PHARMACY COMPOUNDING 2013!

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OUTLINE

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II. Standards, regulations and laws
III. Noncompliance and examples of infractions
IV. The Fallout (Congress, State Boards, Agencies)
V. Importance of quality standards
VI. What are acceptable limitations?
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I. INTRODUCTION

COMPOUNDING

The preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device or device in accordance with a licensed practitioner’s prescription, medication order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice.

COMPOUNDING

- Any manipulation of a drug or drug product outside its official labeling.
- Compounding differs from manufacturing in the presence of the patient/physician/pharmacist relationship.
CATEGORIES OF COMPOUNDING

- Nonsterile
  - Simple
  - Moderate
  - Complex
- Sterile
  - Low-Risk
  - Medium-Risk
  - High-Risk

EXTENT OF COMPOUNDING IN THE U.S.

- More than 70% of pharmacies report they do some compounding (NCPA, 2006)
- Virtually all hospitals do compounding
- Estimated 10% of all prescriptions and medication orders are compounded
- $22-25 billion dollars per year

HISTORY OF PHARMACY COMPOUNDING IN THE U.S.

- In the past, compounding was pharmacy
- 1900s gave way to commercially prepared pharmaceuticals
- Many strengths/dosage forms available
- Economics changed all that
- Limited strengths/dosage forms
- "One Size Fits All" approach
REASONS FOR THE GROWTH OF PHARMACY COMPOUNDING

- Limited dosage forms
- Limited strengths
- Home health care
- Hospice
- Nonavailable drug products/combinations
  - Discontinued Drugs
  - Drug Shortages*
- Orphan drugs
- Veterinary compounding
- New therapeutic approaches
- Special Patient Populations

SPECIAL PATIENT POPULATIONS

- Pediatrics
- Geriatrics
- Bioidentical Hormone Replacement Therapy
- Pain Management
- Dental Patients
- Environmentally & Cosmetic Sensitive
- Sports Injuries
- Veterinary Compounding
- Small, Large, Herd, Exotic, Companion

HOW DID WE GET HERE-2013?

- Loss of manufactured drug products
- Growth of compounding
- Office use
- Drug shortages
- Other
II. STANDARDS, REGULATIONS AND LAWS

GMPS, GCPS, STANDARDS AND REGULATORY ISSUES

- Good Manufacturing Practices (GMPs)
- Good Compounding Practices (GCPs)
- USP Standards
- State Boards of Pharmacy
  - Laws
  - Regulations
  - Congressional Activities

GOOD MANUFACTURING PRACTICES

- Established by FDA
- 1963 Kefauver-Harris Drug Amendments with periodic updates
- Establish requirements for all aspects of pharmaceutical manufacture
- Apply to domestic and foreign suppliers and manufacturers whose bulk components and finished pharmaceutical products are imported, distributed, or sold in this country
- Includes pharmaceuticals, biologicals and devices
GOOD COMPOUNDING PRACTICES

Now incorporated into:

- <795> and <797>
- Input also provided by other chapters

USP STANDARDS

- <795> Pharmaceutical Compounding-Nonsterile
- <797> Pharmaceutical Compounding-Sterile
- <1160> Pharmaceutical Calculations
- <1163> Quality Assurance

Application of the following:

- <51> Antimicrobial Effectiveness Testing
- <71> Sterility Tests
- <85> Bacterial Endotoxins Test
- Others

STATE BOARDS OF PHARMACY

- Laws
- Regulations
- Rapid response issues
- Budget
  - Personnel
  - Inspectors
  - Training
  - Other
III. NONCOMPLIANCE AND EXAMPLES OF INFRACTIONS AT VARIOUS COMPOUNDING PHARMACIES

EXAMPLE INFRACTIONS-1
- Not patient-specific
- No patient-histories, DURs, as req’d by boards
- Distribution prior to receiving sterility testing lots
- Final sterilization did not follow proper standards
- Autoclaves not validated
- Powder hoods in clean rooms?

EXAMPLE INFRACTIONS-2
- Tacky mats visibly soiled
- Leaking boiler adjacent to the clean room.
- Lack of Standard Operating Procedures
- Lack of training of pharmacists
- Lack of training of technicians
- Pharmacists oversight inadequate
UNDERLYING CAUSE(S)?

- Greed
- Ego
- Lack of education (ignorance)
- Not paying attention
- Others
- Criminal Actions?

IV. THE FALLOUT (CONGRESS, STATE BOARDS, AGENCIES)

STATE BOARDS OF PHARMACY CONSIDERATIONS

- In-State
  - Individual Prescriptions
  - Office Use
- Out-of-State
  - Individual Rx only
  - Separate License Required for Sterile Compounding
  - Other
CONGRESSIONAL ACTIVITIES
- Markey Bill
  - Verifying Authority and Legality in Drug Compounding Act of 2012
- DeLauro and Lowery
  - Supporting Access to Formulated and Effective (SAFE) Compounded Drugs Act
- Senate H.E.L.P. Committee
  - Intermediate category
    - Interstate shipment
    - Anticipatory
    - High risk
  - Others

KEY POINTS
- GMPs vs GCPs
- Application of USP Chapters
- State Boards of Pharmacy Responsibilities
- Congressional Activities
- Federal Considerations

QUESTION
- What factors are involved in distinguishing the following:
  - Pharmacy Compounding
  - Pharmaceutical Manufacturing
MANUFACTURING

- The USP defines "manufacturing" as "The production, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction of the drug from substances of natural origin or by means of chemical or biological synthesis.”

PHARMACEUTICAL MANUFACTURER

- A pharmaceutical manufacturer is an entity that produces a drug or drug product for human or veterinary use that:
  - Has been approved by the FDA through the NDA, ANDA or other appropriate regulatory channel, or
  - Is allowed by the FDA to produce a product that is not FDA approved, as in the case of pre-1938 drugs, veterinary, and over-the-counter drugs, etc.
- A pharmaceutical manufacturer is registered with and regulated by the FDA.

PHARMACEUTICAL COMPOUNDER

- A pharmaceutical compounder is involved in other activities concerned with the preparation of drugs as previously defined and is regulated by the individual state boards of pharmacy.
- FDA-Compounding involves a physician-patient-pharmacist relationship for each prescription.
FEDERAL CONSIDERATIONS

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<td>Third category</td>
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V. IMPORTANCE OF QUALITY STANDARDS

-DO IT RIGHT!

QUALITY STANDARDS

- Documentation
- Standard Operating Procedures
- Analytical Testing
- Uniform, Tested Formulas
- Accreditation
- Certification
ANALYTICAL TESTING

- How much is enough
- Types of testing
  - Physical
  - Chemical
  - Microbiological
- Outsourced
- In-house

NEW TECHNOLOGY

- Bar Coding
- Electronic Balance/Bar Coding
- Quality Control/Quality Assurance
- Sterility Test Kits
- Endotoxin Test Kits

VI. WHAT ARE ACCEPTABLE LIMITATIONS?
ACCEPTABLE LIMITATIONS

• Must understand ALL the details of ALL the procedures done in the compounding area (nonsterile and sterile)
• Decide on appropriate “action limits” for ALL aspects of your operation
• Have SOPs implemented to cover the above as well as the required responses when action limits are exceeded
• Zero-Tolerance
  • Sterility
  • Endotoxin levels
  • USP Allowance of +/-10%

VII. QUALITY AND PATIENT CARE

• Pharmacists are “patient-centered”
• Pharmacists are “quality-oriented”
• Pharmacists are charged with providing “quality patient care”
VIII. SUMMARY

• Practicing pharmacy correctly is a conscious decision
• Compounding correctly is a conscious decision
• There is no room for cutting corners
• If one is not going to do it right, then DON'T do it!

Thank You