
RHODE ISLAND
DEPARTMENT OF HEALTH

A Modern Day Challenge: Pharmacy Compounding

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Learning Objectives

The Learner Should:

- Identify what constitutes compounding in the State of Rhode Island
- Compare pharmacy compounding, manufacturing and wholesaling
- Analyze minimum standards of practice with respect to environmental monitoring and facility requirements
- Identify common compounding violations

What is Compounding?

Compounding Isn't "*New*"

The Pharmacist by Norman Rockwell

Compounding Defined

R5-19.1-PHAR-1.22

"Shall be the act of combining two (2) or more ingredients as a result of a practitioner's prescription or medication order occurring in the course of professional practice based upon the individual needs of a patient and a relationship between the practitioner, patient, and pharmacist"

More about Compounding

- Act of combining two (2) or more ingredients:
  - Can range from Vasoline & Triamcinolone oint. to intrathecal baclofen pumps
  - Numerous “sub-types” or “specialties”
    - Non-Sterile
    - Sterile
    - Veterinary
    - Fertility
    - Nuclear
- Compounding applies to pharmacists and prescribers

Non-Sterile Compounding

- Oral solutions, Topicals, Suppositories, Reconstituted Medications, etc.
  - "Magic Mouthwash"
  - Metronidazole in Desonide cream
  - Amoxicillin suspension
  - Nitroglycerin supp.
- Still need to maintain a clean and orderly compounding area
- Must be able to produce prescriptions
- Only compound ahead based on anticipated demand

Sterile Compounding

- Three categories
  - High risk
  - Medium risk
  - Low risk
- Cleanliness & Monitoring KEY

R5-19.1-PHAR-19.11(a)

"All CSPs shall be prepared in a manner that maintains sterility and minimizes the introduction of particulate matter"

Compounding Operations

- Remember the definition of compounding and some key aspects:
  - Practitioner's prescription
  - Individual needs of a patient
  - Practitioner/Patient/Pharmacist relationship

  - Boils down to necessity of a patient specific prescription

Case Scenario #1

You are the Pharmacist-In-Charge at Local Drugstore. You receive a call from Dr. Smith who is inquiring about the availability of Vancomycin capsules. Dr. Smith claims that Vancomycin capsules "cost an arm and a leg" but he uses the substance frequently in his office. Dr. Smith asks you if you could make some capsules for him from the powder since "you have a contract with the wholesaler and can get it much cheaper". You proceed to…

Case Scenario #1

A) Compound the capsules since your pharmacy license permits you to compound

B) Inform Dr. Smith that compounding for office use is prohibited in RI

C) Inform Dr. Smith that compounding a commercially available product is prohibited in RI

D) Inform Dr. Smith you can make commercially available products but need a patient name first

E) B&C

Wholesaler/Manufacturer

- When compounds are created without prescriptions, practitioner/patient/pharmacist relationship or based on individual need:

Dispensing becomes Distribution!

- When pharmacists prepare bulk compounds or “office use” items they are functioning no different than a manufacturer….but without the same CGMP

Wholesaler/Manufacturer

- R5-19.1-PHAR-1.68 “Manufacturing”
  - preparation and promotion of commercially available products from bulk compounds for resale by pharmacists, practitioners, or other persons
    - e.g. Local Drugstore compounds amoxicillin capsules for an area dentist for general office use
    - e.g. Local Hospital compounds morphine injection and distributes surplus to physicians renting space on hospital grounds

Case Scenario #2

You are the Pharmacist-In-Charge at Local Hospital and receive word from a practitioner that a lido/benzo/tetracaine topical solution you compounded for an inpatient worked wonderfully and the practitioner indicated she would like to use it on inpatients at an unaffiliated hospital out of state. The Pharmacist-In-Charge of this out of state hospital contacts you and informs you that he spoke with the practitioner and identified an anticipated need of 8 bottles/month. You proceed to….

Case Scenario #2

A) Compound the substance and send it to the out of state hospital since it is non-sterile and non-controlled

B) Compound the substance and dispense it only if it is being received by the Pharmacist-In-Charge at the out of state hospital pharmacy

C) Do not distribute the medication to the other hospital pharmacy

D) Compound the medication once you can prove the “anticipated demand”

Oversight

- Who has oversight in compounding?
  - Federal
    - US FDA, US DEA, etc.
  - State
    - Dept. of Health, BOP, AG office
  - Local
    - Pharmacy Director/Pharmacy Owner
    - Pharmacist In Charge
    - Staff Pharmacist
    - Technician
    - Hospital Risk Management

All parties involved in compounding have “oversight” over others and/or activities occurring in some shape or form

Oversight

- What factors are contributing to compounding issues?
  - Non resident pharmacies
  - Mfg back orders
  - Overhead cost of in-house services
  - Cost of medications
  - Patient Demand

Standards

- Basic standards of practice apply in all compounding scenarios
  - Sterile & Non-Sterile
  - Institutional & Community
  - Simple & Complex compounds

  - RI BOP is stepping up enforcement of compounding regulations
  - Expect an Inspection

Sterile Compounding & Environmental Monitoring

Sterile Compounding

- CSPs must be compounded using a hood (R5-19.1-PHAR-19.21)
- CSPs must be compounded in an area solely designated for such activity, no dual purpose hood/break room (R5-19.1-PHAR-19.20)
- CSPs must only be compounded by adequately trained personnel under the supervision of a pharmacist (R5-19.1-PHAR-19.19)

Environmental Monitoring

- Monitoring (viable organisms) and regularly scheduled testing crucial
  - Risk level will determine monitoring frequency (surface & air monitoring)
    - High Risk – Weekly
    - Medium Risk – Monthly
    - Low Risk – Monthly
  - In addition ISO 5 air quality requirements for hood(s) every 6 months

Consistent testing is a patient safety check in addition to a quality control check

Sterile Compounding Basics

- Active Pharmaceutical Ingredient (API)
  - Just as it's a mfg or wholesaler's responsibility to ensure sterility and quality of API, pharmacy also has responsibility
    - Check license status of any mfg/wholesaler
    - Do not purchase products from resident or non-resident pharmacy
    - Product must be USP, NF certified or accompanied with Certificate of Analysis (R5-19.1-PHAR-19.10)

Case Scenario #3

It is the beginning of 1st shift on Monday morning at Local Hospital where you practice as a pharmacist. BOP inspectors arrive at the pharmacy and announce they need to perform an inspection of your clean room. Your pharmacy prepares medium risk preparations and compounding is conducted by all staff pharmacists and one pharmacy technician since he is licensed as a pharmacy technician II ("CPhT"). What staff training, at minimum, must you provide?

Case Scenario #3

A) Training competencies for the pharmacists which are updated on a biennial basis

B) Training competencies for all staff engaged in medium risk compounding on an semi-annual basis

C) Nothing is necessary. Training competencies are only required for high risk sterile compounding

D) Training competencies for all staff engaged in medium risk compounding on an annual basis

Inspections

- Inspection forms are available to all pharmacists for self inspection purposes
- Rules & Regs are available online at www.sos.ri.gov
- Inspections are comprehensive and involve all aspects of section 19.0

Inspections

- Common issues
  - Distribution v. Dispensing
  - Record keeping x 2 years
  - Environmental monitoring
  - Training of staff
  - Adequate labeling & use of appropriate API

Questions?