Retail Pharmacy

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Introduction

A pharmacy is the establishment where the medicines and other medicinal articles are sold. Pharmacists are qualified personnel at pharmacies who undertakes the task of preparing and dispensing drugs and medicines.. A pharmacy (commonly the chemist in Australia, New Zealand and the UK; or drugstore in North America or Apothecary, historically) is the place where most pharmacists practice the profession of pharmacy. This document is concerned with the various aspects of a pharmacy that are applicable to the US market

Pharmacies are typically required to have a pharmacist on-duty at all times when open. It is also often a requirement that the owner of a pharmacy must be a registered pharmacist, although this is not the case in all jurisdictions, such that many retailers (including supermarkets and mass merchandisers) now include a pharmacy as a department of their store. In most countries, the dispensary is subject to pharmacy legislation; with requirements for storage conditions, compulsory texts, equipment, etc., specified in legislation

The pharmacies can be classified into multiple types depending on its location, function etc. They are broadly classified as:

Community pharmacy:

It consist of a retail storefront with a dispensary where medications are stored and dispensed and usually where the health professionals who are also retailers

Hospital pharmacy:

These are pharmacies present within the premises of hospitals. Hospital pharmacies usually stock a larger range of medications, including more specialized medications, than would be feasible in the community setting

Clinical pharmacy:

It is the branch of Pharmacy where pharmacists provide patient care that optimizes the use of medication and promotes health, wellness, and disease prevention.

Ambulatory care pharmacy:

It is based primarily on pharmacotherapy services that a pharmacist provides in a clinic. Pharmacists in this setting often do not dispense drugs, but rather see patients in office visits to manage chronic disease states

Compounding pharmacy:

These specialize in compounding, although many also dispense the same non-compounded drugs that patients can obtain from community pharmacies.

Internet pharmacy:

These are also known as online pharmacy or Mail Order Pharmacies and are pharmacies that operate over the Internet and send the orders to customers.

Veterinary pharmacy:

It stock different varieties and different strengths of medications to fulfill the pharmaceutical needs of animals

Nuclear pharmacy:

These focuses on preparing radioactive materials for diagnostic tests and for treating certain diseases

Military pharmacy:

Here, technicians perform most duties that in a civilian sector would be illegal.

Depending on how the patients are served, pharmacies can be classified as

Outpatient pharmacy:

Pharmacies that serve patients in their communities: pharmacies that are not in inpatient facilities

Inpatient pharmacy:

 A pharmacy in a hospital or institutional setting

Types of Retail pharmacy (Community Pharmacy)

An independent pharmacy is a retail pharmacy that is not directly affiliated with any chain of pharmacies and is not owned (or operated) by a publicly traded company. Independent pharmacies are pharmacist-owned, privately-held businesses in varying practice settings. They include single-store operations, pharmacist-owned multiple store locations, franchise, compounding, long term-care (LTC), specialty, and supermarket pharmacy operation. Independent pharmacy owners generally have high standards of customer service and strive to outperform chain pharmacy competitors

Pharmaceutical Centers

- Keep family health information center. Library, extensive reference files
- Direct patient- pharmacist relation
- Pharmacist as frontliners
- Ex: Med-Xpress

Group Practice

Formal association of pharmacists serving different fields of specialties; income is divided according to pre-arranged plan

- Types:
- Geriatrics – nursing homes, dosage adjustment requirement
- Mental Health Phar/ Psychopharmacy
- Oncology Services – protocol devt, data management, inventory control, handling and disposing of cytotoxic materials at home
- Radiopharmacy - radiopharmaceuticals

Chain Drugstore/ Multiple Pharmacy

- Profitable, more than 2 branches

Chain store pharmacists participate in the same activities as independent pharmacists, however, they may be limited to practice the goals of the chain. They are not, however, as closely tied to the income functions of organization, unless they perform in a management capacity. Both types of pharmacies offer a wide array of services, including medical equipment and supplies, consultation to other health care professionals in a variety of environments, and most importantly, quick and easy access for patients' health care questions and concerns

Retail Pharmacy Operations

A retail pharmacy consists of two types of workers, a pharmacists and a pharmacy technician. By law, all employees must be certified by the state board of pharmacy in order to work in the pharmacy and there must be at least 1 pharmacist present in the pharmacy at all times. These employees are responsible for all pharmacy duties which include: inputting new patient

information into the computer database, inputting insurance information into the computer database, reading and typing new prescriptions into the computer database, filling prescriptions (counting out the right number of tablets of the right medication for the right patient then labeling the vial) , counseling patients about new prescriptions, and collecting payment for prescriptions.

Other duties include handling any problems that may arise with insurance or medication errors and accounting for drug inventory.

A pharmacy may be labeled into three groups: high, medium, and low volume stores.

Type of Pharmacy	Number of Pharmacists	Number of Technicians	Length of Shift (Hours)	Total Number of Prescriptions Filled	Length of time spent on each prescription
High Volume	2-3	4-5	12	1000+	<1 min
Medium Volume	1-2	3-4	12	500+	1.4 min
Low Volume	1	0-1	12	<130	5 min

Convenient Drive-Thru

For the convenience, some retail pharmacies have a drive-thru pharmacy that lets customer pick up prescriptions quickly and be on their way. They also have a slot that allows customer to drop-off new prescriptions to be filled and ready the next business day

Terminologies in Pharmacy

Pharmacists

Pharmacists are healthcare professionals with specialized education and training who perform various roles to ensure optimal health outcomes for their patients through proper medication use. Pharmacists must understand the use, clinical effects, and composition of drugs, including their chemical, biological and physical properties. Only a pharmacist can take new prescriptions from customers and also take prescriptions over the phone. Pharmacist also has the duty of visually verifying a filled prescription before it is given to customer. It is the pharmacist who interacts with a patient to inform side effects or possible complications of any medication and to answer any questions the patient may have (counseling).

Superintendent pharmacist

Is a pharmacist who is a superintendent of a retail pharmacy business owned by a body corporate. In hospitals this may be the chief pharmacist

Responsible pharmacist

Is a pharmacist who is responsible for pharmacy procedures of registered pharmacy for the purposes of the Responsible Pharmacist Regulations 2008

Technician

The technician usually performs routine tasks including greeting customers, collecting patient information and insurance information (A pharmacist may complete these duties if he is the only one available at the moment). Technician also helps prepare prescribed medication for patients, such as counting tablets and labeling bottles. A technician may refill a prescription but not fill new prescriptions. Technicians may establish and maintain patient profiles, prepare insurance claim forms, and stock and take inventory of prescription and over-the-counter medications.

PTCB:

Pharmacy Technician Certification Board: Education beyond the basic technical education, usually required for license renewal

CPRP:

The Community Pharmacy Residency Program (CPRP) was established by the American Pharmacists Association in 1986 to foster the development of formal postgraduate education and training experiences for pharmacist in contemporary innovative community pharmacy practice settings. In June 1999, the APhA and the American Society of Health-System Pharmacists (ASHP) announced a partnership to accredit community pharmacy residency programs.

Certified Pharmacy Technician:

A technician who has passed the National Certification Exam-the technician can use the abbreviation CPhT after his or her name

Worker's Compensation

A government-required and enforced coverage for workers injured on the job

NPI

National Provider Identifier

ASPL:

The American Society of Pharmacy Law (ASPL) is an professional organization of pharmacist-attorneys, pharmacists, attorneys, and students in schools of pharmacy or law who are interested in the law as it applies to pharmacy.

Rx

Latin abbreviation for "recipe" commonly used, is often used as a short form for prescription drug in North America

Over-the-counter (OTC) drugs

Are medicines that may be sold directly to a consumer without a prescription from a healthcare professional, as compared to prescription drugs, which may be sold only to consumers possessing a valid prescription.

POS

Point of Sale

Recall

When a drug or medical device must be returned to the manufacturer. Usually drug recalls happens when the medicines or devices are defective or has poses health hazards.

Trade name

Brand-name drug: the company that first applies for a patent on the chemical structure of a medication of generic name is allowed to name the product with a patented name

HIPAA

The HIPAA (Health Insurance Portability and Accountability Act of 1996) Privacy Rule provides federal protections for personal health information held by covered entities and gives patients an array of rights with respect to that information. At the same time, the Privacy Rule is balanced so that it permits the disclosure of personal health information needed for patient care and other important purposes.

The Security Rule specifies a series of administrative, physical, and technical safeguards for covered entities to use to assure the confidentiality, integrity, and availability of electronic protected health information

Title I of HIPAA protects health insurance coverage for workers and their families when they change or lose their jobs. Title II of HIPAA, known as the Administrative Simplification (AS) provisions, requires the establishment of national standards for electronic health care transactions and national identifiers for providers, health insurance plans, and employers.

NCPDP

NCPDP is an ANSI (American National Standards Institute) accredited Standards Development Organization representing almost all sectors of the pharmacy service industry. Through a consensus building process in collaboration with other industry organizations, NCPDP helps to develop business solutions, standards and guidance for promoting information exchange within the healthcare system. The solutions provided also helps to improve safety, reduce costs and also ensure the privacy and healthcare outcomes for patients and healthcare consumers. NCPDP implementation also helps in increasing operational efficiencies that result in multibillion dollar savings in healthcare costs for the industry per annum, while increasing the safety and quality of patient care.

NCPDP members have created standards such as the Telecommunication Standard and Batch Standard, the SCRIPT Standard for Electronic Prescribing, the Manufacturers Rebate Standard and more to improve communication within the pharmacy industry. The Payer/Processor category includes Pharmacy Benefit Management Companies (PBM), Health Insurers, State and Federal Agencies, Health Maintenance Organizations (HMO) and more.

The latest NCPDP Telecommunications Standard Version is D.0 , which is an updated version of the HIPAA standard for pharmacy claims transactions, the compliance date for NCPDP D.0 being January 1, 2012.

NABP:

National Association of Boards of Pharmacy is an international association which assists state licensing boards in developing, implementing, and enforcing uniform regulations in pharmacies to protect public health. This is achieved with the help of its pharmacist license transfer and pharmacist competence assessment programs, as well as through its various accreditation programs such as VIPPS, Vet-VIPPS, VAWD, and DMEPOS.

VIPPS (Verified Internet Pharmacy Practice Sites) and Vet-VIPPS (Veterinary-Verified Internet Pharmacy Practice Sites) is a strong indicator of an Internet pharmacy's compliance with state and federal laws and regulations and NABP's criteria. This accreditation enables the customer to identify whether an internet pharmacy has undergone and successfully completed the NABP accreditation process, which includes a thorough review of all policies and procedures as well as an on-site inspection of all facilities used by the site to receive, review, and dispense medicine. This accreditation thus helps a user to distinguish between a genuine internet pharmacy following all standards and a bogus one or one which is not up to the mark.

VAWD (Verified-Accredited Wholesale Distributors) is an accreditation for pharmaceutical wholesale distribution facilities and is provided for those distributers that are in compliance with state and federal laws and NABP's VAWD criteria.

DMEPOS accreditation is given for those pharmacies seeking durable medical equipment, prosthetics, orthotics, and supplies accreditation and meeting NABP's DMEPOS criteria and is in compliance with the state and federal laws.

NCPDP Provider ID (The NCPDP Provider Identification Number):

Formerly known as the NABP number, it was developed to provide pharmacies with a unique national identifier that would assist pharmacies in their interactions with pharmacy payers and claims processors. It is a seven-digit numbering system that is assigned to every licensed pharmacy and qualified Non-Pharmacy Dispensing Sites (NPDS) in the United States.

FDA

The main mission of the United States Food and Drug Administration (FDA) is to protect public health "by assuring the safety, effectiveness and security of human and veterinary drugs, vaccines and other biological products, medical devices, nation's food supply, cosmetics, dietary supplements and products that give off radiation." Any new medicine that is to be introduced to the US market must have FDA approval which is attained after rigorous testing and research studies. FDA inspects the product that it regulates and also enforces product recalls if the product poses any public health threat. A class 1 recall (ex: a misprinted label on a life-saving drug) is the most serious category.

DEA

Drug Enforcement Administration is a federal law enforcement agency which comes under the United States Department of Justice. The DEA is the agency responsible for combating drug smuggling and its use within the United States. The DEA the lead agency for domestic enforcement of the Controlled Substances Act and shares concurrent jurisdiction with the Federal Bureau of Investigation (FBI) and Immigration and Customs Enforcement (ICE). It has the sole responsibility for coordinating and pursuing U.S. drug investigations abroad as well.

DEA Number

A DEA number is a unique identification number that is assigned by the DEA to the healthcare provider. The healthcare provider can be a medical practitioner, a dentist, a veterinarian etc. Only healthcare providers having valid DEA number are allowed to write prescriptions for controlled substances. The DEA number is solely to be used for tracking controlled substances. A valid DEA number consists of 2 letters, 6 numbers, & 1 check digit. The first letter is a code identifying the type of registrant; the second letter is the first letter of the registrant's last name.

HMO

HEALTH MAINTENANCE ORGANIZATION is a corporation that provides comprehensive maintenance and acute medical care to patients. HMO's usually prescribe their own eligibility limits to their members which coincide with the level of insurance held by the patient. HMO's provide preventive medicine, while employing primary care physicians as referrals for more substantial treatments.

NDC

National Drug Code is a unique product identifier used in the United States for drugs intended for human use. Certain devices are also considered as drugs and carry an NDC code. NDC code is a unique 11-digit; 3-segment numeric identifier listed in 5-4-2 configuration and is a derivative of the 10-digit NDC configuration (4-4-2, 5-3-2, or 5-4-1).

The first segment, the labeler code is 5 digits long and assigned by the Food and Drug Administration (FDA) upon submission of a Labeler Code Request (A labeler is any firm that manufactures, repacks or distributes a drug product).

The second segment, the product code, is 4 digits long and identifies the strength, dosage form, and formulation for a particular firm.

The third segment, the package code, is 2 digits long and identifies package forms and sizes.

While the labeler code is assigned by the FDA, product and package segments are assigned by the labeler.

TPP

Third party payers

PBM:

Pharmacy Benefit Manager (PBM) is a third party administrator (TPA) of prescription drug programs and is the organization that provides drug benefit programs.

PBM charges payer for entire program which includes reimbursement to pharmacies, conducting help desks, conducting computer administration and all support functions. Rebates are negotiated between PBM and payer company.

Hard Copy

The original prescription

Script

A prescription

Sig

It is the medication directions written in pharmacy terms on a prescription. These are essentially medication information and direction written in standard abbreviated format which is understood by the pharmacist and technician.

DAW

The prescriber of the medicine has veto rights to drug control and managed care limitations by the plan sponsor in most instances. Physician discretion and responsibility is the primary justification to allow such veto power. This manifests itself by the prescriber writing "DAW" on the prescription which means 'dispense as written' by the prescriber. This is notice to the provider that the drug prescribed is to be dispensed without substitution.

DAW codes are:

DAW 0 - No product selection indicated

DAW 1 - Physician specifies no substitution

DAW 2 – Member request no substitution

DAW 3 – Pharmacist chooses not to substitute

DAW 4 – No generic in stock

DAW 5 - Brand dispensed as generic

DAW 6 - Override

DAW 7 - Brand drug mandated by law

DAW 8 - Generic not available

DAW 9 - Other

Days' Supply

Days' supply refers to the number of days for which the medication is prescribed by the physician. In most cases, the physician will prescribe a 30-day supply when using a retail pharmacy. Most health plans have maximum days supply set at 90 days.

The Three Day Supply rule is of special importance as the board of pharmacy in most states allows a pharmacist to dispense a 3 day supply of non-controlled meds to a patient whose doctor has not called back with approval for a prescription refill.

Auxiliary Label

It is an adhesive label that is attached to a container with specific instructions or information pertaining to the medication inside. Provided information includes warning, dietary information, instructions for administrating medicine or cautionary details.

Parenteral medications:

Medication administered by injections, such as intravenously or intramuscularly

Hyper-alimentation:

Parenteral nutrition for patients who are unable to eat solids or liquids

Adjudication

Electronic insurance billing for medication payment

PAR

Periodic Automatic Replenishment

PPO

Preferred Provider Organization

PYXIS

Advanced automated medication management system

MSDS

Manufacture Safety Data Sheet

EOB

Explanation of benefits

Classification of Drug Disbursement

Ethical / Prescription drugs

Use for Mx / Tx of diseases

Require prescription form, licensed medicine that is regulated by legislation to require a medical prescription before it can be obtained

Over the counter/ Non-Rx

Use for the prevention of self-limiting or minor ailments

No Rx form needed. As a general rule, over-the-counter drugs (OTC) are used to treat conditions not necessarily requiring care from a health care professional and have been proven to meet higher safety standards for self-medication by patients. Often a lower strength of a drug will be approved for OTC use, while higher strengths require a prescription to be obtained

Type of Drugs

Branded Drug:

Branded drugs are drugs that are introduced to the market by drug innovation companies. These drugs are developed with considerable R&D expenditure (usually in billions of dollars) from the company and also undergo stringent testing and approval processes which can take a large number of years. The formula for these drugs and drug molecules are usually patented and the drugs, when introduced to the market, come at a very steep price depending on the effectiveness of the drug as well as the type of illness which gets treated by the drug.

Generic Drug:

Generic drug is a drug which is manufactured by a company that is not the innovator of the drug. Generic drugs are chemically equivalent to a branded drug and would also have the approval from the FDA. Most generic drug names reflect the chemical name of the drug. These drugs are significantly less expensive while having the same therapeutic value as the branded equivalent drug.

Formularly:

Formularly comes into picture because the insurance providers wish to reduce the usage of certain type of drugs in their health plan as a cost containment measure. In order to achieve that, they usually create a list of drugs or groups of drugs designated by therapeutic class called a formulary. This list is then distributed to prescribers and members. The main function of formularies is to specify which medicines are approved to be prescribed under a particular health plan. The development of formularies is based on evaluations of efficacy, safety, and cost-effectiveness of drugs.

Formularly is again classified as:

Formularly (Positive)

A list of drugs that are included in the benefit or coverage i.e.; the drugs that are preferred or required to be included and available for prescribing/dispensing

Formularly (Negative)

A list of drugs those are not included in the benefit of coverage. This term has also been used to refer to a list of drugs that are not substitutable by the pharmacist.

Formularly (Open)

A positive or negative drug formulary that allows changes in the formulary to occur without a formal, objective review and approval, process.

Formularly (Closed)

A positive or negative drug formulary with a formal, objective review and approval, process that is required before changes in the formulary can occur

Formularly (Hard)

A list of drugs those are absolute and mandatory that excludes or includes the designated drugs. In this case, there is an exception if there is a prior authorization available, it over-rides the absolute prohibition and allows the drug use because of official sponsor intervention.

Formularly (Soft)

A list of drugs that designate the inclusion or exclusion of the formulary items as preferred but non-mandatory.

Controlled Substances:

Controlled substances are any drug or therapeutic agent which comes under the following descriptions as delineated by the Comprehensive Drug Abuse Prevention & Control Act passed in 1970.

Controlled drugs are those drugs which:

      1) Are understood to include narcotics

      2) Has a potential for abuse or addiction

      3) Is held under strict governmental control

Controlled drug substances are classified into five categories or schedules. The broad definitions are as follows

Schedule I drugs - High abuse potential, no accepted medical use in US

      Example: LSD, mar

Schedule II drugs - High abuse potential, potentially leading to severe psychological or physical dependence; schedule II agents have acceptable medical uses

      Example: Narcotics – cocaine, morphine, ethymorphine, powdered opium, raw opium

        Non-narcotics– amphetamine, amobarbital, methamphetamine

 Schedule III drugs - High abuse potential, moderate to low physical dependence, and high psychological dependence potential, with acceptable medical uses,

      Example: Narcotic – nalorphine, paregoric

        Non-narcotic - butabarbital, chlorphentermine

Schedule IV drugs - Minimal abuse potential, limited physical or psychological dependence potential, non-narcotic.

      Example: barbital, chloral hydrate, diazepam, paraldehyde

 Schedule V drugs - Very low abuse/dependence potential

      Example - brown mixture–opium, some codeine preparations

Any drugs using controlled substance are disbursed at pharmacies using additional checks that are used to ensure that the prescription is genuine and no laws/ federal rules are being violated. Medical practitioners are also expected to be extra careful when prescribing medicines having controlled substances. Such medicines are used more in the field of oncology.

The two federal agencies, the DEA and FDA determine which substances are added to or removed from the various schedules.

Generic substitution

When the doctor writes a prescription medication, but the pharmacists substitutes that with a generic medication, the process is termed as generic substitution.

This is perfectly legal and is a good thing for patients in general because the generic is usually just as good as the brand drug with much less price. However, there are some instances where the small difference between the generic and the brand name medication may make a difference. These are usually medicines where doses are very small such as hormones (thyroid medications, birth control pills) and medicines that have to be closely monitored. This does not necessarily mean that the generic is worse than the branded medication, but that switching from one to the other could have potential adverse effects.

Therapeutic substitution

When the doctor writes a prescription for a branded drug and the pharmacist substitutes it not with the generic equivalent, but with a completely different generic drug in the same class, it is termed as therapeutic substitution. In this case, patients are getting a totally different medication coming within the general grouping (example - cholestrol lowering drug), but the effect of the substituted drug differs verymuch from the prescribed drug. This could cause significant health issues if not properly checked.

Compounding of Drugs:

Compounding is the process of combining, mixing, or altering of ingredients to create a customized medication for an individual patient in response to a licensed practitioner's prescription. In its simplest form, it may involve taking an approved drug substance and making a new formulation to meet the medical needs of a specific patient. For example, it may involve formulating the product without a dye or preservative in response to a patient allergy. Or it might involve making a suspension or suppository dosage form for a child or elderly patient who has difficulty swallowing a tablet or a capsule.

Although these products technically may be considered unapproved new drugs because they differ from the approved formulation of the drug, compounding is legitimate but are regulated under state laws governing the practice of pharmacy

Pill-splitting

Pill splitting or Half tab refers to the practice of modifying a tablet, capsule or pill to obtain a lower dose of the active ingredient, or to obtain multiple smaller doses, either to reduce cost or because the drug is not available in the dose desired. Often, pills that are meant to be split (Aspirin for instance) come pre-scored so that one may easily divide the pill into halves or quarters. Many prescription pharmaceuticals are sold on a per dose or tablet basis.

For example a 10 mg tablet of a given drug might be sold for the same or nearly the same price as a 5 mg tablet. Splitting a 10 mg tablet allows the patient to purchase half the number of tablets while still receiving the same amount of the active drug. Therefore, pill-splitting can be an

effective way to save money on pharmaceutical costs and can result in cost savings of up to 50%.

Not all medications can be split and there are state and Federal regulations in place to check and ensure safety with pill-splitting.

Splitting makes sense when the medication:

- Is in tablet form; capsules aren't going to work.
- Is not a sustained-release formula designed to be absorbed at various levels in the gastrointestinal tract, where splitting the tablet could compromise the integrity of absorption over time.
- Has a broad therapeutic performance range, so if consumers get a little more one day and a little less the next they won't compromise the integrity of the drug.
- Has flat pricing independent of the dosage.

Types of Drug Packaging

Pharmaceutical companies carefully examine and follow FDA guidelines and CGMPs when choosing the container closure system for packaging drugs. For instance, considerable time and resources are spent to develop primary packaging to protect drug product quality. And secondary packaging is designed to enhance or protect the primary package and its precious contents. The packaging of drugs is classified into numerous categories depending on the way the drug is packed. Some of the most common package types are explained below

AMPULE

A container capable of being hermetically sealed intended to hold sterile materials.

BOTTLE

A vessel with a narrow neck designed to accept a specific closure.

APPLICATOR

A prefilled non‑injectable pipette, syringe or tube.

CAN

A cylindrical vessel usually made of metal.

CANISTER

A type of can for holding a drug product.

CARTRIDGE

A container consisting of a cylinder with a septum at one end, and a seal at the other end, which is inserted into a device to form a syringe which contains a single dose of a parenteral drug product.

INHALER

A device by means of which a medicinal product can be administered by inspiration through the nose or the mouth

TUBE

A flexible container for semisolid drug products which is flattened and crimped or sealed at one end and has a re-closable opening at the other.

VIAL

A container designed for use with parenteral drug products.

BLISTER PACK

A package that consists of molded plastic or laminates that has indentations (viewed as "blisters" when flipped) into which a dosage form is placed. A covering, usually of laminated material, is then sealed to the molded part. A strip pack is a specialized type of blister pack where there are no pre-formed or molded parts; in this case there are two flexible layers that are sealed with the dosage form in between. Suppositories that are strip packed between two layers of foil are also considered a blister pack. This is the common packaging form for tablets.

Bulk Package

Pharmacy Bulk Package is a container of a sterile preparation for parenteral use which contains many single doses. Multiple single doses are then dispensed from this bulk package using a suitable transfer device and aseptic technique. The bulk package closure will be penetrated only once using this transfer device or dispensing set which allows measured dispensing of contents. The transfer of contents from the Pharmacy Bulk Package is restricted to a suitable work area, such as a laminar flow hood. a maximum time of 8 hours from initial closure entry is permitted to complete fluid transfer operations. The container should not be removed from the aseptic area during the entire 8 hour period. The temperature of the container should not exceed 37℃, after the closure has been entered.

Repackage

Repackaging is the act of removing a preparation from its original primary container and placing it into another primary container, usually of smaller size. i.e.; packaging of solid oral drug products such as tablets and capsules into unit dose configuration pursuant to a prescription.

There are two types of repackaging - first involving pharmacies that dispense prescription drugs and second involving commercial pharmaceutical repackaging firms. In order to repackage a prescription drug, a repackaging entity, including a pharmacy, must have specific information,

and such information must appear on the label of the unit dose container. Without that information, a unit dose package of a prescription drug is considered to be misbranded

Repackager

A repackager is an establishment that repackages the drugs and sends them to a second location in anticipation of a need. Repackaging firms repackage preparation for distribution, a function that is beyond the practice of a regular pharmacy.

In order for a pharmacy to repackage drugs and distribute repackaged drugs to other practitioners or facilities, the pharmacy must be registered with the FDA as a repacker. In addition, the pharmacy must provide FDA with a listing of those products that are being repackaged. This registration is required for both federal legend drugs as well as OTC drugs that are distributed in this fashion. The repackaging of OTC drugs for retail sale to the public by a pharmacy can be done without FDA registration, however, strict labeling requirements must be utilized for any OTC drugs that are repackaged by a pharmacy and exposed for direct sale to the public. Pharmacists should take note that state and federal Food and Drug Acts hold any repackager of OTC items strictly liable for compliance concerning the appropriate labeling of each container of an OTC drug.

Minimum labeling requirements include:

The name of the product;

The name and address of the manufacturer, packer or distributor;

The net contents of the package;

The established name of all active ingredients and the quantity of other ingredients, whether active or not;

The name of any habit-forming drug contained in the preparation;

Cautions and warnings that are needed for the protection of the user;

Adequate directions for safe and effective use;

Pricing Terminologies in Pharmacy

AWP

Average wholesale price (AWP) is the average cost paid by a pharmacy to the wholesaler. AWP is a "list price" and is higher than the cost wholesalers actually pay. AWP depends on factors like drug strength, dosage form, package, size, and manufacturer. AWP does not represent the true cost of the product to purchasers so several new drug payment benchmarks as alternative options more representative of true costs are also in use. There are no requirements or conventions that the AWP reflect the price of any actual sale of drugs by a

manufacturer, or that it be updated at established intervals. It is not defined in law or regulation, and it fails to account for the deep discounts available to various payers, including certain federal agencies, providers, and large purchasers, such as HMOs.

AAC

Average Acquisition Cost (AAC) is the average acquisition cost that pharmacies within that state purchase a drug with, as defined and calculated by the applicable state Medicaid program. Not all states calculate an AAC.

FUL

Federal Upper Limit (previously referred to as Federal Financing Participation Upper Limits—FFPUL) is the upper limit of the amount Medicaid can reimburse for multi-source drugs, and are established for products if there are three or more versions of the product rated therapeutically equivalent. The Centers for Medicare & Medicaid Services (CMS) maintains and publishes the FUL prices.

FSS

Federal Supply Schedule (FSS) is obtained from market transaction data reported by manufacturers. In general, FSS may not be higher than the lowest price charge by the manufacturer for non-federal purchasers. That is, the federal government should never pay more than any other plan or intermediary. Some federal bodies set price according to FSS.

EAC

Estimated Acquisition Cost (EAC) is the other upper limit complementing the FUL. EAC is a state's estimate of price paid by providers for a drug. It is often used for single-source (e.g., "brand") drugs while FUL involves three or more generic drugs. Most states use AWP to calculate EAC.

ASP

Average Sales Price (ASP) is a close match to the manufacturer reported actual sale price and includes discounts based on volume, rebates and other price reductions. It replaced AWP as a payment method for drugs under Medicare's medical benefit. Advantages include publicly available, reimbursement incentives for preferred, lower-cost products, reduces drug payments for Medicare versus AWP and larger groups pay lower prices

AMP

Average Manufacturer Price (AMP) is the average price paid by retail pharmacies or drug wholesalers to manufacturers for drug products distributed to retail pharmacies. Made by CMS for determining Medicaid rebates and is computed every quarter by individual drug manufacturers. It is computed on the basis of total retail sales dollar value per each drug type and strength/ # units sold. The AMP is not a published price. It is calculated by the manufacturer and submitted to CMS for purposes of calculating the Medicaid rebate.

WAC:

It is a published catalog or list price for a drug product to wholesalers by the manufacturer. Essentially, it is the cost that wholesalers pay manufacturers for drug products and serves as basis for price negotiation between manufacturers and private payers (discounts and rebates are subtracted from WAC) for both medical and pharmacy benefit products. Wholesaler acquisition cost is slightly more representative of costs actually paid by wholesalers, and is more accurate with respect to branded pharmaceuticals than generics. Advantages include publicly available, Published on daily basis and is a Payment benchmark

MAC

The highest price a health plan or other intermediary will pay for medications. This cost figure becomes most relevant when there are more than two generic options available for the drug. Pharmacy benefit sponsors like the government institutions usually negotiate with the sellers to create a contract with fixed prices in place of AWP price, which is termed as Maximum Allowable cost (MAC). MAC prices are always fixed lower than the AWP price for. These are usually set for drugs that have the highest utilization and are applicable to a limited number of drugs.

MAB

The maximum allowable benefit is an amount set by the insurance provider for each member or family for a specific health plan. Once the maximum limit is met, members are required to pay cash for future prescriptions for the duration of the contract.

SWP

Suggested Wholesale Price (SWP) represents the manufacturer's suggested price for a drug product from wholesalers to their customers (i.e., retailers, hospitals, physicians and other buying entities) as reported by the manufacturer. SWP is a suggested price and does not represent actual transaction prices.

Direct price

It is the cost of a drug product paid by the pharmacy to the manufacturer if the product is purchased directly from the manufacturer. Direct Price does not represent actual transaction prices and does not include prompt pay or other discounts, rebates or reductions.

Out-Of-Pocket

The patient pays the cash rather than taking care of the payment through a third party insurance provider.
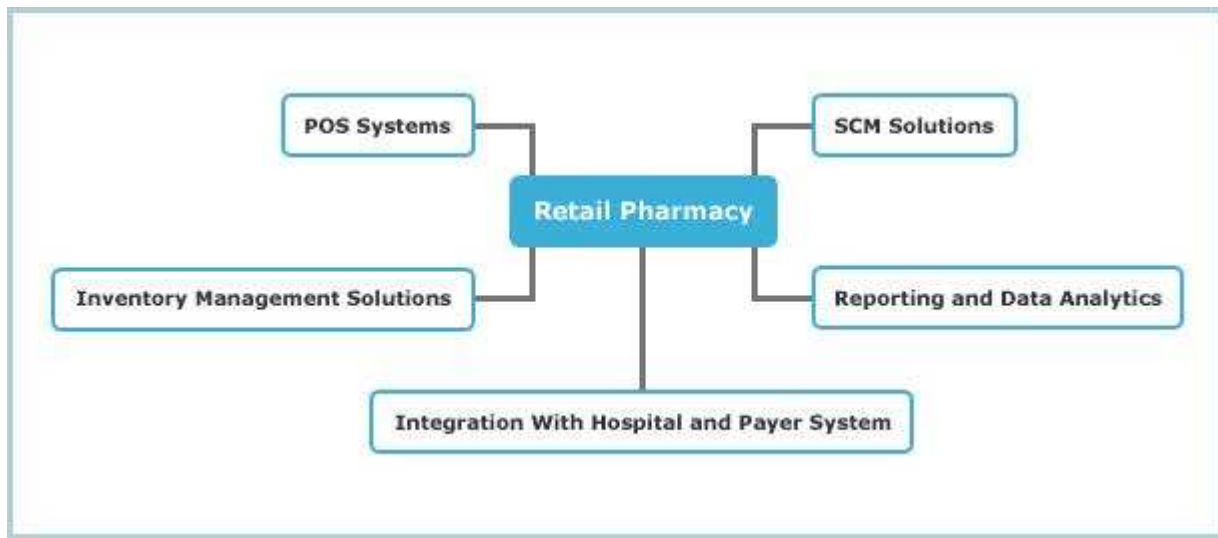
Dispensing Fee

A dispensing fee compensates the pharmacy for transferring the drug from the pharmacy to the patient; overhead, such as stocking and storing medications; and patient counseling. This is a fee that is usually paid by the pharmacy benefit manager to the pharmacist. It is usually a fixed

amount or a percentage of the drug cost and is to account for the labor and administrative effort from the part of the pharmacist. The national average cost of dispensing medications is $10.50 per prescription, while Medicaid only reimburses a dispensing fee on average of $4.50 per prescription and Medicare reimburses $2.27 per prescription

Retail Pharmacy System

Overview on Pharmacy System

The systems need to be interoperable with Hospital Information System (HIS), third-party pharmacy benefit networks, and payer systems, among others. They also need to have an efficient inventory management and supply chain management system to ensure that the inventory is stocked at appropriate levels. All these systems coupled with Point of Sale(POS) systems need to be tightly integrated to ensure operational efficiency.

Activities: dispensing, compounding, selling, storage and handling, advising of patients,selecting product for inventory, identifying fast moving products, administers, supervise the pharmacy (managerial function), entrepreneural function

The Retail/Community Pharmacy is the last link in the supply chain for medicinal product from the Manufacturer to the Patient. The transport and storage of medicinal product requiring Controlled Temperature storage -label requirements "do not store above 25℃" and cold chain storage – label requirements "store between 2℃ an d 8℃" are applicable to this sector.

What Happens at a Pharmacy?

Getting a prescription filled is something many of us have had to do. You hand over a slip of paper, and in return, get a vial of tablets or tube of cream. It seems simple enough, but prescription filling is a detailed process designed for your safety. This process can be separated into different phases: prescription drop-off, patient profile creation/review, order entry, final check, and pick-up. There are also certain deviations from this standard flow to take care of aspects like partial fill, refill, rebill, claims etc (explained below)

Dropping Off the Prescription
Upon receiving your prescription, a pharmacy staff member ensures it is complete and correct. Pharmacy laws vary by state regarding the legalities of a prescription order. The order must, at a minimum, specify a patient's full name, medication name and dosage, directions for taking, physician's signature, and refill information. If any discrepancies are noted, the pharmacist may need to contact your physician.

Enrollment/Patient Intake

Enrollment information can be received at the pharmacy in various forms from multiple sources. As a result, the enrollment process will ensure receipt capabilities from physician/hospital faxed forms, payer electronic feeds, and third party providers via telephone calls and e-mails.

Once enrollment information has been captured, system quickly assesses the missing information based on work flow drivers and payer, disease state, and drug considerations. Identification of missing critical data elements affecting enrollment and future work flow operations will be addressed immediately in order to avoid blockage during current and future work flow operations.

Additional enrollment technical considerations include:

- Capture missing standard demographics and provider information (ie, identifying correct disease states)
- Capture multiple addresses (i.e., home address, shipping address, and nurse/ caregiver information as appropriate)
- Capture full contact information including e-mail addresses for future communications
- Support medication profiling data points including dates and relevant updates on subsequent events (ie, orders, calls, etc)
- Support multiple opt-out options for automated phone calls and events

Patient Profile Review

Assuming the prescription is legal and complete, the pharmacist or pharmacy technician may ask questions about your personal and medical background.

Some of the more common questions are:

- *What is your date-of-birth?*

- *What is your address?*

- *Do you have prescription insurance?*

- *Do you have any drug allergies?*

- *Are you taking other medications that we are not aware of?*

Even if you are an established customer, you may be asked some of these at each visit. Date-of-birth is often used to confirm patient identity in the case of similar names. Address is required by state and federal law, and can also be used as an identifier. Insurance information changes, so the staff may ask for an update. New allergies can develop at any time, and the pharmacist should maintain current records of all medications you take or have taken. All of this information is crucial to your safety. The pharmacist uses it to determine if the new drug is compatible with your other medications, safe for you, and appropriate to your condition. This process is termed "drug utilization review" and is one of the most important tasks of the pharmacist. If any conflict or safety issues is noticed by the pharmacist at this step, pharmacist need to take corrective action which includes overriding the alert based on one's professional judgment (Ex: refill request is too soon or before the eligible refill date), contacting the patient's doctor and discussing the safety issue (ex: too high a dosage or potential allergy or conflict with another medicine being used by the patient) etc.

Order Entry

After gathering the necessary information, the pharmacist or technician enters the prescription into a computerized system. Retail chains may employ digital image scanners for this process. Other systems rely on manual entry via keyboard. Product selection and pricing are also determined during this phase.

To save time, doctors may use pharmaceutical abbreviations or symbols when writing prescriptions. To the untrained eye, these markings may not make sense, but pharmacists and pharmacy technicians are well trained in the use of this medical shorthand. These abbreviations are referred to as Sig codes.

After all data is input, the pharmacy associate does a check to ensure that all data input is correct.

Pharmacies may also employ a satellite link or internet connection to send information to your insurance company. The insurance provider then decides what portion of the prescription is covered and what part you are expected to pay (your "co-payment"). If you do not have prescription insurance, a computer program assigns pricing based on the medication's average wholesale price (AWP) and other market factors. The cost of a prescription typically includes the medication, supplies, and the pharmacist's expertise.

As specified by the M.D.'s order, the pharmacist or technician selects a product from available inventory. Depending on state regulations, the pharmacist may be allowed to substitute a generic equivalent unless the doctor has specified otherwise. The US Food and Drug Administration insure that generic products undergo the same testing and research as brand-name products. Generic drugs can often provide the same benefit at substantial savings.

Insurance Verification

In an effort to expedite the delivery of medications to patients, pharmacies will typically attempt an adjudication transaction based on the information received during the enrollment. Performing automated insurance verification at this point is critical to work flow efficiency, as information obtained from and confirmed by third party services can help to ensure claims will process successfully. Additional insurance verification technical considerations include:

Confirm plan information is entered correctly

Confirm formulary coverage (trial adjudication)

Confirm deductible and co-pay information

Capture all possible insurance information

Capture all Medicare required inputs for claims submissions and Prior Authorizations

Confirm billing override information

Filling and Counting:

Once order entry is complete, the prescriptions associated with the order are ready to be filled.

Filling is the process wherein the pharmacist will select an appropriate container (bottle) into which the medicine can be measured and filled, stick the label containing the information about the medicine present in the container, and fill it with the prescribed medicine in the mentioned quantity. This filling of medicine is carried out in a pharmacy area called filling counter.

The sequence of steps can be listed as follows:

1) Select a tote or bag for placing together all vials/bottles that are filled for a particular order.

2) For each prescription in the order, select a bottle/vial for filling the prescribed medicine.

3) Navigate to the storage shelves, selects the appropriate drug container having the prescribed medicine and move to the filling counter.

4) If the medicine is an oral solid (tablet/capsule), use a tray and spatula to extract and count the correct number of tablets from the container, fill them into the bottle and cap it. In case of liquids, pour into the vial and cap it.

5) Print out the label containing corresponding medicine, dosage, usage and warning information to be stuck to the bottle/vial.

6) Review the label and stick to the bottle/vial.

7) Place the prescription container back into the storage shelf.

8) Place the vial/bottle in the bag/tote.

9) Repeat the process for all available medicines associated with an order.

10) Place the bag/tote at inspection area for verification/final check and delivery.

Note that many pharmacies make use of automated counters to count out and dispense the expected number of tablets/capsules for a prescription

The Final Check/ visual verification

The pharmacist then reviews the order during a process called the "final check,"/" visual verification". In the entire process, this is, perhaps, the most important action of the pharmacist. The various checks at "Final Check" involve proofreading the label on vial/bottle and verifying the drug name, strength, dosing directions and quantity of medicine filled in the bottle, inspecting and verifying the appearance of medication including size, shape and color. Pharmacist will also ensure the prescription has been filled for the correct patient. During this check, any existing discrepancies between the M.D.'s order and the final product should be noted and corrected. If the pharmacist identifies any issues that has come up during the filling step, the filled medication is send back to the appropriate step for corrective action.

Patient Education Leaflets are also placed along with the container for handing over to the customer, especially when the medicine is being bought for the first time. Patient Education leaflets are sheets of paper containing information about the medicine. The different sections in the leaflet contains information on common use of the medicine, directions for using the medicine, precautions to be taken (ex: not to take in case customer has a particular allergy), possible side effects, steps to take before using the medicine ,symptoms of overdose and disclaimer

Prescription Pick-Up

Finally, the pharmacist presents the filled prescription and offers counseling. During pick-up, be sure to ask any questions or address any concerns regarding your medication.

Most retail pharmacies may return a single prescription in 10 to 20 minutes if there are no insurance, inventory, or other issues that require correction. However, it is not uncommon for the process to take half an hour or more during peak times.

Each step in the prescription filling process helps ensure that patient's prescription is complete, appropriate, safe, and correct. It is designed to provide thoughtful, safe delivery of medication to the patient and is time well spent

Patient Counseling

The pharmacist shall provide such information which, in the pharmacist's professional judgment, is necessary for the patient to understand the proper use of the patient's prescription which may include the following:

Name and description of the medication;

Dosage form, dosage, route of administration and duration of therapy;

Special directions and instructions for preparation, administration and use by the patient;

Common severe side and adverse effects or interactions and therapeutic contraindications or precautions with legend and non-legend medications which the pharmacist deems relevant;

Techniques for self-monitoring drug therapy;

Proper storage;

Prescription refill information; and

Action to be taken in the event of a missed dose or adverse reaction

Use the Label

The prescription label is usually wrapped around the medicine bottle. In some cases — especially with medicines like eye drops and skin creams — it may be stuck on the outer box instead.

Here's what to look for on the label:

- **Pharmacy phone number.** This is the number you'll call to place the refill.
- **Prescription number.** This number is often shown on the label as "Rx#". Although a pharmacist can look up your prescription in the computer, the refill process will go a lot faster if you have this number handy.
- **Refills remaining.** The prescription label will tell you how many refills you have left. Most labels show a number of refills with a cutoff date. If you refill your prescription before that date, you should be able to place your order with no problem. However, if the label says something like "Refills require authorization" or if your refills have expired, you'll need to get in touch with the doctor who prescribed the medication. Sometimes the pharmacy can do that for you, but other times the doctor will want to see you or talk to you before authorizing the pharmacy to refill the prescription.

Additional Process Flows and Activities at a Retail Pharmacy

Partial Fill of a Prescription
If the prescribed medicine or an emergency oral medicine is available, but not for the desired quantity, the pharmacist has the option to fill the medicine as a partial fill. For example; a medicine ABC has 15 tablets in stock, but the prescribed quantity is 40 tablets, the pharmacist opts for partial fill wherein the initial partial fill will consist of 15 tablets and later on, once the medicine is in stock, final partial (completion partial) can be disbursed with the remaining 25 tablets. Note that the remaining portion of the prescription (final partial fill) may be filled within 72 hours of the first partial filling. However, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescribing individual practitioner. Beyond this 72 hour limit, no further quantity is expected to be supplied without a new prescription.

Rebilling of a Prescription
When a new user registers at a pharmacy, the user might have been associated with a particular third party insurance provider. Later on, the user might have added a new third party or moved to a different third party. If that modification is not captured in the system, it might get identified only when customer comes to pick up the order. It could also be that the customer had provided payment type as cash at time of enrollment and had later enrolled for third party insurance. In such a case, wherein the third party payment information has to be modified after most pf the steps in the pharmacy are complete, the prescription has to be reprocessed through the different steps once again after entering/correcting the third party information. This process of billing the charges to a different third party or payment mode is termed as rebill.

Refilling a prescription

If a particular medicine is to be used by a patient for a long period, the medical practitioner can mention the number of refills authorized for that medicine in the prescription. If a prescription has refills marked against it, the patient need not get a new prescription every time the pharmacy is visited for purchasing the drug. The same prescription can be used at the pharmacy and pharmacy will keep track of the number of refills that were done on that prescription as well as the number of refills remaining. This process is repeated till the number of refills remaining reaches zero.

There are several ways to refill your prescription:

> **In person.** Go to the pharmacy where you originally filled your prescription and either wait for it or come back to pick it up at a later time.

> **By phone.** Use the pharmacy's phone number listed on medication bottle to call in your refill. Most large pharmacies or chain stores have automated menus that you can use any time, day or night (though of course you'll have to wait for store hours to pick up your refill). The voice prompts will lead you through the process. At smaller pharmacies, you may speak to the pharmacist or pharmacy technician directly.

> **Online.** The pharmacy lets you reorder a prescription online, still have to go to the store to pick it up.

> **By mail.** People who take medication regularly (such as every day to manage a health condition) can sometimes refill prescriptions by mail. This option is convenient because you can often get your medication in batches (say, a 3-month supply of allergy pills) if

doctor gives you a prescription for that amount. If you want to use the mail-order option, you'll need to plan ahead since it may take up to 2 weeks to receive your medicine.

Central Fill

Central fill is an off-site semi-automated system that fills all prescriptions in one central facility rather than filling the prescription at the retail pharmacy outlets at which the prescription was received. Using Central Fill, national retail chain pharmacies can accept the prescriptions from multiple locations and send them across to a centrally located prescription fulfillment center. Once there, prescriptions are arranged, verified, filled and packaged, and are delivered patient-ready back to the originating pharmacy. Purely central fill pharmacies deliver the prepared prescription to the same pharmacy from which the request originated. Also, a purely central fill pharmacy is not allowed to take prescriptions directly from a patient or practitioner or dispense prescriptions directly to a patient or practitioner.

Central fill facilities are used and come in handy for the pharmacies that have an increased demand for services due to the large prescription volume. This also helps in reducing the labor at retail pharmacies, reduces operational costs of filling prescriptions and fills significantly large volume of prescription per day due to high level of automation. Other advantages include lower inventory carrying costs because in-store inventory needs are lower, improved patient care by freeing up pharmacists for other duties like counseling and thus maintain the important patient relationship.

Robotic Filling:

With the evolution of technology and streamlined systems and processes, robotic filling is gaining importance in pharmacies.

Robotic filling is the process where automated systems/robots are responsible for filling the prescription. The steps generally include receiving the prescription information by the robotic system, automatically selecting a bottle/vial for filling the prescription, navigating within the system to the location of the medicine to be filled, automatically counting and dispensing medicine in the desired quantity, applying prescription and auxiliary labels and collating the uncapped vials into slots for final inspection using on-screen drug image verification.

Robotic filling is usually much more accurate than manual filling and is also significantly faster and so improves patient safety. Robotic filling thereby frees up pharmacist's time for other major aspects like counseling.

Automatic Refill / Mail Order Prescription Service

Automatic Refill Prescription Service allows patients to have monthly maintenance prescriptions filled without having to request them each time. Prescriptions may be picked up at local Pharmacy or mailed directly to home at no charge. The pharmacist will also contact your provider for additional refills before your last refill runs out. This

program is designed to provide the best care in the manner most convenient for patients.

Mail order pharmacies are used by many plans as a cost saving and convenient alternative to retail pharmacies. Members typically order their drugs via fax, email or the internet. Prescriptions can be paid with a personal check or credit card. Once a prescription order is transmitted to the mail order pharmacy, members usually receive their prescription within 2-4 days.

Prescription refill reminders

- Choose email or text alerts when it's time for a refill

- Reply to the email or text to order

- Get pick-up alerts when your refill is ready at the pharmacy

Transfer Your Prescriptions
It's Easy to Transfer Prescriptions Online. Customer need to choose how to receive your order– either in-store pickup or home delivery. The Pharmacy will then contact that pharmacy to make the transfer.

Expired prescriptions and prescriptions with no refills cannot be transferred to another Pharmacy. Due to state regulations, some prescriptions cannot be transferred between pharmacies

Immunization Services

The immunization-trained pharmacists can administer a wide range of CDC-recommended immunizations and vaccines for adolescents, adults and seniors.

- Pharmacists will make personalized vaccine recommendations, bill your insurance company directly and work with your primary care provider to obtain all the necessary forms and updates to your file. Flu-seasonal, Shingles (Herpes Zoster) ,Pneumonia (Pneumococcal), Meningitis (Meningococcal) ,HPV (Human Papillomavirus) , Td (Tetanus, Diphtheria) are some vaccines available at pharmacy

Third Party Payers for Retail Pharmacy

A shift has occurred over the past two decades where payments for products and services have evolved from primarily cash payments to from patients to current practice in which approximately 80% of the payments are made by third party payments (TPPs).Patients still contribute in form of cost sharing, but retail pharmacies receives most of their revenues from insurance companies or pharmacy benefit managers (PBMs).

TPPs comprise several groups that are either private or public (government owned) organizations. Private TPPs include privately owned PBMs and health insurance companies. The major public TPPS are Medicare and Medicaid. Medicare is federal health care program for individuals over 65 yrs or older, persons with end-stage renal disease, and certain disabled individuals. Medicaid is federal-state joint program for low income individuals that provide coverage for outpatient prescriptions in all states. Each state is responsible for managing its own Medicaid prescription drug benefit within federal guidelines.
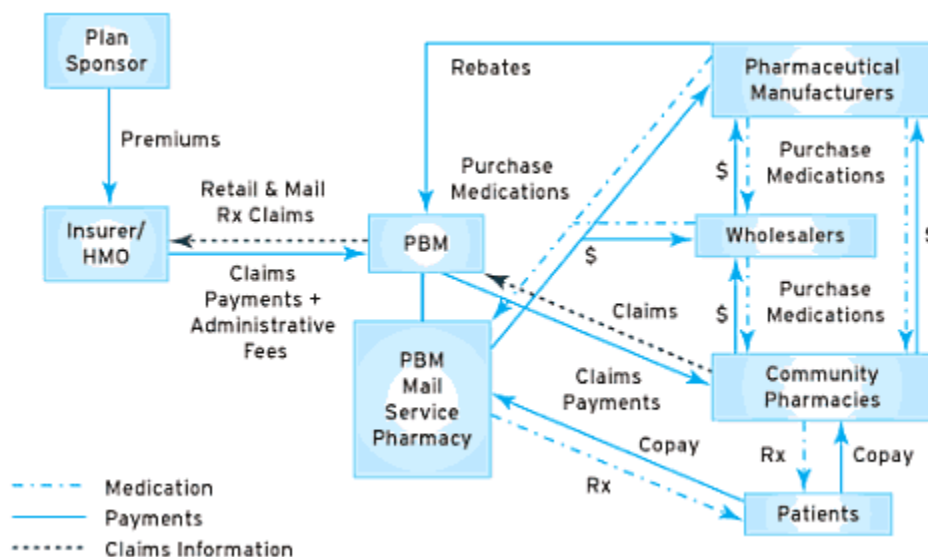
Flowchart for Prescription Medications, Claims, and Payments in the Retail Sector.
Pharmaceutical manufacturers and wholesalers provide community pharmacies and pharmacy benefit manager (PBM) mail-service pharmacies with prescription (Rx) medications and, in turn, receive payment for those medications. Community pharmacies and PBM mail-service pharmacies provide prescriptions to patients and receive payments (co-pays) from patients that cover a part of prescription costs. For the remainder of prescription costs, pharmacies submit claims to PBMs, which then submit retail and mail prescription claims to insurers/health maintenance organizations (HMOs). Insurers and HMOs receive premium payments from plan sponsors. The insurers/HMOs make claim payments to PBMs, which then make claim payments to pharmacies; PBMs also receive rebates from pharmaceutical manufacturers.

Most TPPS pay retail pharmacies for prescriptions and services on a retrospective, fee-for-services basis. In this system, the pharmacist files a claim with the payer when dispensing a prescription or rendering a service, and collects any specified cost sharing (co-payment) amount from the patient. At some later time the payer reimburses the pharmacy.

Cost Sharing Mechanisms

Mechanism	Definition
Copayment	The patient must pay a fixed dollar amount per prescription. Co-pays may range from $1 or $2 (usually in Medicaid plans) up to $100 or more per prescription in private plans. Prescription benefit plans often use tiered co-pays corresponding to the medication's formulary status, with lower co-pays (e.g., $10) charged for generic medications, higher co-pays (e.g., $25) charged for preferred-brand medications, and the highest co-pays (e.g., $50) charged for nonpreferred-brand medications.
Co-insurance	The patient must pay a fixed percentage of the cost of each prescription. This percentage often is set at 10% to 20% but may be as high as 50%. For example, if the allowable cost of a prescription is $100 and the co-insurance is set at 20%, the patient pays $20 and the prescription plan pays $80 for that prescription.
Deductible	The patient must pay for a specified amount of charges per coverage period before the prescription benefit starts to cover expenses. For example, a $250 deductible for prescription coverage means the patient must pay the first $250 of charges for prescriptions during each plan year. Insurance will begin paying benefits after the patient pays the first $250 of charges.
Maximum payment amount	The third-party payer will pay only up to a stated maximum amount for a patient's prescriptions during the plan year (e.g., $1,000). Once prescription charges reach this maximum, the patient must pay out-of-pocket for prescriptions for the remainder of the plan year.

TPPs use various mechanisms to control prescription use and expenditures, including payment formulas, formularies,rebates,patient cost sharing, prior authorizations, generic substituion, quantity limits, step therapy and mail service provisions.

Under **prior authorization programs**, prescribers must get approval from the plan before

patients can receove medcations subject to prior approval requirements, Patients with

contraindications or allergies to a preferred medication or prior treatement failure with a

preferred medication are among those for whom prior approval may be required.

Rebates are given to PBMs by manufactures to encourage PBMs to increase the market share for a particular medication. These rebates generally takes one pf two forms:flat rebates and market share rebates. Ina flat rate method, the rebate amount paid by manufactures to PBM is baesed on a fixed percentage which may range from 2% to 27% of WAC. In the market share method, manufacturers make paymentss to PBMs based on the market share that each PBM achuieved for the drug priduct.

Medicaid

Medicaid is the United States health program that serves U.S. citizens, legal permanent residents, including low-income adults, their children, and people with certain disabilities. It is jointly funded by the state and federal governments, and is managed by the states. Poverty alone does not necessarily qualify someone for Medicaid. Medicaid is the largest source of funding for medical and health-related services for people with limited income in the United States. Medicaid funds about a quarter of the prescription drug expenditures each year. Therefore, Medicaid reimbursement is a significant portion of a pharmacies'profit. Traditionally, prescription drug coverage has only been provided by Medicaid, which is a state entitlement program administered by state agencies. In the 1990s, an amendment to the Social Security Act was enacted to federally mandate that drug manufacturers provide rebates to the State Medicaid Programs for any drugs dispensed to Medicaid patients. Currently, Medicaid uses AMP to calculate federally mandated rebates. Rebates are paid on both brand and generic drugs.For purposes of calculating the rebates, the AMP for a drug is published to the Centers for Medicaid Services ("CMS"), but is not publicly available.

Medicare
Medicare is a national social insurance program, administered by the U.S. federal government and guarantees access to health insurance for Americans ages 65 and older and younger people with disabilities as well as people with end stage renal disease. Medicare spreads the financial risk associated with illness across society to protect everyone, and thus has a somewhat different social role from for-profit private insurers, which manage their risk portfolio by adjusting their pricing according to perceived risk. Medicare offers all enrollees a defined benefit. Hospital care is covered under Part A and outpatient medical services are covered under Part B. To cover the Part A and Part B benefits, Medicare offers a choice between an open-network single payer health care plan (traditional Medicare) and a network plan (Medicare Advantage, or Medicare Part C), where the federal government pays for private health coverage.
A majority of Medicare enrollees have traditional Medicare (76 percent) over a Medicare Advantage plan (24 percent). Medicare Part D covers outpatient prescription drugs exclusively through private plans or through Medicare Advantage plans that offer prescription drugs. Medicare serves a large population of old and disabled individuals. On average, Medicare covers about half (48 percent) of health care costs for enrollees. Medicare enrollees must cover the rest of the cost. These out-of-pocket costs vary depending on the amount of health care a Medicare enrollee needs. They might include uncovered services—such as long-term, dental, hearing, and vision care—and supplemental insurance.

A high level split up of the different parts of Medicare parts is as follows:

Part A: Hospital insurance
Covers inpatient hospital stays (at least overnight), including semiprivate room, food, and tests

Part B: Medical insurance
Helps pay for some services and products not covered by Part A, generally on an outpatient basis. Part B is optional and may be deferred if the beneficiary or his/her spouse is still working and has group health coverge through that employer. There is a lifetime penalty (10% per year) imposed for not enrolling in Part B unless actively working and receiving group health coverage from that employer.

Part C: Medicare Advantage plans

With the passage of the Balanced Budget Act of 1997, Medicare beneficiaries were given the option to receive their Medicare benefits through private health insurance plans, instead of through the original Medicare plan (Parts A and B). These programs were known as "Medicare+Choice" or "Part C" plans. Pursuant to the Medicare Modernization Act of 2003, "Medicare+Choice" plans were made more attractive to Medicare beneficiaries by the addition of prescription drug coverage and became known as "Medicare Advantage" (MA) plans.

Part D: Prescription drug plans
Medicare Part D went into effect on January 1, 2006. Anyone with Part A or B is eligible for Part D. In order to receive this benefit, a person with Medicare must enroll in a stand-alone Prescription Drug Plan (PDP) or Medicare Advantage plan with prescription drug coverage (MA-PD). These plans are approved and regulated by the Medicare program, but are actually designed and administered by private health insurance companies. Unlike Original Medicare (Part A and B), Part D coverage is not standardized. Plans choose which drugs (or even classes of drugs) they wish to cover, at what level (or tier) they wish to cover it, and are free to choose not to cover some drugs at all.

Centers for Medicare & Medicaid Services (CMS)
previously known as the Health Care Financing Administration (HCFA), CMS is a federal agency within the United States Department of Health and Human Services (DHHS) that administers the Medicare program and works in partnership with state governments to administer Medicaid, the State Children's Health Insurance Program (SCHIP), and health insurance portability standards. In addition to these programs, CMS is responsible for simplification of HIPAA , setting quality standards in long-term care facilities through its survey and certification process etc.

Scope of PBMs

PBMs aggregate the buying clout of millions of enrollees through their client health plans, enabling plan sponsors and individuals to obtain lower prices for their prescription drugs through price discounts from retail pharmacies, rebates from pharmaceutical manufacturers, and the efficiencies of mail-service pharmacies. PBMs also use clinical tools aimed at reducing inappropriate prescribing by physicians, reducing medication errors, and improving consumer compliance and health outcome

PBM strategies and tools

All PBMs offer a core set of services to manage the cost and utilization of prescription drugs and improve the value of plan sponsors' drug benefits. Some offer additional tools, such as disease management, that can target specific clinical problems for intervention. It is up to the client of the PBM, however, to determine the extent to which these tools will be employed.

Such tools include:

- **Pharmacy networks** — PBMs build networks of retail pharmacies to provide consumers convenient access to prescriptions at discounted rates. PBMs monitor prescription safety across all of the network pharmacies, alerting pharmacists to potential drug interactions even if a consumer uses multiple pharmacies.

- **Mail service pharmacies** — PBMs provide highly efficient mail-service pharmacies that supply home-delivered prescriptions with great accuracy and safety and at a substantial savings. In a 2005 report, the FTC determined that PBM-owned mail-order pharmacies (1) offer lower prices on prescription drugs than retail pharmacies and non-PBM owned mail pharmacies; (2) are very effective at capitalizing on opportunities to dispense generic medications; and (3) have incentives closely aligned with their customers: the third-party payers who fund prescription drug care.

- **Formularies** — PBMs use panels of independent physicians, pharmacists, and other clinical experts to develop lists of drugs approved for reimbursement in order to encourage clinically appropriate and cost-effective prescribing; PBM clients always have the final say over what drugs are included on the formulary that they offer to their employees or members.

- **Plan design** — PBMs advise their clients on ways to structure drug benefits to encourage the use of lower cost drug alternatives — such as generics — when appropriate. This is done by setting plans up with different co-pay tiers; in this case the client will apply a lower co-pay for generic drugs than it would for brand drugs. The PBMs' role is advisory only; the client retains all responsibility for establishing the plan design.

- **Electronic prescribing (E-prescribing)** — PBMs have pioneered the use of cutting-edge e-prescribing technology, which provides physicians with clinical and cost information on prescription options that allows them to better counsel consumers on which medications—including various lower cost options—will be the safest and most affordable choices. Manufacturer discounts — PBMs pool purchasing power to negotiate substantial discounts from pharmaceutical manufacturers in order to lower benefit costs for clients and consumers.

- **Clinical management** — PBMs use a variety of tools such as drug utilization review and disease management to encourage the best clinical outcomes for patients.

- **Pharmacy discount cards** — PBMs are able to offer the uninsured their pre-negotiated drug prices through the use of a pharmacy discount card. These discount cards can save users without insurance from between 10% and 75% on prescription medication.

Claim Process at Pharmacy

Pharmacy Claims

When a prescription is filled at a non-network pharmacy or a patient has health insurance, an insurance form has to be provided with information like medicine name, dosage, prescription cost etc to the insurance provider for reimbursing the pharmacy cost. The insurance provider after verifying the information in the claim form, can take action on the claim form including reimbursing or rejecting the claim. This process of submitting the claim forms to reimburse the expense incurred at a pharmacy is broadly called the pharmacy claim process.

Claim Reversal

The contract between the pharmacist and the insurance provider usually guarantees to reimburse the pharmacist if the claim specifications comply with the rules of the adjudication in advance of dispensing the drug. If the pharmacist finds that the reimbursement indicated by the insurer is unacceptable, pharmacist may reverse the claim on the central computer by re-transmitting to the central computer a transaction that triggers a credit or erasure of the transaction. Reversal is also done in cases where a participant fails to pick up prescription after the claim was submitted by the pharmacy. Reversals must be made within 60 days from the fill date.

Claims Routing

The electronic forms of pharmacy claims are routed to the appropriate pharmacy benefit managers by employing routing services in a pharmacy. Most routing services host and automatically update payer and provider data while executing a wide range of business rules at a group or beneficiary level.

The claims are routed to the third party payer or government entity in specific format and sends back the claim status and information to the respective pharmacy. Most routing services improves the efficiency of the payment cycle , reduces manual intervention during claim adjudication and re-pricing and identifies and rejects duplicate claim submissions

Switches

Outpatient pharmacies submitting claims to third party payers constantly struggle with the accuracy of prescription data fields before submitting claims for processing at the maximum allowable amount. In a high volume pharmacy, this task is best accomplished through an automated system rather than depending on people to catch every rule and price update. A telecommunication switch (PBM switch) usually takes care of this need and provides the connectivity between a pharmacy and the pharmacy benefit manager. The switch identifies the PBM using BIN/PCN information in the customer's insurance card. It is the switches and routing services that takes care of sending the information from a pharmacy to the correct third party payer and sends back the response from third party payer to the pharmacy.

 If a claim is routed from the pharmacy to a processing switch before it is sent to the payer, there is an opportunity to edit the claim to ensure: 1) maximum reimbursement is paid, 2) legal and payer compliance rules are met, and 3) patient safety initiatives are implemented. Pre and Post Edits (PPE) service evaluates submitted claims which are analyzed to maximize pharmacy reimbursements and reduce possible rejects by insurance providers. If adjustments need to be made, the claim will be stopped and sent back to the pharmacy with an indication of what information should be checked to allow the pharmacy to receive maximum reimbursement from the patients' insurance provider.

The three largest Pharmacy Network Switches:

RelayHealth

Emdeon

QS-1

All major retail pharmacy chains like Wal-Mart, CVS, Walgreens and others use PPE services to optimize their revenue and compliance. These for- profit entities do this because it makes good business sense and help keep their pharmacies compliant with new rules and regulations.

A pharmacy must partner with their primary switch for PPE as the analysis is done within the network before it is routed to the payer for processing. RelayHealth currently routes about 73% of all pharmacy claims in the U.S. and Emdeon captures 24% with QS-1 and others, the remainder. Pharmacies should always evaluate which network switch has the best PPE options available for them when deciding on a network provider.

Co-pay
Co-pay is a technique used by pharmacy providers that helps defer the cost of prescription drugs. If a copayment applies to a member, the member will pay a percentage of the drug cost to the pharmacist. The co-pay amount is determined by the member's health plan and is administered at the benefit level.