Purchasing and Inventory Control
Learning Outcomes

• Demonstrate understanding of formulary system
• Execute lending transactions between pharmacies
• Use proper processes when receiving/storing drugs
• Identify key techniques for
  – reviewing packaging
  – labeling
  – storage considerations
Learning Outcomes

• Demonstrate understanding of special handling necessary for select pharmaceuticals

• Demonstrate application of appropriate processes for maintaining/managing pharmaceutical inventory

• Complete appropriate processes in handling of pharmaceutical recalls & disposal of pharmaceutical products
Key Terms

• Bar code medication administration (BCMA)
• Direct purchasing
• Group purchasing organization (GPO)
• Just in-time inventory management
• Manufacturer
• Maximizing inventory turns
Key Terms

• Par level system
• Perpetual inventory process
• Prime vendor
• Purchase order
• Recall
• Stock rotation
• TALLman lettering
• Wholesaler
Ordering Pharmaceuticals

• Purchasing agent or several staff members involved

• State-of-the-art practice
  – automated technology
  – bar codes for
    • online procurement
    • purchase order generation
    • electronic receiving processes

• Sophisticated inventory management carousel systems
Benefits of Technology

• Up-to-the-minute product availability information
• Comprehensive reporting capabilities
• Accuracy
• Reduced training time
• Improved operational efficiency
• Compliance with various pharmaceutical purchasing contracts
National Drug Code

• Pharmaceuticals registered with FDA
• Drug Registration & Listing System (DRLS)
  – database utilizes unique identification number
    • National Drug Code (or NDC number)
• NDC number on manufacturer’s label
  – 10-digit format
  – 4-4-2  xxxx-xxxx-xx
  – 5-3-2  xxxxx-xxx-xx
  – 5-4-1  xxxxx-xxxx-x
NDC

- 1st set of digits = specific drug manufacturer
- 2nd set of digits = product code
  - formulation
  - dosage form
  - strength
- 3rd set of digits = package type & size
Formulary System

- List of medications that may be prescribed
  - affects hospital pharmacy
- Formulary - cornerstone of purchasing system
- Developed & maintained by P&T Committee
- Medications: safest, most effective, least costly
- 3rd party PBMs establish plan-specific formularies
  - affects retail pharmacy
    - do not restrict items in their inventory
Formats & Updates

• Usually available electronically and/or in print form
• Produced exclusively for health practitioners
• Informs users of
  – product availability
  – appropriate therapeutic uses
  – recommended dosing /administration of medications
• Drugs added/deleted on regular basis
Non-Formulary Protocol

• Use of products not on official hospital formulary
• Pharmacist requests verbal or written justification
  – may challenge request
• Utilization of a non-formulary may be warranted
• Techs need to understand policy
  – specific to each institution
Purchasing Groups

• Group purchasing organization (GPO)
• GPOs contracts with manufacturers
• Purchase pharmaceuticals at discounted prices
  – in return for guaranteed minimum purchase volume
• Contracts: sole-source or multisource products
• Competitive market basket
• GPOs negotiate contracts that are mutually favorable
• GPO guarantees price over contract period
Challenges

• Occasionally, manufacturers unable to supply product
• Must substitute more expensive product
• Provisions to protect pharmacy
  – manufacturer is responsible for rebating difference
  – important to document all off-contract purchases
Direct Purchasing

• Direct purchasing from manufacturer
• Purchase order used

• Advantages of direct purchasing
  – no handling fees to 3rd party wholesaler
  – ability to order on infrequent basis
  – less demanding system for monitoring inventory

• Disadvantages
  – large storage capacity needed
  – large amount of cash invested in inventory
  – delivery challenges
Pharmacies primarily purchase via drug wholesaler
Operate large-scale warehouse
  – located in strategic geographic regions
Helps local pharmacies
  – buy smaller quantities
  – receive drugs in timely manner (often same day)
Some drugs only available through special processes
  – BabyBIG® $45,300 per vial

Funds must be wired to IBTPP within 5 business days
Prime Vendor Purchasing

• Prime vendor= agree to purchase 90-95% drugs

• Wholesalers offer 24/7 emergency service
  – electronic order entry/receiving devices
  – computer system for ordering
  – bar coded shelf stickers
  – printer for order confirmation printouts.
  – highly competitive discount (1 % - 2%) below product cost/contract

• Larger discounts for prepayment arrangement
Borrowing Pharmaceuticals

• Pharmacies must borrow drugs from other pharmacies
  – policies & procedures addressing this situation
  – usually restricted to emergency situations
  – limited to authorized staff

• Limited to products that are commercially available
  – may have forms to document & track merchandise
Receiving Pharmaceuticals

• Useful experience for new pharmacy technician
  – observe how pharmacy receives pharmaceuticals
  – learn various processes for ordering & receiving
  – become familiar with formulary items
  – demonstrates system used to ensure that only formulary items are put into inventory
  – learn various locations in which drugs are stored

• Receiving
  – 1 of the most important parts of pharmacy operation
Receiving Process

• Person receiving different from person ordering
• Especially important for controlled substances – drug diversion
• Receiving personnel verifies order complete & intact
• Process refrigerated products first
• Items come in shippable foam cooler-frozen cold packs
Receiving

• Identify gross shipment damage/incorrect tote counts
  – should be performed in presence of delivery person
  – should be well documented when signing for order

• Identify packages that are received
  – containing broken tablets
  – defective seals
  – reconcile with purchase order
  – product’s expiration remaining and shelf life of 6 months
Storing Process

• Note expiration dates
• Remove expired products
• Stock rotation
• Note optimal storage temperatures & humidity
• Automated dispensing devices
  – facilitate use of computers for inventory management
  – networked via dedicated computer file server
Handling Considerations

• Pharmacy technicians – primary staff for
  – handling & preparing medications
  – assessing & evaluating each product
  – accurately placing products in proper storage location
  – play vital role in minimizing dispensing errors

• Product checks:
  – product’s expiration date
  – liquids or injectable products: color & clarity
  – unusual appearance
# Storage Requirements

<table>
<thead>
<tr>
<th>Storage Type</th>
<th>Temperature Range (Celsius)</th>
<th>Temperature Range (Fahrenheit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freezer</td>
<td>-25º to -10º C</td>
<td>-13º to 14º F</td>
</tr>
<tr>
<td>Cold (Refrigerated)</td>
<td>2º to 8º C</td>
<td>36º to 46º F</td>
</tr>
<tr>
<td>Cool</td>
<td>8º to 15º C</td>
<td>46º to 59º F</td>
</tr>
<tr>
<td>Room Temperature</td>
<td>Temp prevailing in working area</td>
<td></td>
</tr>
<tr>
<td>Controlled Room Temp</td>
<td>20º to 25º C</td>
<td>68º to 77º F</td>
</tr>
<tr>
<td>Warm</td>
<td>30º to 40º C</td>
<td>86º to 104º F</td>
</tr>
</tbody>
</table>
Look-Alike/Sound-Alike Drugs

• 3 main issues of product similarity:
  1. Similar drug names
     – tall man lettering
     – extra precaution in shelf positioning
  2. Similar package sizes
  3. Similar label format
Special Handling For:

- Controlled substances
- Investigational drugs
- Chemotherapy
- Radiopharmaceuticals
- Compounded drugs
- Miscellaneous products
Controlled Substances

• Helpful references
  – ASHP Technical Assistance Bulletin on Institutional Use of Controlled Substances

• 2 important principles for controlled substances:
  – ordering & receiving Schedule II controlled substances
    • require special order forms & additional time ~ 1-3 days
  – perpetual inventory process
Controlled Substances

• Regulations
  – DEA
  – State Board of Pharmacy

• Chain of accountability

• Schedule II regulations
  – require DEA form 222 or CSOS to order
  – CSOS: Controlled Substance Ordering System-internet

• Schedule III, IV, and V regulations
  – state regulation or specific employer’s policy
Chemotherapy

• Hazardous
  – antineoplastic drugs shipped separately
• Special care opening & unpacking totes
• Inventory locations may be completely separate
• Chemotherapy & hazardous materials spill management protocol
  – “chemotherapy spill kit” on hand
Investigational Drugs

• Require special ordering, inventorying, handling

• Use of investigational drugs-2 distinct types:
  – 1) use under formal protocol approved by site’s institutional review board (IRB)
  – 2) compassionate use of investigational drugs for single patient may be authorized by the manufacturer & FDA

• Compassionate drug use is legal, although drug is technically still being scientifically tested
Investigational Drugs

• Physician or primary investigator-orders product
• Pharmacy handles inventory management & distribution
• Research protocols require very rigorous records
  – investigational drug inventory
  – dispensing records
  – perpetual inventory similar to Schedule II drugs
• Pharmacy follows procedures to ensure complete & accurate accounting of precise quantity on hand for drug (down to single unit of measure)
Investigational Drugs

• Record keeping

• Evidence of proper cold chain storage
  – complete daily log of product refrigeration temperatures
  – actions taken if storage temperature range deviated

• Research Site Monitors (regulatory administrators)
  – inspect records during their periodic site visits
Pharmacist-managed Research

• Pharmacies associated with academic institutions
  – organized investigational drug services
  – formally managed by pharmacist

• Pharmacist may have been delegated authority to
  – order, dispense, manage inventory of investigational drugs

• Pharmacy technicians often
  – prepare or handle investigational drugs
RDDS

• Restricted Drug Distribution System
• High risk drugs must be safely
  – procured
  – prescribed
  – dispensed
  – administered
• FDA, manufacturer, distributor collaborate
  – establish tighter controls over designated products
  – example: thalidomide
RDDS

• Drugs may be limited for use for specific disease
• Physician may have to attest to patient-specific criteria
• Administer medication under controlled conditions
• RDDS may require
  – registration of prescribing physician
  – registration of dispensing pharmacy
  – patient information, patient agreement form
  – lab results, adherence to patient counseling protocol, reimbursement information guaranteeing payment
Compounded Products

• Extemporaneously prepared in pharmacy
• Typically have short expiration dates
• Procedures for
  – monitoring patient use
  – product expiration dates
  – additional stock needs
• Pharmaceutical-grade raw materials require pharmacy or medical license prior to shipment
• All chemicals are shipped according to DOT
  – include an MSDS for each chemical
Repackaged Pharmaceuticals

• Pharmacy staff repackages some products
  – unit-dose tablets & capsules
  – unit-dose oral liquids
  – bulk packages of oral solids & liquids

• Technicians coordinate repackaging activities

• Know procedures for repackaging
Non-Standard Items

• Non-Formulary items
  – generally not mixed into system of formulary products
• Medication samples provided to physicians on request
  – free of charge
  – without pharmacy’s knowledge
  – not usually dispensed by pharmacy
• Organizations may allow samples to be stored & dispensed in ambulatory clinics
Radiopharmaceuticals

• Used in diagnostic imaging as contrast media
  – oral & injectable products

• Used therapeutically to treat diseases
  – thyroid gland & forms of cancer
  – radioactive & potentially hazardous to humans

• Special procedures to minimize exposure
Managing Inventory

• Systems range from simple to complex
  – order book (aka the “eyeball” method)
  – minimum/maximum (par) level
  – Pareto (ABC) Analysis
  – fully automated, computerized system
Business Models

• Pareto ABC Analysis = the 80/20 rule
  – groups inventory products by aggregate value & volume of use
• Group A 20% of all items that make up 65% of cost
  – tighter inventory control over these items
• Group B 30% of items that make up 25% of cost
  – automatic order cycle based on par levels
• Group C 50% of items & 10% cost
Manual Systems

• Par level system uses stock min & max #
• Shelf label reflects min & max #
  – when level reaches min, order enough to get to max
• Staff members can scan bar code or enter product stock numbers directly into personal computer
• Modification in par-level may occur
• Computerized database
  – automatically subtracts dispensed & adds in new stock
Just-in-time

• Just-in-time inventory management
  – products are ordered & delivered when needed
  – goals: minimize wasted steps, labor, cost
  – never out & never overstocked

• Maximize inventory turns

• To calculate total inventory turns
  – divide total purchases in period by value of physical inventory
Automated Systems

• Want list or want book
  – “eyeball” approach
  – provides least amount of structured control over inventory
  – success is highly dependent on staff participation

• Automated system supports just-in-time inventory
  – maintain perpetual computerized inventory
  – integration of
  – remote supply distribution cabinets, central dispensing carousel systems, bar code packaging systems
  – product expiration dates & lot numbers
Return of Pharmaceuticals

• Wholesalers limit credit given on returns of short-dated products- expire within 6 months
• Documentation required
• Wholesalers may use electronic documentation systems
• Some pharmacies contract with an outside vendor
  – reverse distributor coordinates return of products for fee
Proper Disposal

- Procedure for disposal depends on product
- Environmental Protection Agency - Resource Conservation and Recovery Act (RCRA)
  - govern disposal of hazardous chemicals including drugs
- Each pharmacy-detailed procedures for disposal of pharmaceutical waste
Disposal

• Disposal of pharmaceuticals should be completed under the supervision of pharmacist

• Other expired products that require disposal return
  – chemicals used in pharmacy laboratory
    • pharmacy’s hazardous waste procedures & state laws
Expired Controlled Substances

• Products can’t be returned to manufacturer
• DEA provides specific form
  – “Registrant’s Inventory of Drugs Surrendered” Form 41
  – record disposal of expired controlled substances
  – actual disposal of expired controlled substances
    • should be completed by company sanctioned by the DEA or by representative of state board of pharmacy
    • DEA may allow destruction of controlled substances by pharmacy, provided appropriate witness process is followed & documented.
DEA Form 41

• Should be completed properly & submitted to DEA immediately after disposal
• Copy of record of disposal form signed by DEA rep & returned to pharmacy to be kept on file
Expired Investigational Drugs

• Return to manufacturer or sponsor of study
• Tech may be responsible for
  – completion of documentation, packaging, shipment
• Expired doses stored with investigational drug
  – clearly marked as expired
• Investigational study sponsor
  – reviews & accounts for expired investigational drugs
Other Pharmaceutical Returns

• Ordering error-requires authorization from supplier

• Prescription Drug Marketing Act
  – mandates pharmacies authorize & retain return records to prevent potential diversion
  – includes sample medications

• Technician may be responsible for
  – documentation
  – filing
  – paperwork
Pharmaceutical Waste

• Environmental impact of pharmaceutical waste a prominent public health issue worldwide
• Pharmaceuticals considered chemical pollutants
• EPA-will enforce proper pharmaceutical disposal
• Adherence with regulations
  – expensive
  – operationally challenging,
Drug Recalls

• Drug recall removes product from market
• Manufacturers recall pharmaceuticals for
  – mislabeling
  – contamination
  – lack of potency
  – lack of adherence to Good Manufacturing Practices
  – other situations that may be significant risk to public
# FDA Drug Recall Classes

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
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<tbody>
<tr>
<td>Class I</td>
<td>The most serious of recalls; ongoing product use may result in serious health threat or death.</td>
</tr>
<tr>
<td>Class II</td>
<td>Moderate severity concern; ongoing product use may pose serious adverse events or irreversible consequences.</td>
</tr>
<tr>
<td>Class III</td>
<td>Lowest severity concern; ongoing product use unlikely to cause adverse health threat; however, a marginal chance of injury may exist, so the product is being recalled.</td>
</tr>
</tbody>
</table>
Role of FDA in Recalls

• Manufacturers voluntarily issue recalls
  – duty to protect public health

• FDA’s role
  – FDA has no statutory (legal) authority to recall drugs
  – FDA helps manufacturers coordinate drug recall
    • performs health hazard evaluations to assess public risk
  – decides on need for public warnings
  – assists recalling agency with public notification
Manufacturers & Distributors

• Manufacturers/distributors implement *voluntary recalls*
• Recall notices sent in writing to pharmacies & include:
  – class of recall
  – reason for recall
  – name of recalled product
  – manufacturer
  – all affected lot numbers of product
  – response required
  – instructions on extent of action required in contacting affected patients
  – how to return product to manufacturer
Pharmacist-In-Charge

- Collect & segregate any inventory
- Arrange for return through wholesale distributor
- Provide notification to medical providers
- Contact patients who may have received recalled product lot number(s) & to offer proper counseling on what to do
- Upon completion of recall activity document
- FDA has been known to request documentation
Drug Shortages

• Causes:
  – inability to obtain raw materials
  – manufacturing difficulties
  – inability to produce sufficient quantities

• Management
  – communicate drug shortages
  – recommend alternative therapies

• Resources
  – ASHP & FDA publish status of current shortages
Counterfeit Pharmaceuticals

• Global concern-counterfeit medications may contain
  – incorrect ingredients
  – subpotency
  – toxic ingredients

• Illegal Internet-based pharmacies were suspected of
  – selling drugs without prescriptions
  – selling fraudulent or counterfeit products
IMPACT to Coordinate Efforts

- International Medicinal Products Anti-Counterfeiting Taskforce involves:
  - international enforcement & regulatory agencies
  - customs & police authorities
  - pharmaceutical manufacturing representatives
  - wholesale companies
  - health care providers
  - patient delegates

- Laws, standards, monitoring & reporting programs, & penal sanctions are being
e-Pedigree

• Pedigree laws
  – require drug wholesaler to prove genealogy of drugs
  – every step in distribution chain documented & verified
    • from point of manufacturer origin to wholesale distribution point

• Electronic pedigree (e-Pedigree)
  – ensures that drug was safely & securely manufactured & distributed