CHAPTER 31

DRUG DISTRIBUTION SYSTEMS
NURSING HOME

Drug Distribution Systems in the Nursing Home

1. Floor Stock - only OTC items permitted
   (example: irrigating solutions and certain IV supplies cannot be floor stocked if it contains a
   “Rx Only” warning statement)

2. Traditional Bottles - Rarely used in Nursing homes

3. Unit Dose
   a. 24-48 hour supply (AutoMed type packaging)
   b. Bingo card (30 to 31 day supply)
   c. 7-30 day supply (ex Opti-Pak, Opus, 7 day Slide pack, Artromick Select Series 7 days)
   d. CMS now requires a 14 day maximum dispensing system for brand name drugs to reduce   waste.

4. System should be
   a. Safe
   b. Timely
   c. Legal

5. Uniform System for all meds to reduce the risk of a med error

6. Drug Distribution System Terms
   a. Refill “On Demand” - this term typically is used for systems that require the nurse to accept
      the responsibility of reordering all medications. The Pharmacy only fills medications at the
      request (or demand) of the nursing staff
   b. Cycle Fill – this term refers to a system where the Pharmacy automatically replenishes the
      routine medications in a facility (usually tablets and capsules except controls) on a preset day
      or cycle. This cycle may be every 14 days, every 28 days or every calendar month on the 1st.
   c. Time Pass – this term refers to a system that somehow identifies medications that will be
      dispensed during a specific med time. The system may separate medications for each med time
      in a separate drawer of the cart or might color code the medications for a specific med time. In
      either case, the nurse does not need to search through all a patient’s medications to identify
      what will be needed during her med pass
   d. Blister Pack – this packaging system is also called a “bingo card” or a “modified unit dose
      system” where medications are packaged in a 7 day, 14 day, 30 dose or 60 dose card. The
      doses in a card are either labeled by day of the week or a decreasing drug count to make it
      easier to count or audit remaining medications. This packaging will typically contains drug
      name, lot #, expiration date (i.e. beyond use date) on the outer package instead of each
      individual dose.
   e. Calendar Card – this is a variation of the blister pack card that provides up to 31 doses of
      medication. The system is designed so that the nurse punches the dose of medication from the
      blister that matches the date. In other words on the 18th of the month the nurse removes dose
      #18 from the card. When combined with a time pass and cycle fill this system can provide an
      excellent audit trail

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DRUG DELIVERY SYSTEM: **Traditional Bottle System**

**SPEED OF MED PASS: VARIES**
- If meds are passed directly from bottles the system is fairly quick
- If meds are pre-poured prior to the med pass the system is slower because of the extra step.
  - Pre-poured meds must be labeled with drug name, strength and resident’s name from the time they are pre-poured until they are administered.

**SYSTEM ACCOUNTABILITY: POOR**
- Since there is no way of knowing when the bottle was started (especially on refills) and the system does not separate meds by dosing time a system audit is difficult if not impossible

**SYSTEM COSTS: INEXPENSIVE**
- From the Pharmacy perspective there is no special packaging (i.e. unit dose) therefore Pharmacy costs are less
- From a Nursing perspective the system may require more nursing time to pass meds therefore nursing costs may be higher

**AUTOMATION: POSSIBLE BUT NOT COMMONLY USED**

**INFECTION CONTROL: CAN BE AN ISSUE**
- Tablets cannot be touched by staff during the med pass or infections can be passed from resident to resident.
- Staff should not combine bottles of the same medication since medications may be contaminated during the process or med errors can occur if wrong bottles are combined

**PHARMACY ISSUES:**
- An easy system to sell against – facilities using this system are easy targets for competitors

**NURSING ISSUES:**
- Label changes are a major problem with this system
- Discontinued medications cannot be returned for credit and must be destroyed
- Pre-pouring can result in med errors and add several hours to the daily med pass
DRUG DELIVERY SYSTEM: 30 Day Box System

SPEED OF MED PASS: SLOWER THAN PUNCH CARD SYSTEMS
- The speed of the med pass system depends greatly on the individual unit dose packaging used.
- Manufacturer’s unit dose products may require more time to open when compared to some
  In-house unit dosed products
- All meds for a patient are stored in the same drawer. Frequently there are multiple boxes of the
  same medication available in the drawer (refills + large volumes that do not fit in one box)

SYSTEM ACCOUNTABILITY: POOR
- Each medication is reordered by nursing 5 to 7 days before medications run out
- Boxes of medication may not be started on the date delivered. Therefore, it is very difficult to
  verify that all medications are given appropriately
- If medications are left over there is no way to determine which shift and which day medications
  were missed
- Facilities using this system often treat Antibiotic orders as they treat controlled substances (with
  shift count sheets) since they have doses left over at the end of a treatment regimen. These
  remaining doses usually indicate that other medications are also being missed.

SYSTEM COSTS: DRUG COSTS MAY BE HIGHER
- Manufacturer’s unit dose products may actually cost the patient up to 10% more than product
  packaged in house

AUTOMATION: THE USE OF MANUFACTURER’S “UNIT DOSE”
- Using manufacturer’s unit dose product greatly reduces the need for manual pre-packing within
  the Pharmacy
- The actual filling of unit dose boxes and label application is still a manual process

INFECTION CONTROL: GOOD
- Unit dosed medication reduce the risk of contamination
- Boxes are replaced with each refill therefore less chance of cross contamination

PHARMACY ISSUES:
- This system cuts internal Pharmacy costs since the Pharmacy can buy pre-packaged unit dose
  products
- This system is typically “refill on demand” therefore the Pharmacy does not offer a “cycle-fill” or
  re-supply service.
- In some states there is a significant reimbursement benefit since Medicaid pays a higher price for
  manufacturer’s unit dose medications
- Pharmacy returns are easier to handle since each dose is individually labeled

NURSING ISSUES:
- The med pass is slower than punch card systems and typically takes 1-2 hours/day/cart longer to
  pass medications than some of the other systems
- Routine meds must be reordered by nursing which can lead to missing doses or 3rd party billing
  issues if ordered too early (i.e. Medicaid)
- Storage of multiple boxes of the same med for the same patient may lead to storage issues in the
  cart
NURSING HOMES

DRUG DELIVERY SYSTEM: Traditional Bingo Card System (30 day supply)

SPEED OF MED PASS: RELATIVELY FAST
   ➢ The med pass is typically faster than systems using manufacturer’s pre-packed unit dose

SYSTEM ACCOUNTABILITY: POOR
   ➢ Each medication is reordered by nursing 5 to 7 days before medications run out
   ➢ Cards of medication may not be started on the date delivered. Therefore, it is very difficult to verify that all medications are given appropriately
   ➢ If medications are left over there is no way to determine which shift and which day medications were missed.

SYSTEM COSTS: PATIENT COST LESS EXPENSIVE
   ➢ Since most medications are packaged internally the cost per dose is less than manufacturer’s unit dosed packaging
   ➢ The pharmacy may not be able to recover the internal packaging costs from 3rd party payors (i.e. Medicaid). Florida Medicaid does pay 1.5 cents per dose for this packaging as long as the patient is in a Nursing Home or ICF-DD

AUTOMATION: AVAILABLE FOR LARGER VOLUME PHARMACIES
   ➢ Packaging equipment is available to automate this packaging system however setup of the system between drugs may not be cost effective for smaller production runs
   ➢ There is a growing number of sources for pre-packaged (i.e. manufacturer based) blister cards. The list of drugs available are primarily designed for nursing home practices

INFECTION CONTROL: GOOD
   ➢ Unit dosed medication reduce the risk of contamination
   ➢ Blister Packs are replaced with each refill therefore less chance of cross contamination

PHARMACY ISSUES:
   ➢ There are staffing issues since most unit dosing today is done in-house unless the Pharmacy is owned by a national provider (many have there own repackaging companies)
   ➢ Returning medications to inventory is more problematic than hospital type unit dose since the product has a shorter “beyond use date” and must be re-labeled with lot # and “beyond use date” until it is re-dispensed
   ➢ Since the system is typically “refill on demand” billing issues may arise with 3rd party payors when medications are ordered too early

NURSING ISSUES:
   ➢ Under the traditional system all doses of a drug required for the patient come from the same unit dose card. This makes it difficult to determine is all doses are administered as required
   ➢ Since many prescriptions will require multiple cards for a 30 day supply and refills are “on-demand” 5-7 days before meds are needed storage may be an issue.
   ➢ Backup storage areas are frequently used and must be checked often to ensure that dc’ed orders and med for discharged patient get removed in a timely manner
   ➢ Because of the size of the bingo card drug carts may be limited to 30-35 patients which may not fit the facilities need
NURSING HOMES

DRUG DELIVERY SYSTEM: Bingo Card Cycle Fill Time Pass (30 day supply)

SPEED OF MED PASS: RELATIVELY FAST
- The med pass is typically faster than systems using manufacturer’s pre-packed unit dose.
- This system separates meds by med pass time which means that the 8am nurse only looks through meds used for that med time. This speeds up the med pass slightly over the traditional Bingo Card system

SYSTEM ACCOUNTABILITY: Good
- Routinely dosed tablets and capsules are automatically refilled by the Pharmacy on a set refill cycle. Old blister cards are removed which reduces clutter in the drug cart
- Since the pharmacy can determine when a med is started and meds are separated by med pass it is much easier to determine when a dose is missed. This assumes that all nurses use the system as designed
- Orders that are started between cycle fill dates are typically filled for enough doses to get to the next cycle fill.

SYSTEM COSTS: PATIENT COST LESS EXPENSIVE
- Since most medications are packaged internally the cost per dose is less than manufacturer’s unit dosed packaging
- The pharmacy may not be able to recover the internal packaging costs from 3rd party payors (i.e. Medicaid). Florida Medicaid does pay 1.5 cents per dose for this packaging as long as the patient is in a Nursing Home or ICF-DD

AUTOMATION: AVAILABLE FOR LARGER VOLUME PHARMACIES
- Packaging equipment is available to automate this packaging system however setup of the system between drugs may not be cost effective for smaller production runs
- There is a growing number of sources for pre-packaged (i.e. manufacturer based) blister cards. The list of drugs available are primarily designed for nursing home practices

INFECTION CONTROL: GOOD
- Unit dosed medication reduce the risk of contamination
- Blister Packs are replaced with each refill therefore less chance of cross contamination

PHARMACY ISSUES:
- There are staffing issues since most unit dosing today is done in-house unless the Pharmacy is owned by a national provider (many have their own repackaging companies).
- Since daily orders are filled with just enough meds to get to the next cycle date prepackaged medications (cards of 30) cannot be used for these partial fills
- Returning medications to inventory is more problematic than hospital type unit dose since the product has a shorter “beyond use date” and must be re-labeled with lot # and “beyond use date” until it is re-dispensed
- The Pharmacy will most often send staff out to the facility to do the re-supply which can cause staffing and cost issues for the pharmacy
- Since the system generates more returns (i.e. partial cards removed at the cycle fill) the re-working of these meds is time consuming

NURSING ISSUES:
- Because of the size of the bingo card, drug carts may be limited to 30-35 patients which may not fit the facilities need.
- This system saves nursing time since less meds are reordered by nursing staff
- The system may create problems in facilities which use frequent agency nurses unless they are trained on the proper use of the “time pass” system
DRUG DELIVERY SYSTEM: **OPUS**

**SPEED OF MED PASS: FAST**
- Medications are packaged in plastic reusable boxes that separate medications by day and dosing time. Color coded boxes are used to identify when a medication will be administered (e.g., all AM meds are packaged in pink bins).
- The top of each storage box contains break-away plastic covers that allow access to a single dose of the medication. This system is easier for a resident to handle (e.g., ALF’s with supervised medications) when compared to punching a bingo card or opening a manufacturer’s unit dose package.

**SYSTEM ACCOUNTABILITY: EXCELLENT**
- Since doses are identified by patient, time of day, and day of the week, and there is a limited supply of medication (usually 14 days), an audit trail is easy to follow.

**SYSTEM COSTS: PATIENT COST LESS EXPENSIVE**
- Since most medications are packaged internally, the cost per dose is less than manufacturer’s unit dosed packaging.
- The pharmacy may not be able to recover the internal packaging costs from 3rd party payors (i.e., Medicaid). Florida Medicaid does pay 1.5 cents per dose for this packaging as long as the patient is in a Nursing Home or ICF-DD.

**AUTOMATION: NOT AVAILABLE**
- At this time all packaging must be done manually. This makes the system very labor intensive both in the filling process and the re-use of the packaging system.
- Most large volume LTC pharmacies will not offer this system because of the high internal costs of using this system.

**INFECTION CONTROL: POTENTIALLY POOR**
- The system is designed to allow reuse of the plastic bins after replacing a plastic liner and cover which are the only parts of the system that come in direct contact with the drug.
- Many pharmacies reuse this system without replacing the plastic liner which can lead to cross-contamination from the previous medication.
- The external portion of the bin is reused and often sent from one facility to another with a new medication. Unless the pharmacy has an established cleaning program between uses, there is the potential of a package handled by staff (or residents) from one facility to be re-dispensed to a resident in a new facility.
- Reused external plastic bins must be scraped or heated to remove old prescription labels. It is not uncommon to find pharmacies that simply place the new label over a previous patient’s label. This represents both a HIPAA issue and creates the potential for a medication error.

**PHARMACY ISSUES:**
- Since the system is very labor-intensive, many pharmacies find it difficult to grow the business and remain profitable.
- This system is most often filled as a 14 day supply. The Pharmacy must fill the medication twice monthly and send staff to the facility for the re-supply twice monthly. This results in higher internal pharmacy costs.
- The 14 day supply system creates problems with 3rd party payors. This billing cycle may not be compatible with billing requirements by the 3rd party insurer. In addition, there are 4 months per year that require 3 resupplies.

**NURSING ISSUES:**
- Nursing staff (especially in an ALF) like this system since it is color coded and easy to use.
DRUG DELIVERY SYSTEM: **Opti-Pak 14 day system**

**SPEED OF MED PASS: FAST**
- Medications are packaged in disposable 14 day blister packs that separate medications by day and dosing time. Color coded labeling is used to identify when a medication will be administered (e.g., all AM meds may be packaged in with pink “AM” auxiliary labels).
- This system is easier for a resident to handle (e.g., ALF’s with supervised medications) when compared to punching a 30 dose bingo card or opening a manufacturer’s unit dose package. Therefore, the med pass is slightly faster than the traditional 30 day bingo card system.

**SYSTEM ACCOUNTABILITY: EXCELLENT**
- Since doses are identified by patient, time of day and day of the week, and there is a limited supply of medication (usually 14 days) an audit trail is easy to follow.

**SYSTEM COSTS: PATIENT COST LESS EXPENSIVE**
- Since most medications are packaged internally the cost per dose is less than manufacturer’s unit dosed packaging.
- The pharmacy may not be able to recover the internal packaging costs from 3rd party payors (i.e., Medicaid). Florida Medicaid does pay 1.5 cents per dose for this packaging as long as the patient is in a Nursing Home or ICF-DD.

**AUTOMATION: AVAILABLE**
- Packaging equipment is available to automate this packaging system however setup of the system between drugs may not be cost effective for smaller production runs.
- There are no pre-packaged sources for this system.

**INFECTION CONTROL: GOOD**
- Unit dosed medication reduce the risk of contamination.
- Blister Packs are replaced with each refill therefore less chance of cross contamination.

**PHARMACY ISSUES:**
- There are staffing issues since most unit dosing today is done in-house.
- Since daily orders are filled with just enough meds to get to the next cycle date prepackaged medications cannot be used for these partial fills.
- Returning medications to inventory is more problematic than hospital type unit dose since the product has a shorter “beyond use date” and must be re-labeled with lot # and “beyond use date” until it is re-dispensed.
- The Pharmacy will most often send staff out to the facility twice per month to do the re-supply which can cause staffing and cost issues for the pharmacy. This represents twice the work of a 30 day system for the same dispensing fee.
- Since the system generates more returns (i.e. partial cards removed at the cycle fill) the re-working of these meds is time consuming.

**NURSING ISSUES:**
- This system provides many of the benefits of an OPUS system without the infection control issues.
- Residents in an ALF or group home prefer the smaller packaging to a 30 day bingo card.
- This system saves nursing time since less meds are reordered by nursing staff.
DRUG DELIVERY SYSTEM: Medicine onTime

SPEED OF MED PASS: FAST
- Medications are packaged in reusable Frames containing 30 day blister packs that separate medications by day and dosing time. Labeling on the individual blister allows a facility to tear off a single dose and hand to a resident. The dose is adequately labeled even when separated from the card.
- This system is easier for a resident to handle (ex ALF’s with supervised medications) when compared to punching a 30 dose bingo card or opening a manufacturer’s unit dose package. Therefore, the med pass is on average 30% faster than the traditional 30 day bingo card system.

SYSTEM ACCOUNTABILITY: EXCELLENT
- Since doses are identified by patient, time of day and day of the week, and there is a limited supply of medication (7 days) an audit trail is easy to follow.

SYSTEM COSTS: PATIENT COST LESS EXPENSIVE
- Since most medications are packaged internally the cost per dose is less than manufacturer’s unit dosed packaging. If all meds fall within the 4 main med times you only use 4 cards per month which is also more cost effective.
- The pharmacy may not be able to recover the internal packaging costs from 3rd party payors (i.e. Medicaid). Florida Medicaid does pay 1.5 cents per dose for this packaging as long as the patient is in a Nursing Home or ICF-DD.

AUTOMATION: AVAILABLE
- Packaging equipment is not available to automate this packaging system which makes this system less desirable than new systems like Dispill and MTS RX Map systems.
- There are no pre-packaged sources for this system since every card is customized to the patient's individual orders.

INFECTION CONTROL: GOOD
- Unit dosed medication reduce the risk of contamination.
- The reusable Frames moves from facility to facility and do represent a potential infection control risk.

PHARMACY ISSUES:
- There may be staffing issue since unit dosing is done manually and each multi-pak card can take up to 20 minutes to fill and verify.
- Since daily orders are filled with just enough meds to get to the next cycle date prepackaged medications cannot be used for these partial fills.
- Medications cannot be returned to inventory since USP considers them cross contaminated once they are combined with other meds in the same blister.
- Multi-Pak systems in general have shorter “beyond use date” since USP mandates a 60 day discard policy on these systems.
- The Pharmacy will most often send staff out to the facility weekly to do the re-supply which can cause staffing and cost issues for the pharmacy. This represents four times the work of a 30 day system for the same dispensing fee.
- Order changes (especially dc’ed drugs or dose changes) requires pickup and re-packaging of these cards which is time consuming.

NURSING ISSUES:
- The labeling is not as impressive as the new systems like DisPill or SynMed labeling on the RXMap product.
- It is a faster Med Pass than Bingo cards.
- Residents in an ALF or group home can manage their own meds safely or be given a single labeled packet to take medications later in the day.
- These Frames stay upright in the cart even when doses are removed.
- The tear off part of the card has HIPAA protected information on it and this cannot be thrown into regular trash.
- Good communication for order changes, dc'ed orders etc between the facility and pharmacy is critical to avoid medication errors.
DRUG DELIVERY SYSTEM: **DisPill 7 day Cards**

**SPEED OF MED PASS: FAST**
- Medications are packaged in disposable 7 day blister packs that separate medications by day and dosing time. Labeling on the individual blister allows a facility to tear off a single dose and hand to a resident. The dose is adequately labeled even when separated from the card.
- This system is easier for a resident to handle (ex ALF’s with supervised medications) when compared to punching a 30 dose bingo card or opening a manufacturer’s unit dose package. Therefore, the med pass is on average 30% faster than the traditional 30 day bingo card system.

**SYSTEM ACCOUNTABILITY: EXCELLENT**
- Since doses are identified by patient, time of day and day of the week, and there is a limited supply of medication (7 days) an audit trail is easy to follow.

**SYSTEM COSTS: PATIENT COST LESS EXPENSIVE**
- Since most medications are packaged internally the cost per dose is less than manufacturer’s unit dosed packaging. If all meds fall within the 4 main med times you only use 4 cards per month which is also more cost effective.
- The pharmacy may not be able to recover the internal packaging costs from 3rd party payors (i.e. Medicaid). Florida Medicaid does pay 1.5 cents per dose for this packaging as long as the patient is in a Nursing Home or ICF-DD.

**AUTOMATION: AVAILABLE**
- Packaging equipment (SynMed) is available to automate this packaging system however manual use of the system in small pharmacy operations may require more staff time and it's more difficult for a pharmacist to validate the card since you may have up to 15 meds in the same blister.
- There are no pre-packaged sources for this system since every card is customized to the patient's individual orders.

**INFECTION CONTROL: GOOD**
- Unit dosed medication reduce the risk of contamination.
- Blister Packs are replaced with each refill therefore less chance of cross contamination.

**PHARMACY ISSUES:**
- There may be staffing issues if the unit dosing is done manually since it can take up to 20 minutes per card to fill and verify.
- Since daily orders are filled with just enough meds to get to the next cycle date prepackaged medications cannot be used for these partial fills.
- Medications cannot be returned to inventory since USP considers them cross contaminated once they are combined with other meds in the same blister.
- Multi-Pak systems in general have shorter “beyond use date” since USP mandates a 60 day discard policy on these systems.
- The Pharmacy will most often send staff out to the facility weekly to do the re-supply which can cause staffing and cost issues for the pharmacy. This represents four times the work of a 30 day system for the same dispensing fee.
- Order changes (especially dc'ed drugs or dose changes) requires pickup and re-packaging of these cards which is time consuming.

**NURSING ISSUES:**
- This system provides color pictures of each drug and the patient on it's labeling which reduces the risk of med errors.
- It is a faster Med Pass without the infection control issues of older systems like Medicine on Time.
- Residents in an ALF or group home can manage their own meds safely or be given a single labeled packet to take medications later in the day.
- These cards are flimsy and many facilities report that as meds are removed from the card the card has a tendency of falling into the cart.
- The tear off part of the card has HIPAA protected information on it and this cannot be thrown into regular trash.
- Good communication for order changes, dc'ed orders etc between the facility and pharmacy is critical to avoid medication errors.
DRUG DELIVERY SYSTEM: **RX-MAP system by MTS**

**SPEED OF MED PASS: FAST**
- Medications are packaged in disposable 7 day blister packs that separate medications by day and dosing time. Labeling on the individual blister allows a facility to tear off a single dose and hand to a resident. The dose is adequately labeled even when separated from the card
- This system is easier for a resident to handle (ex ALF’s with supervised medications) when compared to punching a 30 dose bingo card or opening a manufacturer’s unit dose package. Therefore, the med pass is on average 30% faster than the traditional 30 day bingo card system

**SYSTEM ACCOUNTABILITY: EXCELLENT**
- Since doses are identified by patient, time of day and day of the week, and there is a limited supply of medication (7 days) an audit trail is easy to follow

**SYSTEM COSTS: PATIENT COST LESS EXPENSIVE**
- Since most medications are packaged internally the cost per dose is less than manufacturer’s unit dosed packaging. If all meds fall within the 4 main med times you only use 4 cards per month which is also more cost effective
- The pharmacy may not be able to recover the internal packaging costs from 3rd party payors (i.e. Medicaid). Florida Medicaid does pay 1.5 cents per dose for this packaging as long as the patient is in a Nursing Home or ICF-DD

**AUTOMATION: AVAILABLE**
- Packaging equipment (MTS 400 or SynMed) is available to automate this packaging system however manual use of the system in small pharmacy operations may require more staff time and it’s more difficult for a pharmacist to validate the card since you may have up to 15 meds in the same blister
- There are no pre-packaged sources for this system since every card is customized to the patient's individual orders

**INFECTION CONTROL: GOOD**
- Unit dosed medication reduce the risk of contamination
- Blister Packs are replaced with each refill therefore less chance of cross contamination

**PHARMACY ISSUES:**
- There may be staffing issues if the unit dosing is done manually since it can take up to 20 minutes per card to fill and verify.
- Since daily orders are filled with just enough meds to get to the next cycle date prepackaged medications cannot be used for these partial fills
- Medications cannot be returned to inventory since USP considers them cross contaminated once they are combined with other meds in the same blister.
- Multi-Pak systems in general have shorter “beyond use date” since USP mandates a 60 day discard policy on these systems
- The Pharmacy will most often send staff out to the facility weekly to do the re-supply which can cause staffing and cost issues for the pharmacy. This represents four times the work of a 30 day system for the same dispensing fee
- Order changes (especially dc'ed drugs or dose changes) requires pickup and re-packaging of these cards which is time consuming

**NURSING ISSUES:**
- This system provides color pictures of each drug and the patient on it's labeling which reduces the risk of med errors.
- It is a faster Med Pass without the infection control issues of older systems like Medicine on Time.
- Residents in an ALF or group home can manage their own meds safely or be given a single labeled packet to take medications later in the day.
- These cards are sturdier than the Dispill card and many nurses prefer this card over the flimsier Dispill card.
- Good communication for order changes, dc'ed orders etc between the facility and pharmacy is critical to avoid medication errors
- The tear off part of the card has HIPAA protected information on it and this cannot be thrown into regular trash
DRUG DELIVERY SYSTEM: **MultiPak Envelopes (AutoMed, PacMed, Talyst)**

**SPEED OF MED PASS: FAST**
- Medications are packaged in disposable envelopes that separate medications by day and dosing time. Labeling on the individual envelope allows a facility to tear off a single dose and hand to a resident.
- This system is easier for a resident to handle (ex ALF’s with supervised medications) when compared to punching a 30 dose bingo card or opening a manufacturer’s unit dose package. Therefore, the med pass is on average 30% faster than the traditional 30 day bingo card system

**SYSTEM ACCOUNTABILITY: EXCELLENT**
- Since doses are identified by patient, time of day and day of the week, and there is a limited supply of medication (2 days, 2 days 2 days 3 days or 7 days max) an audit trail is easy to follow

**SYSTEM COSTS: PATIENT COST LESS EXPENSIVE**
- Since medications packaging is automated the cost per dose is less than manufacturer’s unit dosed packaging. If all meds fall within the 4 main med times you only use 4 envelopes per day
- The pharmacy may not be able to recover the internal packaging costs from 3rd party payors (i.e. Medicaid). Florida Medicaid does pay 1.5 cents per dose for this packaging as long as the patient is in a Nursing Home or ICF-DD

**AUTOMATION: AVAILABLE**
- Packaging equipment (multiple companies) is essential to use this system
- There are no pre-packaged sources for this system since every envelope is customized to the patient's individual orders

**INFECTION CONTROL: GOOD**
- Unit dosed medication reduce the risk of contamination
- An envelope is used once then discarded therefore less chance of cross contamination

**PHARMACY ISSUES:**
- Since multiple meds are in the same envelope checking the final product can be difficult.
- Medications cannot be returned to inventory since USP considers them cross contaminated once they are combined with other meds in the same blister.
- Multi-Pak systems in general have shorter “beyond use date” since USP mandates a 60 day discard policy on these systems
- Reworking these envelopes when orders change is a major issue which forces many pharmacies to send fewer days at a time.
- When a medication is dc’ed Florida regulations mandate that it be removed from the cart which increases the urgency of getting new envelopes sent to the facility
- Some pharmacies are placing these machines on site at the nursing home and custom packing each med pass by nursing unit. This is especially effective in acute care facilities who have many admissions each day. This can save the facility significant dollars on wasted meds but is a significant start-up expense for the pharmacy

**NURSING ISSUES:**
- There are less meds on the cart and packaging errors are more difficult to catch.
- It is a faster Med Pass without the infection control issues of older systems like Medicine on Time and Opus.
- Residents in an ALF or group home can manage their own meds safely or be given a single labeled packet to take medications later in the day.
- Good communication for order changes, dc’ed orders etc between the facility and pharmacy is critical to avoid medication errors. Inspectors have been known to unfairly call these envelopes "suicide packs" since they have investigated so many errors. The majority of these errors are caused by gaps in communication not by the technology involved
- The envelope has HIPAA protected information on it and this cannot be thrown into regular trash
Class II Institutional Pharmacies – Automated Distribution and Packaging.

(1) Definitions.

(a) “Automated medication system” means a robotic, mechanical or computerized device that is not used for medication compounding and is designed to:
1. Distribute medications in a licensed health care facility; or
2. Package medications for final distribution by a pharmacist.

(b) “Centralized automated medication system” means an automated medication system located in a pharmacy department from which medication is distributed or packaged for final distribution by a pharmacist.

(c) “Decentralized automated medication system” means an automated medication system that is located outside of a pharmacy department but within the same institution.

(d) “Distribute” or “Distribution” means the process of providing a drug to an individual authorized to administer medications and licensed as a health care provider in the state of Florida pursuant to an order issued by an authorized prescriber.

(e) “Medication” means a medicinal drug or proprietary preparation.

(f) “Override medication” means a single dose of medication that may be removed from a decentralized automated medication system prior to pharmacist review because a practitioner licensed pursuant to Chapter 458, 459 or 466, F.S., determined that the clinical status of the patient would be significantly compromised by delay.

(g) “Low risk override medication” is a medication determined by a practitioner licensed pursuant to Chapters 458, 459, or 466, F.S., to have a low risk of drug allergy, drug interaction, dosing error, or adverse patient outcome, and may be removed from a decentralized automated medication system independent of a pharmacist’s review of the medication order or clinical status of the patient.

(h) “Physician controlled medication” is medication distributed in an environment where a practitioner controls the order, preparation and administration of the medication.

(2) General Requirements for the Use of Automated Medication Systems.

(a) The consultant pharmacist of record shall be responsible for:
1. Maintaining a record of each transaction or operation;
2. Controlling access to the system;
3. Maintaining policies and procedures for;
   a. Operation of the automated medication system;
   b. Training personnel who use the automated medication system;
   c. Maintaining patient services whenever the automated medication system is not operating; and
   d. Defining a procedure for a pharmacist to grant or deny access to the medication in the system.
4. Security of the system;
5. Assuring that a patient receives the pharmacy services necessary for good pharmaceutical care in a timely manner;
6. Assuring that the system maintains the integrity of the information in the system and protects patient confidentiality;
7. Establishing a comprehensive Quality Assurance program;
8. Establishing a procedure for stocking or restocking the automated medication system; and
9. Ensuring compliance with all requirements for packaging and labeling.

(b) A pharmacist shall perform prospective drug use review and approve each medication order prior to administration of a medication except an override medication, a low risk override medication or a physician controlled medication.

(c) A pharmacist shall perform retrospective drug use review for an override medication.

(3) Multidisciplinary Committee for Decentralized Automated Medication Systems.

(a) The consultant pharmacist of record shall convene or identify a multidisciplinary committee, which is charged with oversight of the decentralized automated medication system.
(b) The Multidisciplinary Committee shall:
1. Include at least one pharmacist;
2. Establish the criteria and process for determining which medication qualifies as an override medication or a low risk override medication in a decentralized automated medication system;
3. Develop policies and procedures regarding the decentralized automated medication system; and
4. Have its decisions reviewed and approved by the consultant pharmacist of record.

(4) Stocking or Restocking of a Decentralized Automated Medication System.
(a) Medications in a decentralized Automated Medication System shall be stocked or restocked by a pharmacist, registered pharmacy intern, or by a registered pharmacy technician supervised by a pharmacist.
(b) The stocking or restocking of a decentralized automated medication system shall follow one of the following procedures to assure correct medication selection:
1. A pharmacist shall conduct a daily audit of medications placed or to be placed into an automated medication system that includes random sampling.
2. A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of medication placed or to be placed into an automated medication system. The utilization of a bar code, electronic, or similar verification technology shall require an initial quality assurance validation followed by a monthly quality assurance review by a pharmacist.

(5) Centralized Automated Medication Systems. A pharmacist utilizing a centralized medication system may distribute patient specific medications within the licensed health care facility without checking each individual medication selected or packaged by the system, if:
(a) The initial medication order has been reviewed and approved by a pharmacist; and
(b) The medication is distributed for subsequent administration by a health care professional permitted by Florida law to administer medication; and
(c) A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of medication placed or to be placed into an automated medication system. The utilization of a bar code, electronic verification, or similar verification technology shall require an initial quality assurance validation, followed by monthly quality assurance review by a pharmacist.

(6) Quality Assurance Program. The consultant pharmacist of record shall be responsible for establishing a quality assurance program for the automated medication system. The program shall provide for:
(a) Review of override and low risk override medication utilization;
(b) Investigation of a medication error related to the automated medication system;
(c) Review of a discrepancy or transaction reports and identify patterns of inappropriate use or access;
(d) Review of the operation of the system;
(e) Integration of the automated medication system quality assurance program with the overall continuous quality improvement of the pharmacy as defined in Rule 64B16-27.300, F.A.C.; and
(f) Assurance that individuals working with the automated medication system receive appropriate training on the operation of the system and procedures for maintaining pharmacy services when the system is not in operation.

(7) Record Keeping.
(a) The consultant pharmacist of record shall maintain records related to the automated medication system in a readily retrievable manner.
(b) The following records shall be maintained for at least 60 days:
1. Daily audits of stocking or restocking, if applicable;
2. Daily audits for the output of centralized automated medication system, if applicable; and
3. Transaction records for all non-controlled medications or devices distributed by the automated medication system.
(c) The following records shall be maintained for at least two (2) years:
1. Any report or analysis generated as part of the quality assurance program;
2. A report or database related to access to the system or any change in the access to the system or to medication in the system; and
3. Transaction records from the automated medication system for all controlled substances dispensed or distributed.

(8) Compliance. The consultant pharmacist of record shall assure compliance with all requirements of Chapter 465, F.S., and the rules of Chapter 64B16, F.A.C.

(9) Security. A decentralized automated medication system that contains controlled substances shall prohibit simultaneous access to multiple drug entities, drug strengths, or dosage forms of controlled substances, unless otherwise contained in labeled patient-specific form.

AUTOMATED PACKAGING SYSTEMS

AUTOMED
www.automedrx.com
(888) 537-3102

DOSIS
Manchac Technologies
www.manchac.com
(877) 626-2422

M.T.S.
www.mts-mt.com
(800) 845-0053

PACM ED
www.mckesson.com
(800) 594-9145

PARATA
www.parata.com
(888) 727-2821

TALYST
www.Talyst.com
(877) 482-5978

TCG RX
www.tcgrx.com
(262) 279-5307

AutoMed Style Packaging
EXAMPLE OF A PACKAGING UNIT

AUTOPACK by Talyst

Sample of Multi-dose packaging
(AutoMed)
DRUG DISTRIBUTION AND CONTROL SYSTEMS

One of the most important responsibilities in institutional pharmacy practice.

All services to patients are based on a quality drug distribution system.

Unit Dose - ready to administer without dosage calculation, further manipulation or “note strength” label.

Elements of a Unit Dose System
♦ Medication contained in and administered from single unit or unit dose packages
♦ Medications dispensed in ready to use form
♦ Generally not more than a 24 hour supply of doses provided
♦ Patient medication profile is maintained for each patient
♦ Used in collaboration with a Medication Administration Record (MAR)

Advantages of the unit dose system
♦ Decreased medication errors
♦ Reduced total cost of medication related activities
♦ More efficient use of pharmacist and nurse time
♦ Provides overall drug control
♦ Reduced pilferage
♦ More accurate patient billing
♦ Reduced drug waste
♦ Enhanced quality of patient care
♦ Provides pharmacist review of order prior to administration

MEDICATION Unit dose delivery systems

I. Cart fill = 24 hour batch delivery
II. Decentral Automated Dispensing Cabinets
III. Hybrid models
I. CART FILL

♦ Pharmacy profile is used to batch a 24 hour supply of medications referred to as a “cart fill”
♦ Organized by patient in a bin or envelope
♦ Medications are unit dose in a ready to administer form
♦ Daily “cart exchange” when the new medications are delivered and unused medications are returned to the pharmacy
♦ Throughout the day as new orders are written doses are dispensed from the pharmacy (i.e., first doses)

♦ Advantage: Easy medication pass
♦ Disadvantages:
  o Nurses “borrow” medications
  o Turn around time for dispensing new orders
  o Missing medications
  o 30% rework

Patient specific medications delivered by pharmacy staff to medication drawers or hanging file folders separated by patient.

24 hour supply exchanged daily.

MAR (paper or electronic) used to administer meds

Carts/Cabinets – various shapes/sizes

Example of a locked bedside cabinet where patient medications are stored
Drug storage and retrieval systems (~20% hospitals) using bar code technology:

FLOORSTOCK – authorized medications are stored outside of the pharmacy
   Generally emergency medications & controlled substances
   SAFE for patient and employee
   STORAGE requirements met
   MAINTAIN RPh review of medication orders
   Mechanism to CHARGE

REFRIGERATED MEDICATIONS

MULTIDOSE items (for example eye drops, inhalers, ointments)

II. Decentralized drug distribution system
   ♦ Automated dispensing cabinets (e.g., Pyxis, Omnicell, AcuDose, MedDispense, etc.)
     ~ 80% hospitals

   Dispensing cabinet is interfaced to pharmacy medication profile.
   Medication access is restricted to what is in the patient’s medication profile.
   Users have unique logon and password.
   Recordkeeping is electronic.

- With adequate cabinet capacity and number of cabinets per nursing unit, the traditional “cart fill” may be replaced with automated dispensing cabinets.
Essentially no cart fill.

End user (such as the nurse or respiratory therapist) obtains medications from the dispensing cabinet

Pharmacy customizes the cabinets based on utilization

Traditional FLOORSTOCK is replaced with “OVERRIDE” function from the cabinet

REFRIGERATED MEDICATIONS – system may have refrigerator capacity

♦ Advantage:
  o Drug control and security in locked cabinets
  o Improved medication availability
  o Reduced medication errors – omissions, wrong drug
  o Safety systems built into the technology
  o Efficient for nursing and pharmacy
  o Orders reviewed by RPh prior to access with cabinet access linked to the medication profile
  o Provides data to improve patient care and drug control
  o Opportunity to redesign practice

♦ Disadvantages
♦ Do NOT eliminate important pharmacist review of medication order
  o Monitor “override” drug removals
♦ Automate carefully – introduces new opportunities for errors
♦ Nursing perception of performing “cart fill”

III. Hybrid model – combination of cart fill and Automated Dispensing cabinets – more often seen in larger facilities

OTHER Automation
♦ BARCODING
  o Receiving order into pharmacy
  o Prior to dispensing
  o Before medication administration – 58.6% (bedside scanning, eMAR)

♦ Remote order entry – 10.1%
Computerized provider order entry (CPOE, ePOM) 4
-19% hospitals with decision support
-3.5% were not integrated to pharmacy system (RPh reentered all orders)

Electronic records – electronic medical record 4
58.6% partial or complete EMR

Electronic outpatient prescriptions ~35.4% hospitals 4

Wireless temperature monitoring ~25% hospitals

Smart infusion pumps – programmable to prevent calculation errors
~65% with pharmacists actively involved with creating the drug libraries

References:
2 Pharmacy Purchasing & Products August 2008 www.pppmag.com

(1) Definitions.

(a) “Remote Medication Order Processing” includes any of the following activities performed for a Class II Institutional Pharmacy from a remote location:
1. Receiving, interpreting, or clarifying medication orders.
2. Entering or transferring medication order data.
3. Performing prospective drug use review.
4. Obtaining substitution authorizations.
5. Interpreting and acting on clinical data.
6. Performing therapeutic interventions.
7. Providing drug information.
8. Authorizing the release of a medication for administration.

(b) “Medication” means a medicinal drug or proprietary preparation.

(c) “Prospective drug use review” means an evaluation of medication orders and patient medication records for:
1. Over-utilization or under-utilization of medication.
2. Therapeutic duplication of medication.
3. Drug-disease contraindications.
4. Drug interactions.
5. Incorrect drug dosage or duration of drug treatment.
6. Clinical abuse or misuse of medication.

(2) General requirements.

(a) All pharmacists participating in remote medication order processing shall be Florida licensed pharmacists.

(b) A Class II Institutional pharmacy may utilize remote medication order processing if the pharmacist performing the remote medication order processing has access to sufficient patient information necessary for prospective drug use review and approval of medication orders.

(c) A pharmacist shall perform the final check of a medication order.

(d) If the pharmacist performing remote order processing is not an employee of the Class II Institutional pharmacy, the Class II Institutional pharmacy must have a written agreement or contract with the pharmacist or entity employing the pharmacist. The written agreement or contract shall:
1. Outline the services to be provided.
2. Delineate the responsibilities of each party including compliance with federal and state laws and regulations governing the practice of pharmacy as well as state and federal medical privacy requirements.
3. Require that the parties adopt a policies and procedures manual.
4. Provide that the parties have access to or share a common electronic file such that the pharmacist performing remote medication order processing has sufficient patient information necessary for prospective drug use review and approval of medication orders.

(3) Policy and Procedures. A policy and procedures manual shall:

(a) Be accessible to each party involved in remote medication order processing.

(b) Be available for inspection by the Board or an authorized agent of the Department.

(c) Outline the responsibilities of each party involved in remote medication order processing.

(d) Include a current list of the name, address, telephone number, and license number of each pharmacist involved in remote medication order processing.

(e) Include policies and procedures for:
1. Protecting the confidentiality and integrity of patient information.
2. Ensuring that a pharmacist performing prospective drug use review has access to appropriate drug information resources.
3. Ensuring that medical and nursing staff understand how to contact a pharmacist.
4. Maintaining records to identify the name, initials, or identification code of each person who
performs a processing function for a medication order.

5. Complying with federal and state laws and regulations.

6. Operating or participating in a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

7. Reviewing the written policies and procedures and documenting the review every year.

(4) Records.

(a) A Class II Institutional Pharmacy involved in remote medication order processing shall maintain a record that identifies the name, initials, or identification code of each person who performed a processing function for every medication order. The record shall be available by medication order or by patient name.

(b) The record may be maintained in a common electronic file if the record is maintained in such a manner that the data processing system can produce a printout which identifies every person who performed a processing function for a medication order.

(c) The record shall be readily retrievable for at least the past two (2) years.

(d) The record shall be available for inspection by the Board or an authorized agent of the Department.


64B16-28.605 Class II Institutional Pharmacies - Automated Distribution and Packaging.

(1) Definitions.

(a) “Automated medication system” means a robotic, mechanical or computerized device that is not used for medication compounding and is designed to:

1. Distribute medications in a licensed health care facility; or
2. Package medications for final distribution by a pharmacist.

(b) “Centralized automated medication system” means an automated medication system located in a pharmacy department from which medication is distributed or packaged for final distribution by a pharmacist.

(c) “Decentralized automated medication system” means an automated medication system that is located outside of a pharmacy department but within the same institution.

(d) “Distribute” or “Distribution” means the process of providing a drug to an individual authorized to administer medications and licensed as a health care provider in the state of Florida pursuant to an order issued by an authorized prescriber.

(e) “Medication” means a medicinal drug or proprietary preparation.

(f) “Override medication” means a single dose of medication that may be removed from a decentralized automated medication system prior to pharmacist review because a practitioner licensed pursuant to Chapter 458, 459 or 466, F.S., determined that the clinical status of the patient would be significantly compromised by delay.

(g) “Low risk override medication” is a medication determined by a practitioner licensed pursuant to Chapters 458, 459, or 466, F.S., to have a low risk of drug allergy, drug interaction, dosing error, or adverse patient outcome, and may be removed from a decentralized automated medication system independent of a pharmacist’s review of the medication order or clinical status of the patient.

(h) “Physician controlled medication” is medication distributed in an environment where a practitioner controls the order, preparation and administration of the medication.

(2) General Requirements for the Use of Automated Medication Systems.

(a) The consultant pharmacist of record shall be responsible for:

1. Maintaining a record of each transaction or operation;
2. Controlling access to the system;
3. Maintaining policies and procedures for;
   a. Operation of the automated medication system;
   b. Training personnel who use the automated medication system;
   c. Maintaining patient services whenever the automated medication system is not operating; and
   d. Defining a procedure for a pharmacist to grant or deny access to the medication in the system.
4. Security of the system;
5. Assuring that a patient receives the pharmacy services necessary for good pharmaceutical care in a timely manner;
6. Assuring that the system maintains the integrity of the information in the system and protects patient confidentiality;
7. Establishing a comprehensive Quality Assurance program;
8. Establishing a procedure for stocking or restocking the automated medication system; and
9. Ensuring compliance with all requirements for packaging and labeling.

(b) A pharmacist shall perform prospective drug use review and approve each medication order prior to administration of a medication except an override medication, a low risk override medication or a physician controlled medication.

(c) A pharmacist shall perform retrospective drug use review for an override medication.


(a) The consultant pharmacist of record shall convene or identify a multidisciplinary committee, which is charged with oversight of the decentralized automated medication system.

(b) The Multidisciplinary Committee shall:
   1. Include at least one pharmacist;
   2. Establish the criteria and process for determining which medication qualifies as an override medication or a low risk override medication in a decentralized automated medication system;
   3. Develop policies and procedures regarding the decentralized automated medication system; and
   4. Have its decisions reviewed and approved by the consultant pharmacist of record.

4) Stocking or Restocking of a Decentralized Automated Medication System.

(a) Medications in a decentralized Automated Medication System shall be stocked or restocked by a pharmacist or by a pharmacy technician supervised by a pharmacist.

(b) The stocking or restocking of a decentralized automated medication system shall follow one of the following procedures to assure correct medication selection:
   1. A pharmacist shall conduct a daily audit of medications placed or to be placed into an automated medication system that includes random sampling.
   2. A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of medication placed or to be placed into an automated medication system. The utilization of a bar code, electronic, or similar verification technology shall require an initial quality assurance validation followed by a monthly quality assurance review by a pharmacist.

5) Centralized Automated Medication Systems. A pharmacist utilizing a centralized medication system may distribute patient specific medications within the licensed health care facility without checking each individual medication selected or packaged by the system, if:

(a) The initial medication order has been reviewed and approved by a pharmacist; and

(b) The medication is distributed for subsequent administration by a health care professional permitted by Florida law to administer medication; and

(c) A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of medication placed or to be placed into an automated medication system. The utilization of a bar code, electronic verification, or similar verification technology shall require an initial quality assurance validation, followed by monthly quality assurance review by a pharmacist.

6) Quality Assurance Program. The consultant pharmacist of record shall be responsible for establishing a quality assurance program for the automated medication system. The program shall provide for:

(a) Review of override and low risk override medication utilization;
(b) Investigation of a medication error related to the automated medication system;
(c) Review of a discrepancy or transaction reports and identify patterns of inappropriate use or access;
(d) Review of the operation of the system;
(e) Integration of the automated medication system quality assurance program with the overall continuous quality improvement of the pharmacy as defined in Rule 64B16-27.300, F.A.C.; and
(f) Assurance that individuals working with the automated medication system receive appropriate training on the operation of the system and procedures for maintaining pharmacy services when the system is not in operation.

(7) Record Keeping.
(a) The consultant pharmacist of record shall maintain records related to the automated medication system in a readily retrievable manner.
(b) The following records shall be maintained for at least 60 days:
   1. Daily audits of stocking or restocking, if applicable;
   2. Daily audits for the output of centralized automated medication system, if applicable; and
   3. Transaction records for all non-controlled medications or devices distributed by the automated medication system.
(c) The following records shall be maintained for at least two (2) years:
   1. Any report or analysis generated as part of the quality assurance program;
   2. A report or database related to access to the system or any change in the access to the system or to medication in the system; and
   3. Transaction records from the automated medication system for all controlled substances dispensed or distributed.

(8) Compliance. The consultant pharmacist of record shall assure compliance with all requirements of Chapter 465, F.S., and the rules of Chapter 64B16, F.A.C.

(9) Security. A decentralized automated medication system that contains controlled substances shall prohibit simultaneous access to multiple drug entities, drug strengths, or dosage forms of controlled substances, unless otherwise contained in labeled patient-specific form.