that is, it needs to deliver a comparable amount of the drug into the blood-stream within a similar time period as the brand name drug). Here's how generics and brand name drugs differ:
- They look different. (Federal law requires this.) – They could have different sizes, shapes, colors or markings. – They have different names.
- They might have different inactive ingredients. – Drugs are made up of both active and inactive ingredients. Some people may be sensitive to inactive ingredients. For example, some people have reactions to certain dyes used in some drugs.
- The generic costs less than the brand name drug. – The cash price and insurance co-pay is usually lower. Generics can cost between 20 and 80 percent less, but keep in mind that cost is only one factor when considering the right medication for your condition.
- Generics vary by manufacturer, which means you could receive different versions based on where you purchase your medications and what type of generic they dispense.

4 - Pharmacy Drug Pricing….

Glossary of pharmacy and drug price terms - > http://keionline.org/node/1309
Drug Pricing Policy -> http://www.fdbhealth.com/policies/drug-pricing-policy/
Overview of the 340B Drug Pricing Program ->

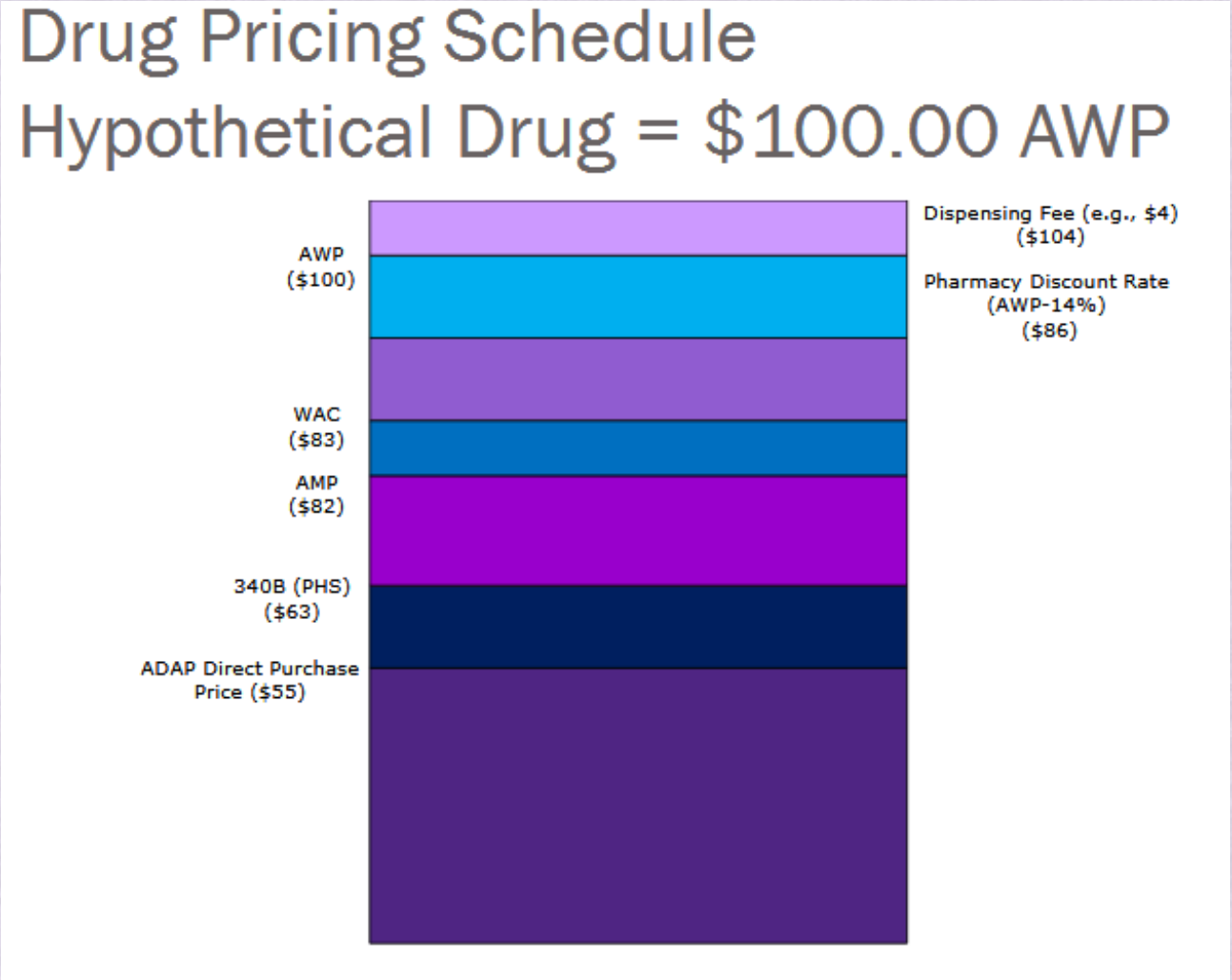
- **http://www.340bhealth.org/340b-resources/340b-program/overview/**

Pharmacy Pricing Data Medicaid.gov ->

- **https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html**
- **https://data.medicaid.gov/**

Center for Drug price Evaluation and Research ->
https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/

1. Average Wholesale Price (**AWP**):
2. Wholesale Acquisition Cost (**WAC**):
3. Average Manufacturer Price (**AMP**)
4. Public Health Service (**PHS**)
5. AIDS Drug Assistance Programs (**ADAPs**)



- **Dispensing Fee:** The charge for the professional services provided by the pharmacist.
- **Average Wholesale Price (AWP):** A benchmark used for pricing and reimbursement of prescription drugs for both government and private payers. AW P is not a true representation of actual market prices for either generic or brand drug products. AWP has often been compared to the “list price” or “sticker price”, meaning it is an elevated drug price that is rarely what is actually paid. It is provided by pricing services (i.e., MediSpan, Redbook).
- **Pharmacy Discount Price :** The price paid to the Pharmacy by a program (i.e., ADAP, Medicaid) for drugs.
- **Wholesale Acquisition Cost (WAC)** : WAC is the price set by manufacturers.
- **Average Manufacturer Price (AMP) :** The average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. A confidential price.
- **Best Price**: The lowest price paid to a manufacturer for a brand name drug, taking into account rebates, chargebacks, discounts or other pricing adjustments.
- **340B (PHS) Price:** The maximum price that manufacturers can charge covered entities participating in the Public Health Service’s 340B drug discount program.
- **Wholesaler Discount:** Discount offered by wholesalers to direct purchasers for large volume and prompt payment.
- **Federal Upper Limit Price (FUL):** Federally established maximum price (175% of the lowest published price) for a drug product, if there are three (or more) generic versions of the product rated therapeutically equivalent (A-rated) and at least three suppliers.

- **State Maximum Allowable Cost (SMAC):** Optional State Medicaid program to achieve additional savings by setting lower reimbursement amounts for more multiple source drugs than are included in the FUL program.
- **Acquisition Cost (AC)**: The net cost of a drug paid by a pharmacy and includes discounts, rebates, chargebacks and other adjustments.
- **ADAP Supplemental Discount/Rebate**: An additional discount for direct purchase states or rebate for pharmacy network states, negotiated with individual drug manufacturers by the ADAP Crisis Task Force.

5 – Drug Code Standards in USA ….

- A method for categorizing drugs into a series of numbers or "codes"
- Simplifies the ability to identify the appropriate medication
- Mechanism/Class, Usage, Strength, Dose Form, etc.
- Used in payment, billing, and analysis of medications in the healthcare system
- There are multiple classification systems available in the U.S.
- 4 main systems in this presentation:
  - National Drug Code by FDA (**NDC**)
  - Generic Product Identifier (**GPI**)
  - American Hospital Formulary System (**AHFS**)
  - Generic Code Number (**GCN**)
- One is not "better" than another. Each has their own logic and individual methods in organizing medications.

5.1 Who has not heard of the National Drug Code (NDC)?

https://www.fda.gov/drugs/informationondrugs/ucm142438.htm

PRODUCTID	PRODUCTNDC	NDCPACKAGECODE	PACKAGEDESCRIPTION
0002-1200_e62214a4-82fd-4e06-90a0-577a32fea93f	0002-1200	0002-1200-30	1 VIAL, MULTI-DOSE in 1 CAN (0002-1200-30) > 30 mL in 1 VIAL, MULTI-DOSE
0002-1200_e62214a4-82fd-4e06-90a0-577a32fea93f	0002-1200	0002-1200-50	1 VIAL, MULTI-DOSE in 1 CAN (0002-1200-50) > 50 mL in 1 VIAL, MULTI-DOSE
0002-1407_14757f9d-f641-4836-acf3-229265588d1d	0002-1407	0002-1407-01	10 mL in 1 VIAL (0002-1407-01)
[illegible]	[illegible]	[illegible]	[illegible]

PRODUCTID	PRODUCTNDC	PRODUCTTYPENAME	PROPRIETARYNAME	PROPRIETARYNAMESUFFIX	NONPROPRIETARYNAME	DOSAGEFORMNAME	ROUTENAME	STARTMARKETINGDATE	ENDMARKETINGDATE	MARKETINGCATEGORYNAME	APPLICATIONNUMBER	LABELERNAME	SUBSTANCENAME	ACTIVE_NUMERATOR_STRENGTH	ACTIVE_INGRED_UNIT	PHARM_CLASSES	DEA
0002-1200	0002-1200	HUMAN P	Amyvid		Florbetap	INJECTION	INTRAVEN	20120601		NDA	NDA20200	Eli Lilly an	FLORBETA	51	mCi/mL	Radioactive Diagn	
0002-1407	0002-1407	HUMAN P	Quinidine Gluconate		Quinidine	SOLUTION	INTRAVEN	19500712		NDA	NDA00752	Eli Lilly an	QUINIDIN	80	mg/mL	Antiarrhythmic [EP	
0002-1433	0002-1433	HUMAN P	Trulicity		Dulaglutid	INJECTION	SUBCUTAI	20141107		BLA	BLA12546	Eli Lilly an	DULAGLUT	0.75	mg/.5mL	GLP-1 Receptor Ag	
0002-1434	0002-1434	HUMAN P	Trulicity		Dulaglutid	INJECTION	SUBCUTAI	20141107		BLA	BLA12546	Eli Lilly an	DULAGLUT	1.5	mg/.5mL	GLP-1 Receptor Ag	
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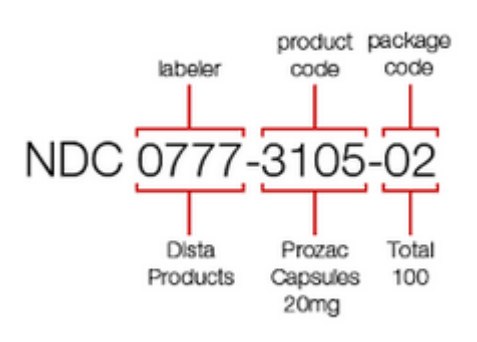
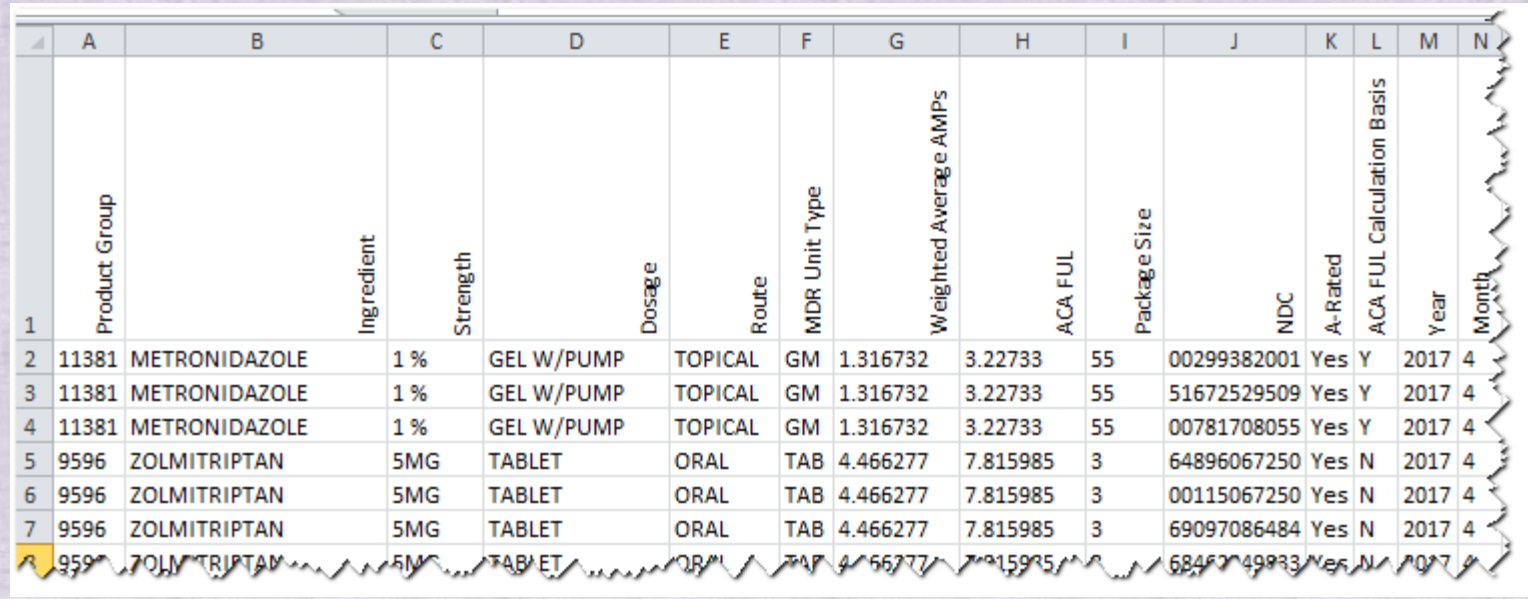


- Three segments to each NDC code
  1. Labeler code – 4 or 5 digits – not necessarily the manufacturer - assigned by FDA (Food and Drug Administration
  2. Product code- 3 or 4 digits – assigned by labeler
  3. Packaging code- 2 or 1 digit – assigned by labeler
- Always 10 digits of information, but not always the same format
  -E.g., the segments could be (4-4-2) (5-3-2) or (5-4-1)
- Medicare: Uses NDC 11 (5-4-2) Developed by the National Council on Prescription Drug Program) in response to HIPPA legislation
- Medicaid.gov

https://data.medicaid.gov/Drug-Pricing-and-Payment/Federal-Upper-Limits-2017-04/mgt2-8aba



	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1	Product Group	Ingredient	Strength	Dosage	Route	MDR Unit Type	Weighted Average AMPs	ACA FUL	Package Size	NDC	A-Rated	ACA FUL Calculation Basis	Year	Month
2	11381	METRONIDAZOLE	1 %	GEL W/PUMP	TOPICAL	GM	1.316732	3.22733	55	00299382001	Yes	Y	2017	4
3	11381	METRONIDAZOLE	1 %	GEL W/PUMP	TOPICAL	GM	1.316732	3.22733	55	51672529509	Yes	Y	2017	4
4	11381	METRONIDAZOLE	1 %	GEL W/PUMP	TOPICAL	GM	1.316732	3.22733	55	00781708055	Yes	Y	2017	4
5	9596	ZOLMITRIPTAN	5MG	TABLET	ORAL	TAB	4.466277	7.815985	3	64896067250	Yes	N	2017	4
6	9596	ZOLMITRIPTAN	5MG	TABLET	ORAL	TAB	4.466277	7.815985	3	00115067250	Yes	N	2017	4
7	9596	ZOLMITRIPTAN	5MG	TABLET	ORAL	TAB	4.466277	7.815985	3	69097086484	Yes	N	2017	4
8	9596	ZOLMITRIPTAN	5MG	TABLET	ORAL	TAB	4.466277	7.815985	3	68462049833	Yes	N	2017	4

5.2 Generic Product Identification (GPI)

The Generic Product Identifier (GPI) is a 14-character hierarchical classification system that identifies drugs from their primary therapeutic use down to the unique interchangeable product regardless of manufacturer or package size. The code consists of seven subsets, each providing increasingly more specific information about a drug available with a prescription in the United States.

Wolters Kluwer provides a database under the Medi-Span brand called Medispan Electronic Drug File that links this code to other prescription drug classification codes commonly used for payment and analysis in the United States Health Care System, as well as embedded drug information like adverse drug effects. http://www.wolterskluwercdi.com/drug-data/

GPI	Coding	Example
58-	Drug Group	Antidepressants
58-20-	Drug Class	Tricyclic agents
58-20-00	Drug sub-class	Tricyclic agents
58-20-00-60	Drug name	Nortriptyline
58-20-00-60-10	Drug name extension	Nortriptyline HCL
58-20-00-60-10-01	Dosage form	Nortriptyline HCL Capsule
58-20-00-60-10-01-05	Strength	Nortriptyline HCL Capsule 10mg

5.3 American Hospital Formulary Service (AHFS)

http://www.ahfsdruginformation.com/ahfs-pharmacologic-therapeutic-classification/#1455225455483-38135b76-9975

From American Society of Health-System Pharmacists (ASHP)

Example: Labetalol (β Blocker w/ activity)

- 24 : 04 : 04: 16
- CV Drug : Cardiac Drug : Antiarrhythmic (AA) Drug: Class II AA
- 24 : 08 : 04
- CV Drug : Hypotensive Agent : Alpha-Adrenergic Blockade
- 24 : 08 : 08
- CV Drug : Hypotensive Agent : Beta-Adrenergic Blockade
- 24 : 24
- CV Drug : Beta-Adrenergic Blocking Agents

Example: Gentamicin (Aminoglycoside Antibiotic)

- 8 : 12 : 02
- Anti-Infective Agent : Antibacterial : Aminoglycoside
- 52 : 04 : 04
- Eye, ear, nose, and throat (EENT) Preparations : Anti-infective : Antibacterial

5.4 Generic Code Number (GCN)

https://www.fda.gov/drugs/informationondrugs/ucm142438.htm

- From First Databank (FDB)
- 5-digit code to represent a **clinical formulation**
- Specific to: Ingredient, Strength, Form, and Route
- Same across manufacturers and/or package size
- Can be used to group **pharmaceutically equivalent products** together

  One drug can have multiple GCNs depending on product's available strength, forms, and route of administration.
- *Ex: Nutritionnel supplément or multivitaminés*
- The numbers itself *have no significance*
- Example:

  21414: Gabapentin 300 mg tablet

  21414: Neurontin 300 mg tablet

5.6 Drug Manufacturers

- Pfizer, USA
- Johnson & Johnson
- Novartis
- Bayer
- GlaxoSmithKline

5.6 Pharmaceuticals Distributors

- AmerisourceBergen Corporation **ABC**
- Cardinal Health, Inc **CAH**
- Owens & Minor, Inc **OMI**
- Henry Schein, Inc **SCHEIN**
- FFF Enterprises **FFF**

GPO – Group Purchasing Org

USA Government Drug Pricing Policies & Programs

- Wholesale Acquisition Cost (WAC)
- Direct Price (DP)
- Suggested Wholesale Price (SWP)
- 340B
- Emerging Price Types
- Federal Upper Limit (FUL) …….

Pharmaceuticals Distributors & Vendors

Manufacturers

The End

My special thanks to Andy !

Thank you every one
and wish you the best in your next modules.

Cheers !!!

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