Medication Compounding

Expectations and Survey Process

Wayne Murphy and Paul Ziaya
Field Directors
Accreditation and Certification Operations
Hospitals and Home Care

More similarities than differences

- Planning
- Selection and Procurement
- Storage
- Ordering
- Preparation and Dispensing
- Monitoring and Evaluation
Survey Process

Whether in Hospitals or Home Care the process is the same

- Individual Tracers
  - Evaluate the care provided to a given patient and the processes supporting that care

- System Tracers
  - Evaluate the overarching system involved in the safe provision of medications
Planning

- Written policies and procedures
- Pharmacy area planning considerations
- High-alert and hazardous medications
  - Defined by the organization
  - Plan for management throughout the organization
Selection and Procurement

- Process for drug selection
- Who is responsible for those decisions
- Drug list/formulary
- Medication Shortages and Backorders
- Substitution protocols
- Education of staff and providers
Storage

- Written policy for medication control and its appropriate implementation

Storage requirements
- Consistent with manufacturer recommendations
- Secured to prevent diversion and access by unauthorized persons
- Only approved medications available
Storage

- Proper labeling of medications and components used in preparation
- Expired medications are removed so they cannot be used
- Storage of medication in any other locations i.e. ambulatory infusion suites
- Management of emergency medications
Ordering and Transcribing

Written policies

- What types of medication orders are acceptable
  - PRN
  - Orders for compounded drugs or drug mixtures not commercially available
- Required elements of a complete order
Preparation and Dispensing

Pharmacist review of medication orders in accordance with law and regulation

- Review of allergies, interactions, appropriateness
- Variation from approved indications, dose, frequency and route of administration
Preparing and Dispensing

- Pharmacist preparation or supervision
- Environment – hood, clean room
  - Laminar hood or other ISO Class 5
- Cleaning and maintenance of room and equipment -
- Review of compounding process – direct observation
- Staff technique and competency
- Infection control process throughout
Preparation and Dispensing

- Appropriate labeling
- Dispensing of quantities consistent with need
- Maintains records in accordance with Law and Regulation
- Timely
- Dispensed in form not needing additional admixture or preparation
Administration

- Verification the medication selected matches the order and product label
- Proper time, dose, route
- Inspection for particulates, discoloration, loss of integrity
- Not expired and no contraindications
- Counseling of patient and family
- Policies and competencies for medication administration
Monitoring and Evaluation

Organizational policies and procedures

- Process for identifying, investigating and responding to actual and potential adverse events
- Process for tracking medications from source to patient
- Process for verifying infection control and equipment maintenance for internal compounding sites
- Periodic process observations
Monitoring

- Identifying and Investigating – Must be willing to look
  - Patient counseling
  - Data collection
    - During hospitalization
    - Post-hospitalization
    - Home Care
Evaluation

- Data tracking over time
- Investigation
  - Medication tracking
  - Epidemiological evaluation
  - Observation for breaks in the process
  - Equipment sequestering and testing
- Corrective action
- Reevaluation
Externally Compounded Medications
Contracts for Compounding

- Leaders must still ensure care is provided safely and effectively
  - Describe in writing the nature and scope of contracted services
- Leaders approve contracts
  - Clinical leaders and medical staff have input
Contracts for Compounding

- Leaders monitor contracted services
- Establish expectations
- Must follow law and regulation
- However, must do some verification
  - Potential examples
    - Staff have initial and ongoing training
    - Staff have competency testing
    - Environmental testing is performed
    - Proper storage temperatures
Contracts for Compounding

- Communicate expectations in writing
  - Include provision to see quality reports, logs and verification of training and competency upon request

- Monitor by evaluating compared to expectations
  - Schedule reports from the contractor or periodically request confirmatory information

- Take steps if expectations not met
Special Considerations

Provision of medications in alternate settings
- Clinics
- Ambulatory
- Physician offices

Home care pharmacies may provide medications to the above and also to a hospital