Community and Ambulatory Care Pharmacy Practice
Learning Outcomes

• Describe history of pharmacy practices
• Describe differences among practice sites
• Describe importance of communication
• Explain various steps in filling a prescription
• Identify trends in pharmacy practices
• Describe evolving role of technician in pharmacy practices
Key Terms

- Adverse reaction
- Ambulatory pharmacy
- Brand-name drug
- Chain pharmacy
- Clinic pharmacy
- Community pharmacy
- Copayment (copay)
- Dispensing
Key Terms

• Drug interactions
• Formulary
• Health Insurance Portability and Accountability Act (HIPAA)
• Independent pharmacy
• Managed care pharmacy
• Mail-order pharmacy
• Medication guides
Key Terms

• National Drug Code (NDC)
• Over-the-counter (OTC) drugs
• Patient counseling
• Prescription
• Reimbursement
• Third-party payer
History of Pharmacy Practice

• Community pharmacies-1st pharmacies
• Ambulatory care pharmacies
  – for walk-in patients
  – evolved from community pharmacies
  – usually located in close proximity to clinics, hospitals, or medical centers
  – provide prescription services & limited number of OTC medications
History of Pharmacy

• Pharmaceutical remedies were limited
• Pharmacists
  – prepared, or compounded remedies
  – used natural sources & raw chemicals
• No regulations on drugs
• Pharmacists compounded remedies
  – based on
    • patient’s evaluation & diagnosis
    • patient’s symptoms or requests
Key Legislation

• 1938-Food, Drug, and Cosmetics Act (FDCA)
  – required pre-market approval for new drugs (safety)
  – Prohibited false therapeutic claims for drugs
  – “Prescription-only” drug designation per manufacturer

• 1951-Durham-Humphrey Amendment to FDCA
  – “Prescription-only” drug designation based on safety & potential for addiction
  – Two categories of drugs were established:
    • legend drugs
    • over-the-counter (OTC)
1950’s-1980’s

• 50’s Focus on pharmacist dispensing
  – information about prescriptions limited to doctor-patient relationships
  – inappropriate for pharmacist to discuss drug therapy with patient

• 60’s-70’s Drug interactions /adverse reactions
  – more drugs on market
  – pharmacies began maintaining patient profiles

• 80’s Pharmaceutical care was gaining wider acceptance
3\textsuperscript{rd} Party Payers

• Examples:
  – government employers
  – government programs
    • Medicaid
  – employers’ health insurance policies
  – private insurance purchased by individuals

• Effects:
  – decreased reimbursement for pharmacies
  – restricted drugs covered
  – control of copays
OBRA

• 1990-Omnibus Budget Reconciliation Act
• Required pharmacists to perform 3 functions for Medicaid prescriptions:
  1. Prospective drug utilization review (DUR)
  2. Patient counseling
  3. Patient record main

• Now these functions performed for all prescriptions
OBRA→Pharmacy Technicians

• Role of pharmacist
  – evolved from preparers of drug products to dispensers of drug products
  – managers of medication therapies

• Role of pharmacy technicians
  – assumed technical functions drug distribution
  – development of professional standards for technicians
Practice Sites

• Community & ambulatory care pharmacy settings
  – community pharmacies
  – clinic pharmacies
  – managed care pharmacies
  – mail-order pharmacies
Community Pharmacies

• Two groups
  – independent pharmacies
    • # of pharmacies declining
  – chain pharmacies
    • # of pharmacies increasing
Clinic Pharmacies

• Located in clinics or medical centers
• May be owned by the facility or independently
• Similar to community pharmacies
  – more direct contact with prescribers
  – more involved in managing drug therapies
  – offer health screening & immunization services
  – smaller in size
  – limited amount of OTC medications
Managed Care Pharmacies

- Owned by managed care system such as HMO
- Resemble clinic pharmacies
- Restricted to patients in system
- Typically located in close proximity to medical facility
- More coordinated communication among health care professionals
Mail-Order Pharmacies

• Classified as ambulatory pharmacies
• Fill very large volumes of prescriptions
• Specialize in maintenance medications
• Highly automated
• Less direct contact with patients
  – telephone, or electronically, via Web sites
• Like warehouses with pharmacists & technicians
Technician Responsibilities

- Communicating with patients
- Ensuring patient privacy
- Receiving prescriptions and registering patients
- Transferring prescriptions
- Entering prescriptions in computer
- Handling restricted-use medications
- Resolving third-party payer issues
- Filling & labeling pharmaceutical products
- Compounding prescriptions
- Collecting payment & offering patient counseling
- Fulfilling miscellaneous responsibilities
Communicating with Patients

• Act professionally and in a caring manner at all times
  – Often first and last person to interact with a patient
• Patients may not feel well
• Technician must
  – show concern for patients
  – respect patients’ privacy
• Confrontations with patients
Ensuring Patient Privacy

• 1996-HIPAA passed
• Included “privacy rule” which is national standard
• Specific guidelines for private patient information
  – use care when discussing private patient information
  – ensure documents with private information be placed in the appropriate location for destruction
  – written policy for handling private patient information
Receiving Prescriptions

• Identify returning patient with 2 identifiers such as name and:
  – date of birth, address, or phone number

• Registering new patients, obtain:
  – correct spelling of name
  – address and phone number(s)
  – insurance information from patient’s insurance card
  – date of birth
  – drug allergies
  – prescriptions or OTC medications the patient takes regularly
  – health conditions
Receiving Prescriptions

• Methods of receipt
  – directly from patient
  – from prescriber via
    • telephone
    • fax
    • electronic transmission

• Determine when patient will pick up prescription
  – important for customer service & workflow
  – process prescriptions in order of when they are due
Fill With Brand or Generic?

• Generic drugs less expensive
  – FDA provides list of equivalent generics
  – state regulations vary regarding generic substitution

• “Would you like us to fill your prescription with a less expensive generic alternative, if one is available?”
  – do not offer if prescriber has not allowed
  – do not offer if generic not available
Transferring Prescriptions

• Subject to specific state regulations
• Pharmacist is responsible for information transferred
• Transfer must be accomplished only pharmacist to pharmacist in some states
• Upon request for transfer
  – obtain information about prescription
  – pharmacist will use to help with transfer process
Computer Order Entry

- Variety of prescription processing software
- Specific steps varies among systems
- Often prescription scanned into system
  - hard copy readily accessible at each step of filling or refilling
- Information on prescription entered into appropriate fields
Restricted-Use Medications

• FDA requires Risk Evaluation and Mitigation Strategy (REMS) for certain medications
  – determines strategy to ensure benefits outweigh potential risks
  – may require registration
  – may require other action by the physician, pharmacist, and patient

• May also apply specifications for prescriptions
  – limits on how many units may be dispensed
  – if refills are allowed
  – stickers or other documentation on the face of the prescription
Examples of Drugs with REMS

• alosetron (Lotronex)
• clozapine (Clozaril, Fazaclo)
• isotretinoin (Accutane, Amnesteem, Claravis, Sotret)
• thalidomide (Thalomid)
• dofetilide (Tikosyn)
Alosetron

• Treats a type of irritable bowel syndrome (IBS)
• Serious adverse reactions of gastrointestinal tract
  – some necessitate a blood transfusion or surgery
  – some even lead to death
• Restricted by Prescription Program for Lotronex (PPL)
  – requires physician enrollment & submission of Patient-Physician Agreement Form
• Prescriptions must be written by physician & must include PPL sticker on face of prescription
Clozapine

• Treats patients with schizophrenia
• Can cause serious drop in white blood cells
  – monitoring must be done regularly
• Pharmacies must register to dispense clozapine
• Specific day supply may be dispensed
  – (1, 2, or 3 weeks depending on monitoring frequency)
• Pharmacy must receive documentation of blood work
Isotretinoin

• Treats severe acne & can cause serious birth defects

• iPledge Program
  – registration required by
    • doctors
    • patients
    • Pharmacies
  – must meet specific requirements / answer questions with iPledge Program each time drug dispensed
  – quantity dispensed is limited
Thalidomide

- Treats multiple myeloma/erythema nodosum leprosum
- Causes birth defects
- Thalidomide Education & Prescribing Safety (S.T.E.P.S.) Program
  - prescribers, patients, pharmacies must register
  - pharmacy must verify that the prescriber is registered with S.T.E.P.S. before dispensing medication
Dofetilide

• Treats irregular heart rhythms
• Can cause serious complications
• Patients must be hospitalized to initiate therapy
• Tikosyn in Pharmacy System (T.I.P.S.)
  – prescribers & pharmacists must register
  – pharmacy must verify the prescriber’s registration
Medication Guides

• FDA designates drugs requiring Medication Guide
  – patient information approved by FDA

• Purposes
  – avoid serious adverse events
  – inform patient of known serious side effects
  – provide directions for use
  – promote adherence to treatment

• Available for specific drugs/classes of drugs such as
  – Non-steroidal anti-inflammatory drugs (NSAIDs)
  – Antidepressants
Third-Party Payer

- 3rd party payer = someone other than patient pays
- May be insurance company, federal or state government agency, employer, etc.
- 3rd party claim sent electronically as Rx information entered into pharmacy computer=adjudication
Third-Party Payment

• If claim is accepted
  – payer has agreed to pay claim
  – appropriate copayment for claim will be noted
    • copay is amount of patient is responsible for paying
    • copays vary among plans and could be:
      – percentage of the total cost of the prescription or
      – flat dollar amount per prescription or
      – three-tier copays
3rd Party Plans

• 3-tiered system
  1. low copay for generic drugs
  2. higher copay for “preferred” brand name drugs
  3. still higher copay for “non-preferred” brand name drugs

• formulary
  – list of drugs/tiers that 3rd party payer will cover
PBMs=Pharmacy Benefit Managers

- Work for multiple third-party payers
- Process transactions
- Help establish & enforce their formularies
Rejections from PBMs

• If there is a problem with claim
  – pharmacy receives rejected claim message
  – resolving third-party rejections is time-consuming

• Common rejections
  – missing/invalid patient ID number
  – refill too soon
  – plan limitations exceeded
  – prior authorization required
Resolving 3rd Party Rejections

• May be resolved by simply verifying information
• May require phone call to third-party payer or PBM
• More information in Chapter 20
Prescription Filling & Labeling

• Select correct drug product & container
  – correct drug
  – correct dose
  – correct dosage form
  – correct quantity

• Package in prescription container before labeling
Manufacturer’s Containers

• Manufacturers packages available in commonly dispensed quantities (e.g., 30, 60, or 90)
• Topical preparations, inhalers, nasal sprays
• Apply prescription label to manufacturer’s package
• Expiration date, lot number, storage requirements should not be covered by label
Safety

• Use great care & accuracy
• Mistakes present possible dangers to patient
• After completing filling & labeling process re-check
  – correct drug
  – correct dose
  – correct dosage form
• Use National Drug Code (NDC) as a double check
Technology

• Counting devices may
  – use a scale to count units based on their weight
  – use light beams to count units as they are poured
  – bulk quantities in “cells” to dispense required number of units into vial

• Devices may place label on vial

• Technicians fill, clean, & maintain equipment
Compounding Prescriptions

• Preparation of special formulations
  – simple mixtures of liquids or creams
  – complicated mixtures – preparing liquid form of tablet or capsule

• Technicians may prepare compounded formulations under a pharmacist’s supervision in some states

• “Recipe book”
  – ingredients
  – directions for preparing
Log of Compounds

• Required in many states
• Logs document
  – who was involved in the preparation /verification
  – ingredient names,
  – ingredient quantities
  – lot numbers
  – expiration dates
• More information in Chapter 15: Nonsterile Compounding and Repackaging
Collecting Payment

• Point-of-sale (POS) transactions
  – checking out patients /collecting payment

• 4 important aspects
  – verify patient’s name & 2\textsuperscript{nd} identifying information
  – legal requirements must be met regarding patient counseling.
  – provide privacy policy in compliance with HIPAA regulations
  – collect patient signature for these reasons:
    • required by HIPAA
    • in some states to document refusal of patient counseling
    • by 3\textsuperscript{rd} -party payers to prove receipt of prescription
Miscellaneous Responsibilities

• Managing inventory
• Managing pharmacy records
• Helping patients locate OTC drugs
  – questions that require clinical knowledge or judgment must be referred to a pharmacist
• Pseudoephedrine sales
  – federal and state laws regulate quantity of OTC medications containing pseudoephedrine
  – technicians are allowed to process transactions under these guidelines
Practice Trends

• Disease state management
• Health screenings
• Immunizations
• Dietary supplements
• Specialty compounding
Disease State Management

• Clinical management of medication therapies
  – pharmacists collaborate with prescribers
  – make adjustments or changes to medications
    • hypertension
    • hyperlipidemia
    • asthma
    • anticoagulant therapy
Health Screenings

- Blood pressure measurements
- Blood glucose levels
- Cholesterol panels
- Bone density scans
- Technicians may assist pharmacist
Immunizations in Pharmacies

• May include
  – influenza vaccine
  – shingles
  – pneumonia
  – travel vaccines

• Pharmacists need special training

• Technicians may assist with immunizations
  – register patients
  – order, store & prepare vaccine doses
  – keep required records
Dietary Supplements

• Supplements loosely regulated
• Sold in health food stores & other non-pharmacy outlets
• Pharmacists have unique opportunity to provide
  – informed recommendations
  – important warnings
• Technicians may help patients locate specific products
Specialty Compounding

• Compounding pharmacies make:
  – capsules, suppositories, transdermal gels, topical preps
  – compounding supply companies provide
    • equipment
    • bulk chemicals
    • formulations and stability information

• Technicians assist in compounding under pharmacist supervision