

Mail-Order Pharmacy

- Mail-order pharmacies are _____ pharmacies that dispense maintenance medications to members through mail delivery. The first mail-order pharmacy was U.S. Veterans Administration in the 1940s. _____ started a mail-order pharmacy in 1950s.
- _____ medications are taken on an ongoing basis for chronic conditions such as high blood pressure, cholesterol or diabetes
- _____ medications are taken on an urgent condition such as infection or pain

Types of Mail-Order Pharmacies

- Traditional
 - Fills prescriptions for individuals for maintenance medications in general
- Specialty
 - A mail-order pharmacy that concentrates on specific areas of the prescription drug market

Advantages/Disadvantages of Mail-Order

- Advantages
 - Cost savings
 - Patient convenience
 - 24 hours pharmacy consultation
 - Improved compliance
 - Increased pharmacy efficiency and decreased errors
 - Patient privacy
 - Availability of medications

- Disadvantages

- Lack of personal contact
- Medication waste
- Time delays

High Volume Pharmacies

- Central fill pharmacy - centrally fills prescriptions for a number of individual pharmacies
- Internet pharmacy - established commercial website that enables a patient to obtain prescription and over the counter medications by way of the internet, usually at reduced prices
 - Rogue sites - _____

Elements of Mail-Order Prescription

- Personnel

- Pharmacist
- Pharmacy technician
 - »Item entry technician
 - »Filling technician
 - »Support technician

- Inventory

- Maintenance medication

- Pharmacy design

- Various and large workflow areas
- Increased automation

Prescription Filling Process

- Workflow - an organized way of filling prescriptions

- Order entry
- Screening
- Packaging and shipping
- Quality assurance check
- Dispensing

Mail-Order Services

- Disease Management Programs - used to prevent acute episodes of a chronic disease
- Drug Utilization Review - analyzing prescription data generated by filling prescriptions
- Formulary Management - help physicians and patients adhere to formulary
- Compliance Monitoring - identify patients who do not refill their medications appropriately
- Patient Education - provides patient information in a written form

Legislation and Regulations

- OBRA 1990
 - Requires drug utilization reviews
 - Requires patient counseling
- Nonresident Pharmacy Legislation
 - A nonresident pharmacy must possess a license or business permit for states to which they deliver prescriptions
- DEA
 - Federal law permits more than 30 days supply or more than _____ units of C-II medications, some states don't allow this. Pharmacies must follow the more stringent guideline
- Internet Pharmacy Legislation
 - Internet pharmacy sales have been largely unregulated

_____ (VIPPS)
seal was developed by the National Association of Boards of
Pharmacy (NABP) as a certification for legal online pharmacies

Role of Pharmacy Technician

•Task specialization - an individual task assigned to a technician as part of the mail-order workflow scheme. The technician should have knowledge of:

- Traditional retail pharmacy and prescription filling process
- Commonly prescribed medications and automated pharmacy systems
- Computer and communication skills
- Translation of prescription orders
- Legislation and regulations

Nuclear Pharmacy Overview

•Nuclear Pharmacy (_____) - a pharmacy that prepares, stores, and dispenses radiopharmaceuticals

- Radiopharmaceutical -

Types of Nuclear Pharmacy

- Institutional nuclear pharmacy - operates within a nuclear medicine dept. in an institution like a hospital
- Centralized nuclear pharmacy - operates out of a site in the community and services various customers

Radioactivity

- Atom - _____
 - Radionuclide - _____. When this atom disintegrates the result is radiation.
- Half-life - time required for

-
- PET Drugs (_____) - drugs with short half used for diagnosis

Radioactivity

- Radiation (expressed in curies (Ci))
 - _____-radiation - short range radiation
 - _____-radiation - more penetrating radiation
 - _____-radiation - most penetrating radiation which requires shielding with lead, concrete, or steel
- Radionuclides release radiation within the body that can be detected by instruments that assist and diagnose disease; or are used to destroy cancer cells.
 - Technetium-99 - used for _____
 - Iodine-131 - very volatile medication used for thyroid cancer and hyperthyroidism

Radiopharmaceuticals

- Radiopharmaceutical - a radioactive drug that release radiation in the body. Those with _____ are used for diagnosis. Those used for treatment have longer half-lives.

Consists of:

- Radionuclide
- Carrier drug - delivers the radionuclide to the desired area of the body; _____

•Radioactive blood elements - _____ combined with radionuclides used for diagnosis

•Drug Interactions

–Some traditional drugs may interact with a radiopharmaceutical, causing too much or too little radiopharmaceutical to be deposited in the target organ. Example steroids or meperidine.

Elements of a Nuclear Pharmacy

•Inventory

–Very limited inventory due to time-sensitive radionuclides. JIT _____ inventory - tightly controlled inventory.

•Equipment

–Fume hood - laminar flow hood adapted for compounding radiopharmaceuticals because it is _____

–Dosimeter - personal device used to measure the _____ of an individual

–Autoclave - _____ materials

–Centrifuge - spins down samples of blood to separate _____

–Geiger-Muller counter - measures _____

Prescription-Filling Process

•Verbal orders

–Prescription orders for radiopharmaceuticals used for _____ may be accepted by a nuclear _____

–Prescription orders for radiopharmaceuticals used for treatment may only be accepted by a nuclear pharmacist

- Compounding may be done by a nuclear pharmacist or technician and consists of the use or combination of a radionuclide with a substance
- Preparing a Batch of Radiopharmaceuticals
 - Reagent kits - a commercially available bulk supply of a _____ which allows a batch to be prepared at one time
- Preparing Individual Doses of Radiopharmaceuticals
 - Prepared in a unit-dose syringe form under a fume hood with a lead barrier shield
 - The dose prepared is not the dose prescribed by the physician. The radionuclide begins to decay as soon as it is prepared, therefore a calculation must be made to account for the amount of decay that will occur until the drug is administered

Prescription-Filling Process

- Quality Control
 - Products must be _____, and it must be free of radionuclide, radiochemical or chemical impurity
- Packaging
 - The shipping container must be surveyed for external radiation exposure using a _____
- Waste Disposal
 - Radioactive compounds with a half-life of _____ days or less is allowed to be held in a lead-lined box and allowed to decay
 - After being held for _____ half-lives they are considered dead and are disposed of in regular trash or biomedical waste
- Radioactive exposure
 - Side effects are nausea and vomiting, hair loss, burns, and damage to _____

Legislation of Nuclear Pharmacy

- OBRA - counseling requirement _____
because medication is not dispensed to patients
- NRC (Nuclear Regulatory Commission)
 - Facilities must have a license from the NRC to operate
 - _____ - personnel of nuclear pharmacy must meet specialized requirements for training and experience in the handling of radioactive materials

Legislation of Nuclear Pharmacy

- DOT (_____)
 - Regulates the shipment of hazardous or radioactive materials
 - Shipping containers, shipping papers and delivery vehicles must be specifically labeled with the category of radioactivity
- FDA
 - _____ the manufacture of radiopharmaceuticals in its regulations
- USP
 - Sets _____ for radiopharmaceuticals

Role of Pharmacy Technician

- Knowledge required includes:
 - Abbreviations, terms, symbols or radiopharmaceuticals
 - Basic radiopharmaceutical calculations
 - Compounding and quality control testing
 - Packaging, record keeping, and labeling requirements or radiopharmaceuticals
 - Radiation safety
 - Inventory control
 - Legislation pertaining to nuclear pharmacy

Hospice Pharmacy

Overview

- Hospice - an organized program of services designed to meet the physical, spiritual, emotional and social needs of a patient who is terminally ill.

- Allows patient to live the remainder of his life as free from pain and other symptoms as possible by focusing on _____.

- Terminal ill patients are those who have an illness that is expected to result in death within _____.

- Treats the patient and family together as a unit

Hospice Pharmacy

- Hospice pharmacies prepare and dispense medications, supplies and pharmaceutical care services to hospice patients at home or in an institution

- Typical personnel of a long-term care pharmacy

- Inventory is limited and specialized. It does not include medications used for the treatment of disease. Primarily contains medication for _____

- Wide variety of _____

Hospice Pharmacy Services

- Pain management - pharmacologic treatment of pain.

- ATC (_____) dosing of pain medications to prevent _____

- _____ are not limited to a _____ dose, there should be no fear of addiction when dispensing narcotics

- Adjuvant pain medications

- NSAIDs

- Tricyclic antidepressants (TCA) for neuropathic pain

_____ - increases analgesic effect of morphine

Hospice Pharmacy Services

- Symptom management - pharmacologic treatment of symptoms
_____ are the most common symptoms
- Specialized compounding
 - Hospice pharmacies compound medications for alternative dosage forms needed by the patient who may not be able to take traditional drug dosage forms
- Starter kits - _____
 - Prepared by a hospice pharmacy to provide a "start" in treatment for the majority of urgent problems that can occur in the last days or weeks of life

Legislation

- OBRA
 - Pharmacist is required to counsel patient or family about the safe and effective use of medication
- FDA
 - Safe Medical Devices Act requires medical devices such as PCA pump be tracked
- CMS
 - Hospice must provide medication and supplies to the patient on a _____
 - Hospice must evaluate patient's response to therapy
- JCAHO
 - Accreditation of hospice program
- DEA
 - Faxed prescriptions of C-II drugs are allowed and are considered the _____

-Partial filling may be partially filled and the remainder dispensed for up to _____

Role of Pharmacy Technician

•Knowledge Required

- Hospice concept
- Commonly prescribed medications for pain and symptoms
- Sterile and extemporaneous compounding
- Pharmaceutical calculations
- Legislation
- Communication and computer skills

Federal Pharmacy Overview

•Federal pharmacy is a practice of pharmacy within the federal government

- _____
- _____
- _____

Military Pharmacy

•Military pharmacy technicians can be civilians or enlisted members of the U.S. Army, U.S. Navy or U.S. Air Force

- _____ technicians do not undergo basic training nor receive extensive pharmacy technician training
- _____ is performed throughout the military
- Military pharmacy technicians are allowed to _____ patients up to their level of knowledge and training

•First army hospital employed an _____ to compound and dispense medications

- Enlisted pharmacy technicians are allowed to run large pharmacies in army and field hospitals
 - Portable laminar flow hoods are used for compounding in field hospitals
- Navy Technicians are allowed to dispense medications without pharmacist supervision aboard ships with a limited formulary
- Army Medical Department (AMEDD) trains pharmacy technicians in an extensive 18 week course for typical pharmacy duties in peacetime and war, army regulations and in medical readiness. (being prepared for a medical emergency as a result of wartime or peacetime mission)
- Navy Pharmacy Technician School trains technicians in a 23 week program.

Public Health Service

- IHS (Indian Health Service) provides health care to Native Americans
 - Pharmacist provides primary care in ambulatory clinic setting.
 - Pharmacist is allowed to _____ medication for certain acute illnesses and manages certain chronic conditions. He may also order _____
 - All medications are prescribed directly from the patient charts.
 - There is no need for _____.

Veterans Affairs

- VA processes the majority of outpatient medications through the mail and is the largest mail-order pharmacy operation in the U.S.
- VA employs civilian pharmacists and technicians
- Allows tech-check-tech

Pharmaceutical Industry

Drug Approval Process

- FDA must approve all drugs manufactured and marketed in the U.S for _____ use, as being safe and effective.
 - Average time of 12-15 years and \$500 million dollars for a new drug to reach the market
 - Approximately 5 out of 5,000 that undergo preclinical testing go on to clinical trials
- Preclinical trials - testing of the drug in a laboratory and in animals to test for safety and pharmacological activity
- Investigational New Drug Application (INDA)- is submitted to the FDA to request _____ and to transport the investigational drug across state lines
- Clinical Trials
 - Phase I - small number of healthy humans are tested to determine a safe dose, absorption, distribution, metabolism and excretion of the new drug
 - Phase II - several hundred patients are tested to determine the effectiveness of the drug and side effects
 - Phase III - Larger trials on thousands of patients to verify phase II
- New Drug Application (NDA) - submitted to the FDA to request approval for marketing
- Approval - NDA is reviewed by the FDA and by law has _____ months to review the information
- Post-marketing studies (phase IV) - used to monitor the long term effects of drug utilization and detect undiscovered side effects

Patent

- A new drug is awarded a patent for _____ years from the date that the patent is awarded or _____ years from the date that the patent is applied for, whichever is greater
- When the patent expires, other drug manufacturers are free to market the drug

Drug Manufacturing Process

- Drug manufacturers are required to follow _____ (GMPs). These are regulations that set minimum standards for the manufacturing of drugs. Master batch records are required that details the steps necessary to develop the product on a commercial scale.
- Samples of the finished product are sent to the _____ to determine if they meet standards for purity, strength, identity and quality

Drug Marketing Process

- _____ - using pharmaceutical representatives to promote the sale of drug
- _____ - provision of samples to physicians
- DTC (_____) advertising - promotion of a new drug directly to patients instead of health care professionals
 - Regulated by the FDA which requires drug's effectiveness, _____ must be mentioned in advertising

Generic Pharmaceutical Industry

- A generic drug is considered to be _____ to a brand name if it delivers the same amount of active ingredient into the patient's blood stream in the same amount of time.
- It is considered a therapeutic equivalent if it contains the same active ingredient, in the same amount, has same dosage form, and works the same way in the body

Pharmaceutical Biotechnology

- _____ is defined as the use of biology and technology to solve problems concerning living organisms.
 - Drugs are produced from living bacteria, yeasts or human cells
 - Recombinant DNA involves combining DNA from different sources to produce a new product. _____ was the first drug created this way. The human gene responsible for producing insulin is inserted into the E. coli bacteria, which replicates insulin

Legislation

- Pure Food and Drug Act of 1906
 - Prohibits _____ (impure) and _____ (improperly labeled) drugs into commerce
 - Recognized the USP and NF
 - Created the _____ in 1927
- Federal Food, Drug, and Cosmetic Act (1938)
 - NDA must be submitted to the FDA and must submit evidence to the FDA proving the drug was safe
 - _____ (1951) made the distinction between OTC and legend drugs. It also required physician approvals for refills and allowed prescription to be verbally ordered
 - _____ (1962) required manufacturers to prove drugs are safe and effective

- Orphan drug act (1983)

- Provides tax incentives and _____ on drug sales for drugs produced for rare diseases.

- Waxman-Hatch Act of 1984(_____)

- Shortened drug approval process for generic versions of brand name drugs

- Gave brand name manufacturers an extra 5 years of patent protection and a possible 3 years of extra protection when testing a new dosage form or dosing schedule

- First generic manufacturer to produce a new generic is allowed _____ months of exclusive marketing

- _____ (1988)

- Imposes tight control of the distribution of samples

- Protects Americans from drugs that may be adulterated or misbranded during shipping and handling

- Prescription Drug User Fee Act (1992)

- Manufacturer must pay a _____ to hasten the review process for a new drugs

- Generic Drug Enforcement Act (1992)

- Forbids an individual or company convicted of crimes relating to the manufacturer of drugs from participating in the _____ industry.

- Passed because of _____ in 1989 and falsifying data

- General Agreement on Tariffs and Trade (GATT) 1994.

- Changed patent from 17 years to 20 years from date patent applied for and allows an extra 3 years of patent protection in certain instances.

•Food and Drug Modernization Act (1997)

–Grants an additional 6 months of exclusive marketing in exchange for conducting _____.

–Allows manufacturers to provide information about the _____ use of a medication

Role of Pharmacy Technician

- Knowledge of manufacturing processes
- Laboratory analysis
- Quality control
- GMPs
- Aseptic technique
- FDA regulations

Policy and Procedure Manuals

- In every organization there exist rules or policies that are developed to accomplish the objectives of the organization.
- A _____ is a definite course or method of action; a high level overall plan embracing general goals and objectives of what is to be done
- A _____ is a particular way of accomplishing the objectives set forth in the policy; a series of steps followed in definite order; the established way of how things are to be done

Functions of Manual

- Train new employees
- Prevent errors from verbal communication
- Minimize waste of manpower and materials
- Comply with JCAHO

- Ensure consistency of policy and job performance
- Evaluate job performance
- Serve as legal documents in a lawsuit

The Manual

- All policies and procedures should:
 - Follow a similar format
 - Include a title and date
 - Signatures of persons approving the policies

Contents

- _____ section - contains policies and procedures that pertain to the operation of the department and its personnel including:
 - Job descriptions
 - Incident reporting
 - Formulary operation
- _____ section - contains activities involved in patient-related monitoring and clinical activities including:
 - Clinical monitoring of patients
 - Discharge counseling
 - Drug interaction screening
- _____ section - deals with the acquisition, storage, ordering, dispensing, documentation and disposal of drugs and supplies including:
 - Unit dose drug distribution
 - Drug ordering

Approval process

- The _____ committee is usually responsible for approving the policies and procedures of the pharmacy department.

- The policy and procedural manual is constantly revised and changing

Employer Responsibility

- All employers are responsible for showing their employees the location of the policy and procedure manual.

The End