Community Pharmacy Inspections

Arkansas State Board of Pharmacy

About the Arkansas Board of Pharmacy

- Autonomous Board
- 8 FTE with 5 being pharmacists
  - Exec. Dir., Asst. Dir., 3 Inspector/Investigators
- The Board tracks over 21 different license configurations / types including pharmacies, wholesaler/manufacturers…
- Approx. 750 retail pharmacies including compounders
  - Inspected annually with about a 14 month maximum turnaround

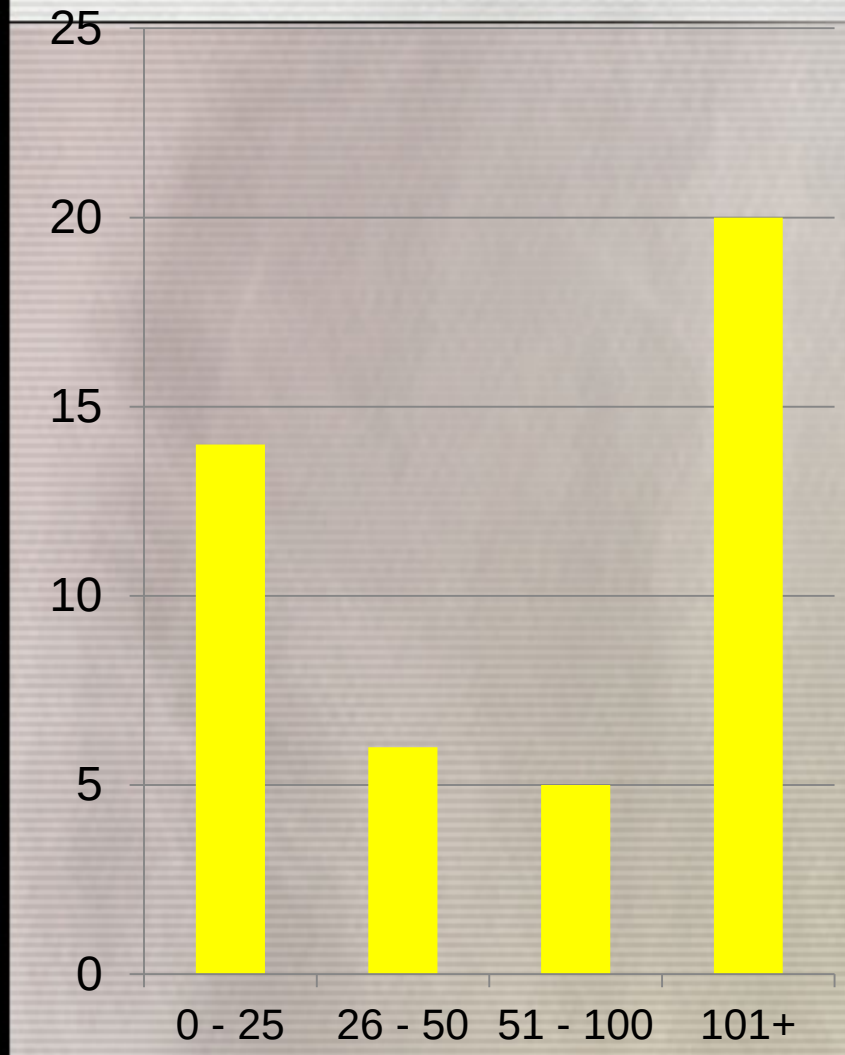
Why Do We See Compounders

- Knee jerk is always money
- Should be for specialized needs
  - Compliance packaging
  - Preservative free preparations when needed
  - Drug Shortages (verified shortages)
- Hospitals need product in most readily usable form

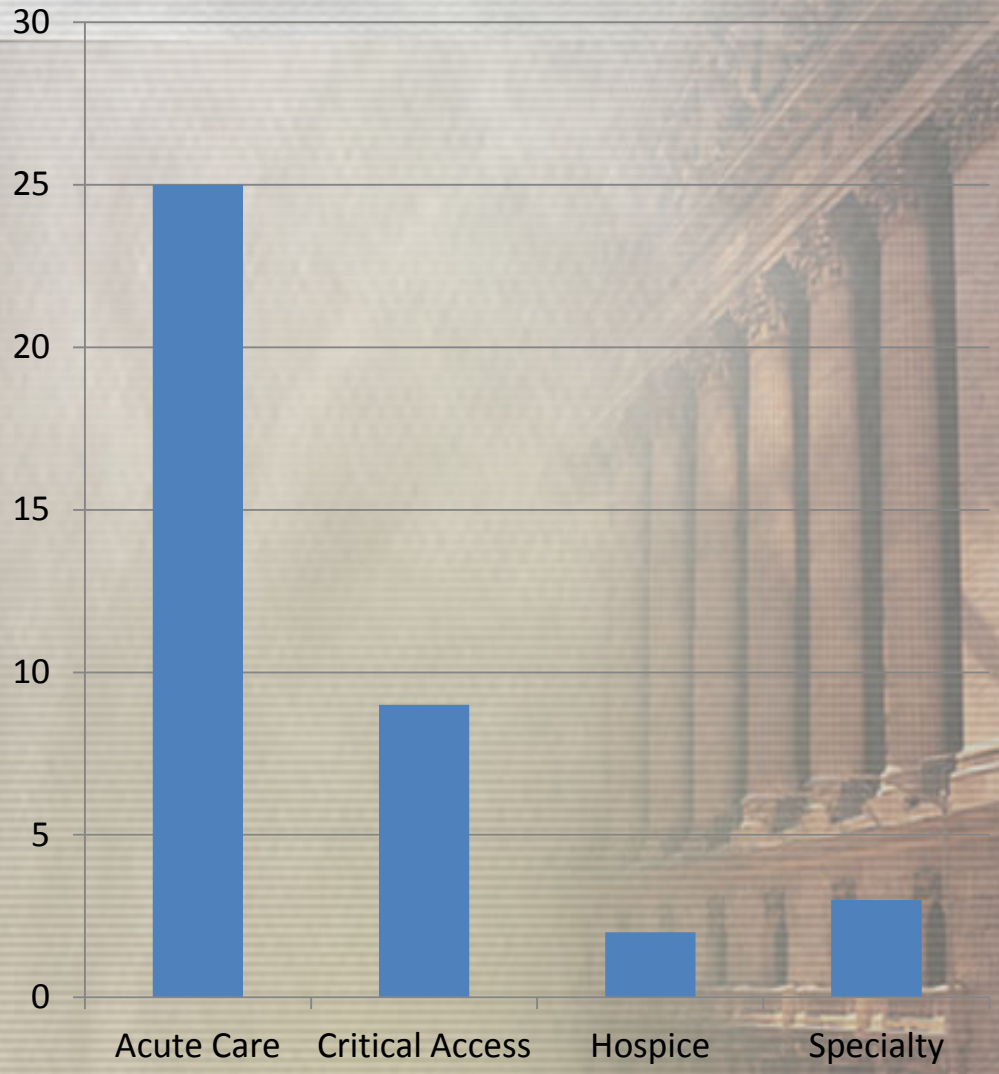
Arkansas Hospital Survey

- Performed to address FDA questions to our Department of Health prior to December 2012 intergovernmental meeting
- 43 responses in a very short turnaround

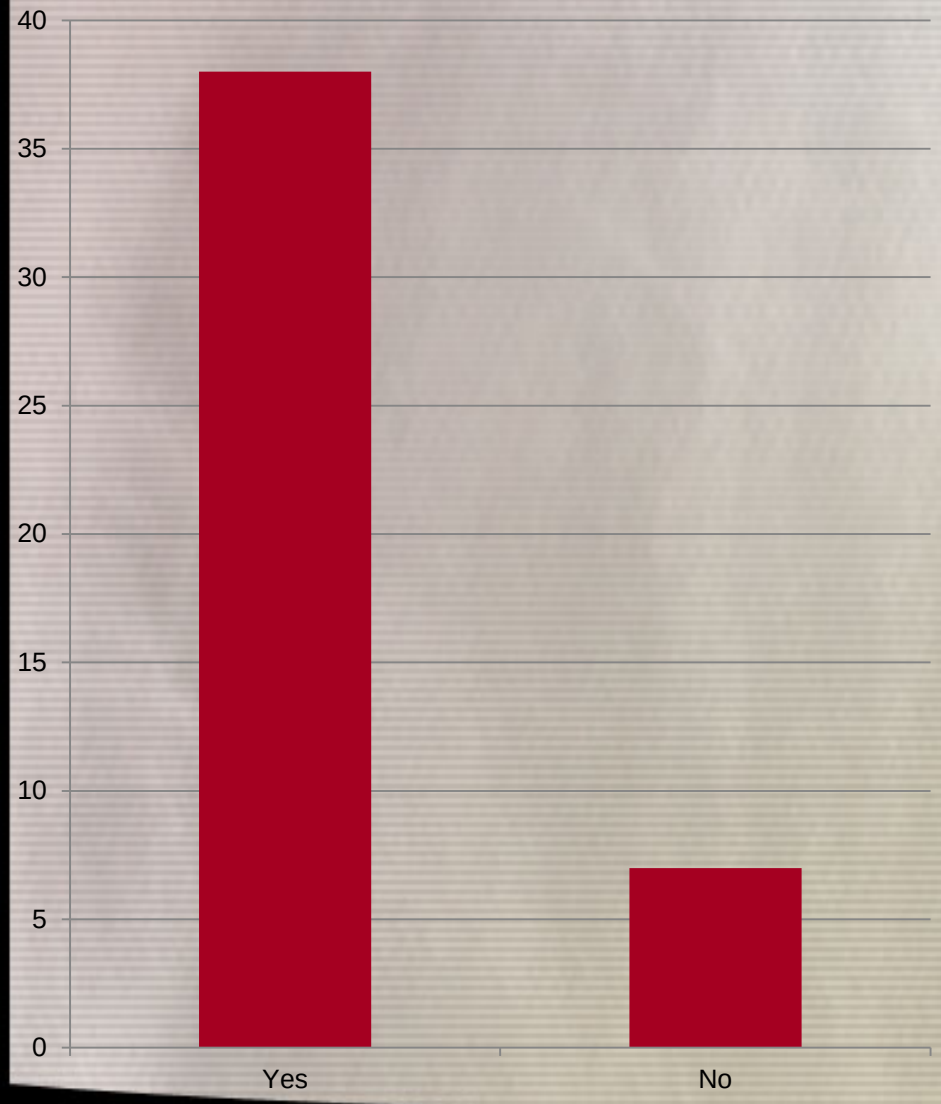
How many beds are you licensed for?



Type of facility:

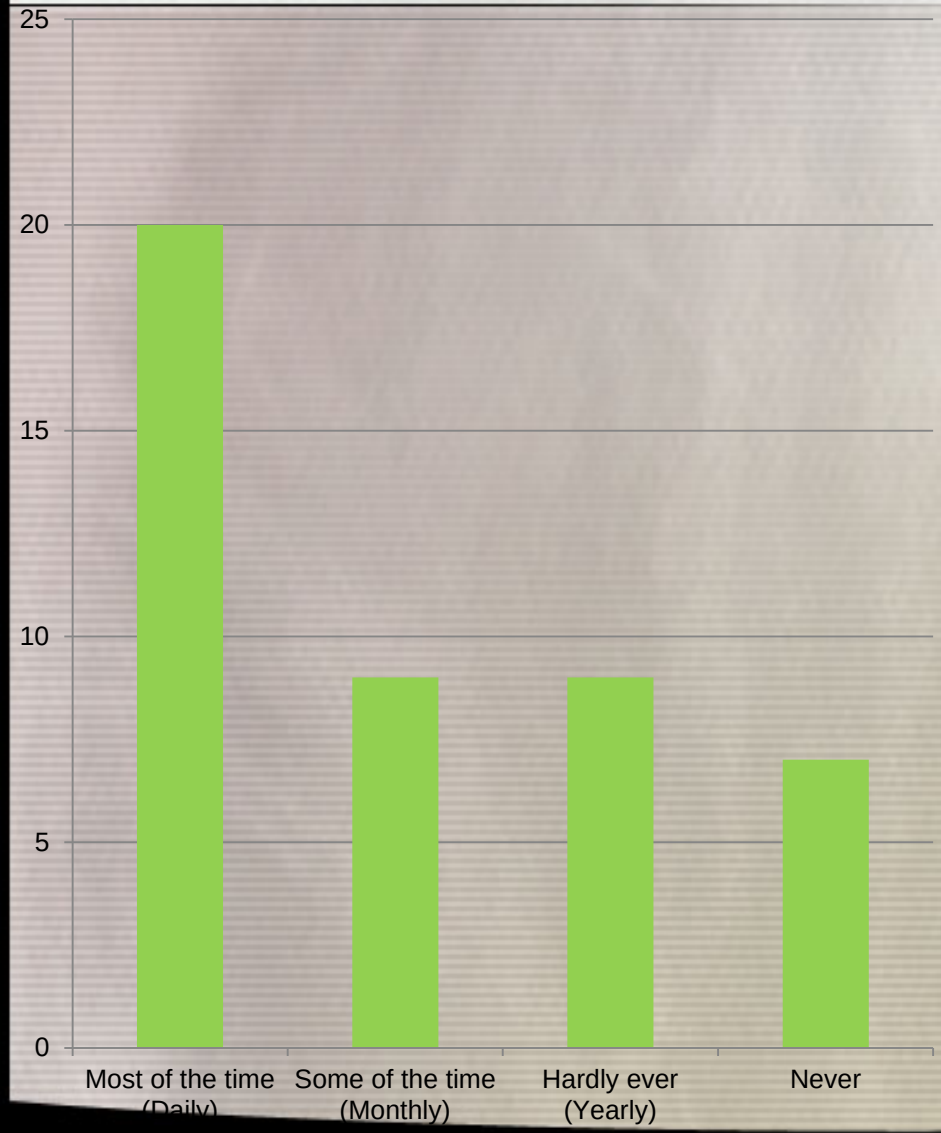


Does your facility utilize compounded products?

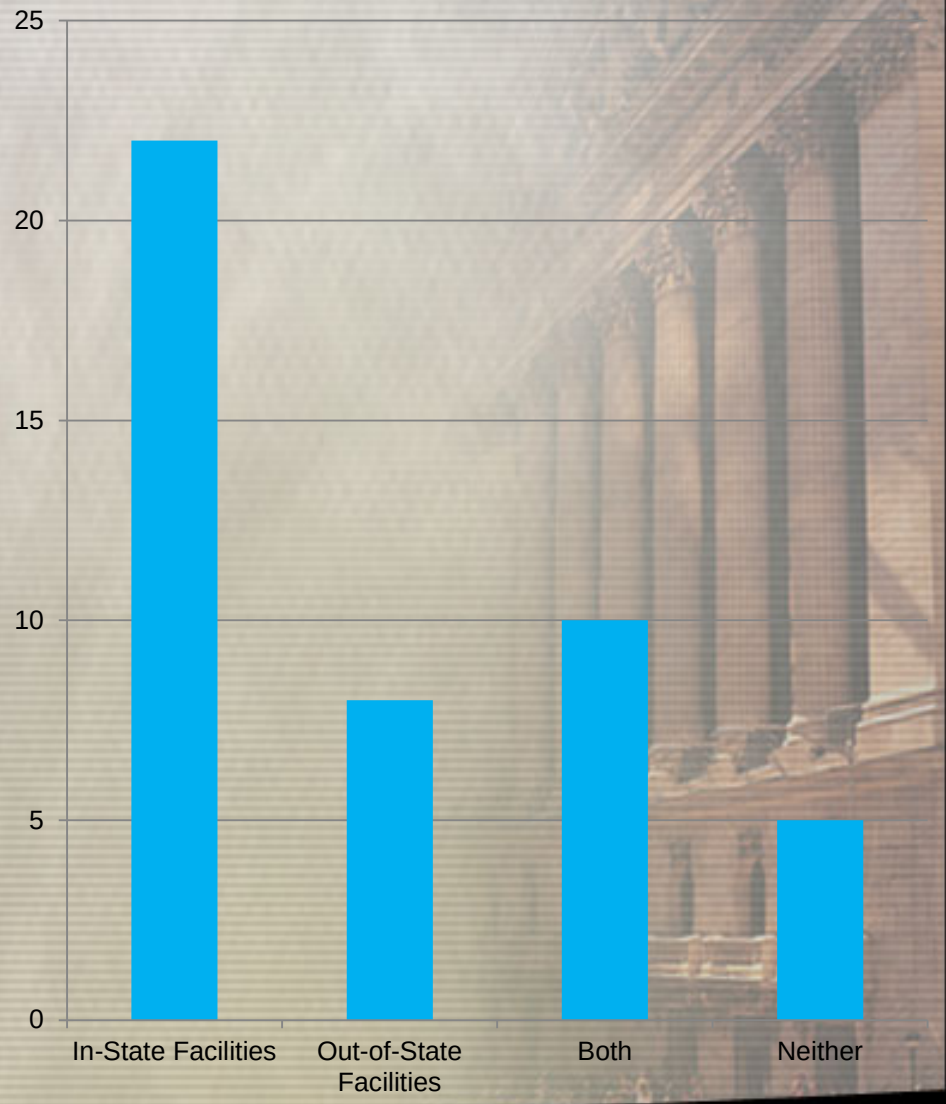


- No Answers
  - 1 Endoscopy Center
  - 3 Behavioral Health
  - 1 Eye Surgery Center
  - 1 Acute Care Facility
  - 1 Critical Access Hospital (now using compounded products for shortages)

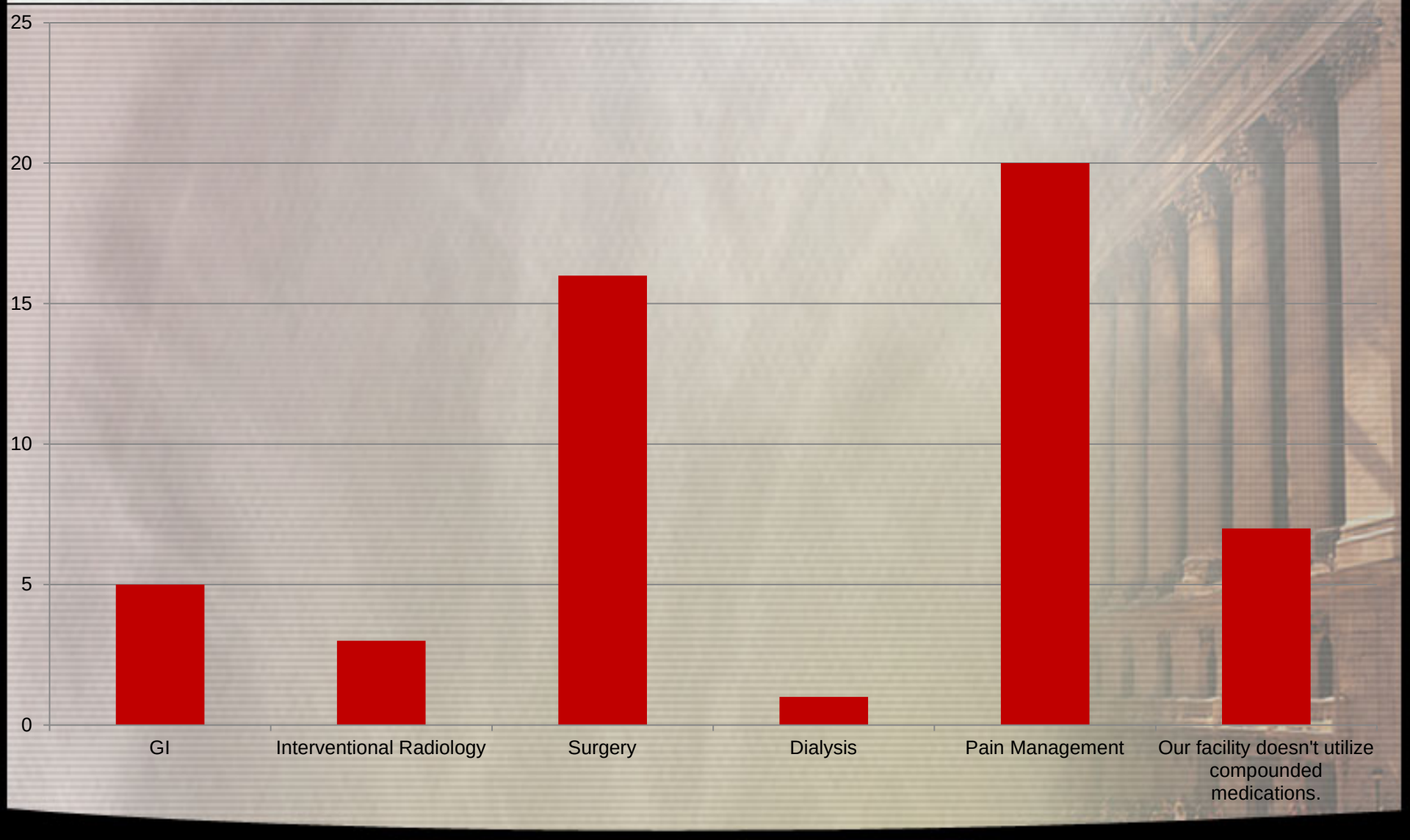
To what extent does your facility utilize products from compounding pharmacies?



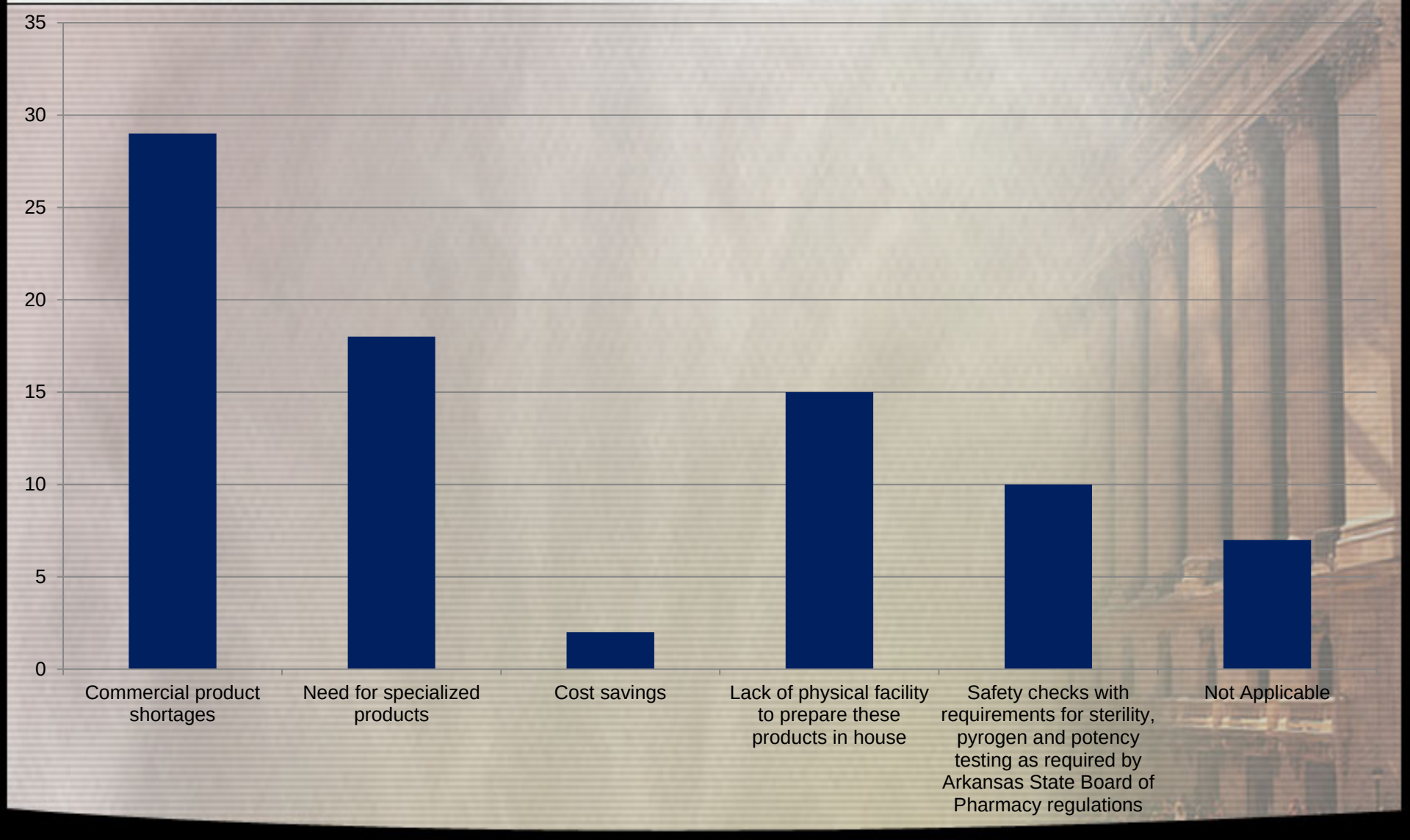
When you do utilize products from compounding pharmacies, where do you get them?



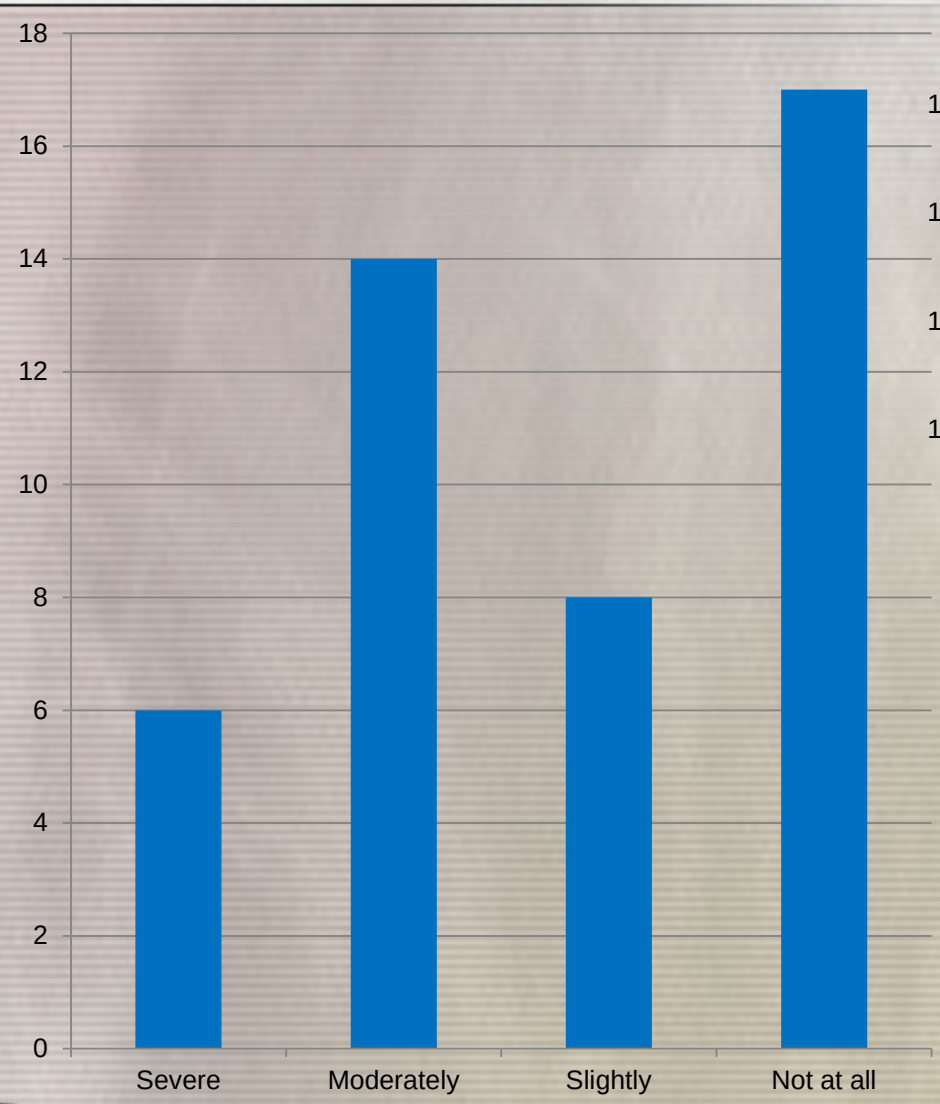
Please select all the areas of your facility that utilize compounded medications: (Select all that apply)



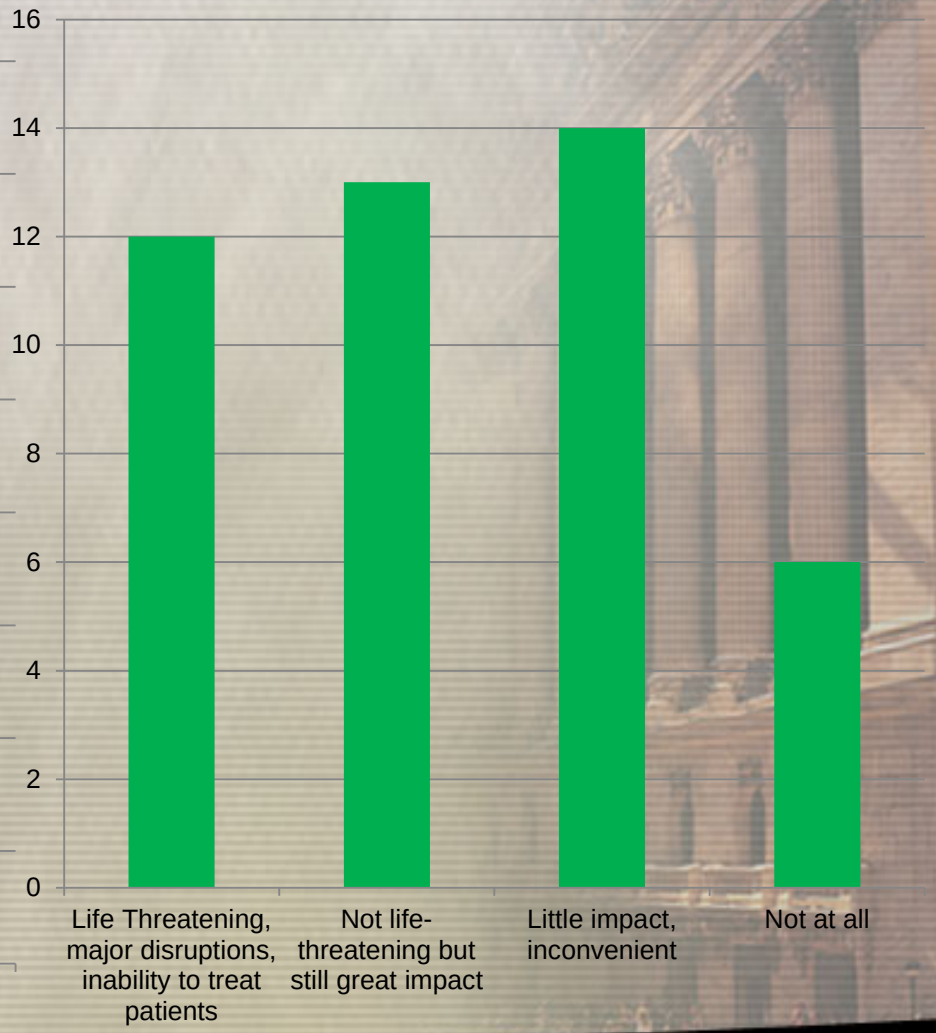
Why do you utilize outsourced compounded medications? (Select all that apply)



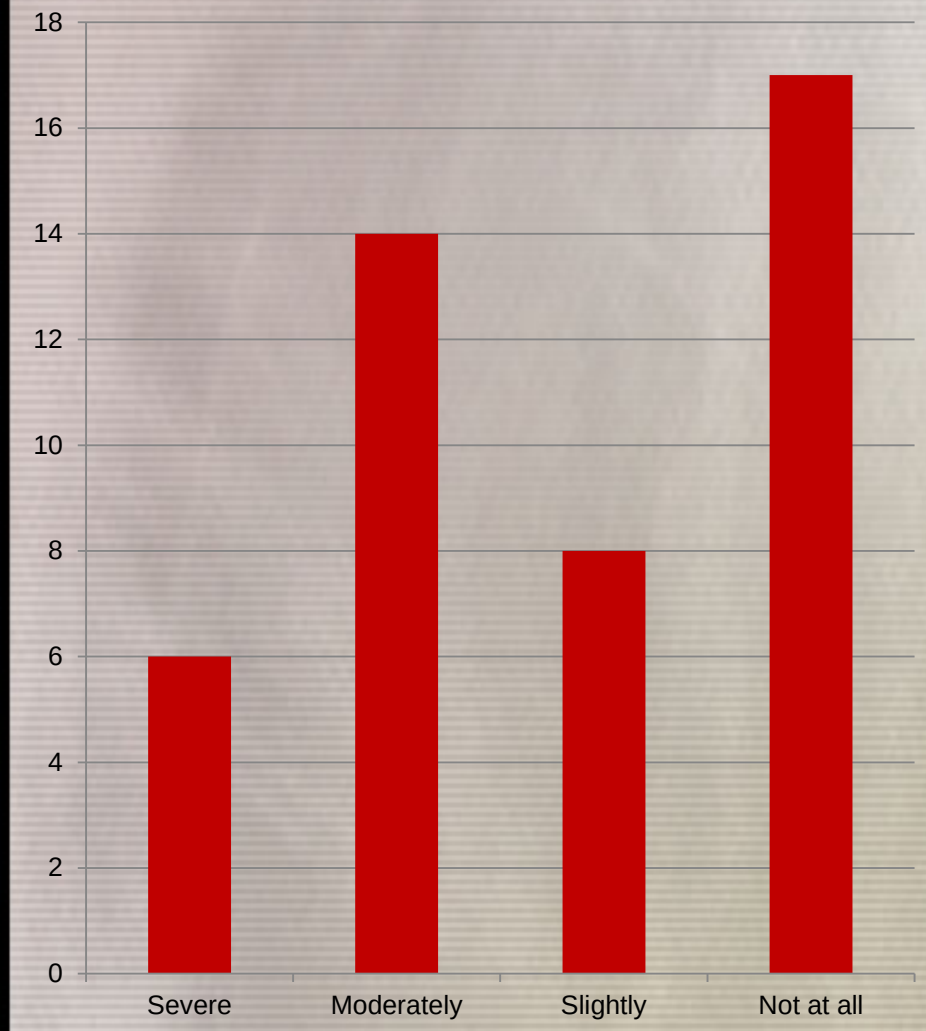
How severe would the finanical impact be to your facility if there were an abrupt loss of supply or shortages from compounding pharmacies?



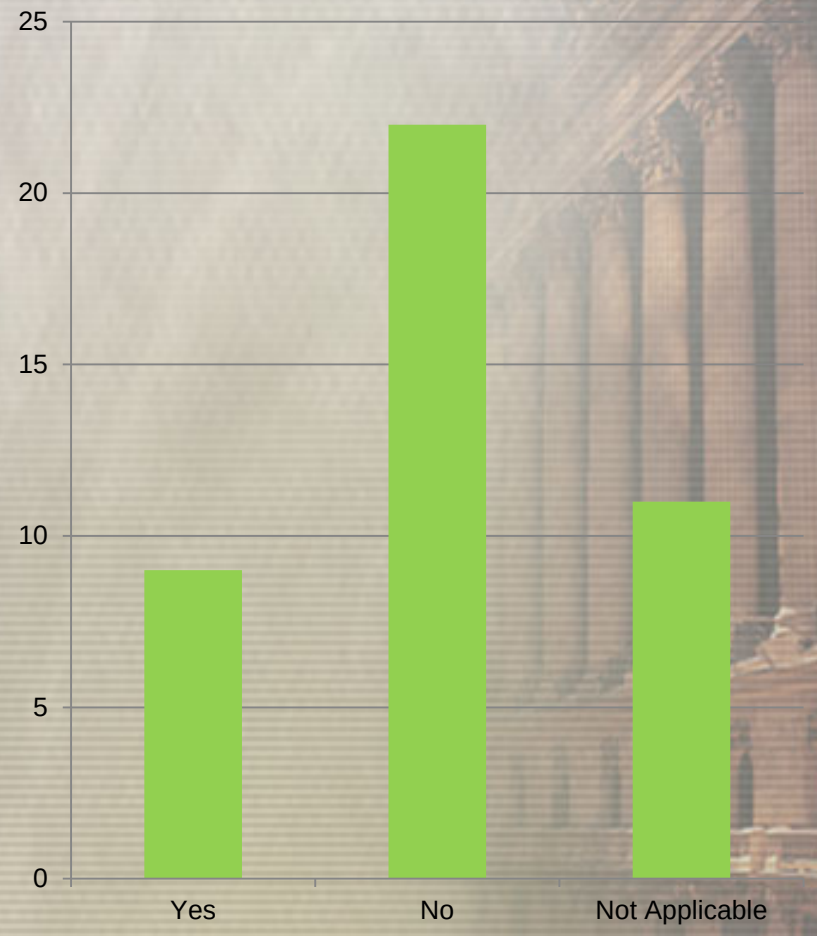
How severe would the disruption of care or risk to patients be if there were an abrupt loss of supply or shortages from compounding pharmacies?



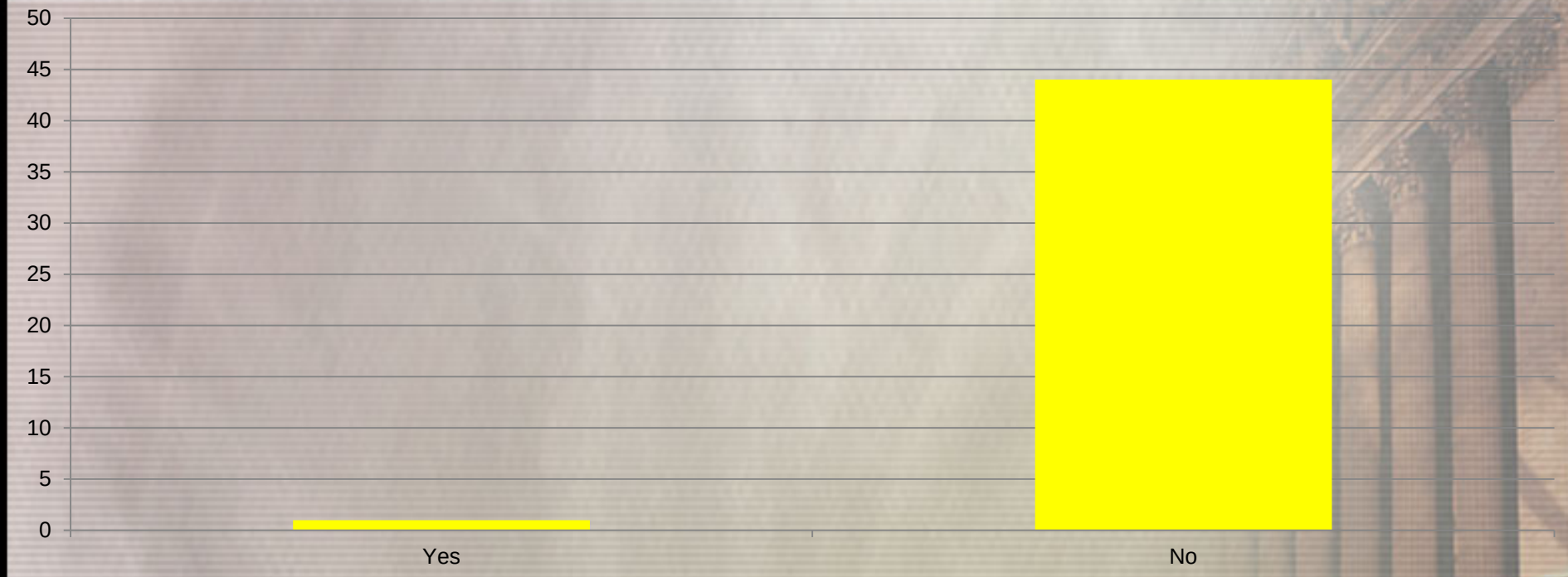
How severe would the finanical impact be to your facility if there were an abrupt loss of supply or shortages from compounding pharmacies?



Are alternative suppliers or preparation methods available for these products that your facility will be able to use if you are not able to obtain products from compounding pharmacies?



Is your facility equipped to prepare sterile injectables from non-sterile bulk ingredients?



- Only 1 answered YES
  - FYI. I answered yes to "Is your facility equipped to prepare etc." because once the renovation of the cleanroom is complete we will be equipped.

Arkansas Regulations

- **07-02-0001—STANDARDS FOR COMPOUNDING AND DISPENSING STERILE PRODUCTS**

- Compounding a drug product that is commercially available in the marketplace or that is essentially a copy of a commercially available FDA-approved drug product is generally prohibited. However, in special circumstances a pharmacist may compound an appropriate quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available based on documentation provided by the prescribing physician of a patient specific medical need (e.g. the physician requests an alternate product due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available. The unavailability of such drug product must be documented prior to compounding. The recommended methodology for documenting unavailability is to print the screen of wholesalers showing back-ordered, discontinued, or out-of-stock items. This or similar documentation must be available when requested by the Board.

- Except for those products where stability prohibits advanced compounding, all products dispensed by the pharmacy shall be in a form ready for administration, except in health care facilities where medications may be provided as demanded by policies and procedures.

Pharmacist Requirements:

Any pharmacist in charge who performs or supervises the preparation or sterilization of sterile medications shall:

1) Have available written policies and procedures for all steps in the compounding of sterile preparations. In addition, said policies and procedures shall address personnel education and training and evaluation, storage and handling, clothing, personal hygiene, hand washing, aseptic technique, quality assurance, expiration dating, and other procedures as needed.
2) Certify that all participating pharmacists and pharmacy technicians have completed a Board approved training and testing program in sterile product preparation. Documentation of training and testing shall be available for review, by February 30, 2002.
3) Develop policies and procedures to annually test and review the techniques of participating pharmacists and pharmacy technicians to assure adherence to aseptic procedures.

Sterile products compounded under any of the following conditions are considered high-risk sterile products:

(A) Nonsterile ingredients are incorporated, or a nonsterile device is employed before terminal sterilization

(B) Sterile ingredients, components, devices, and mixtures are exposed to air quality inferior to a Class 100 environment. This includes storage in environments inferior to a Class 100 environment of opened or partially used packages of manufactured sterile products that lack antimicrobial preservatives.

(C) Nonsterile preparations are exposed no more than 6 hours before being sterilized.

(D) It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients.

(E) For a high-risk preparation, in the absence of passing a sterility test, the storage periods shall not exceed the following time periods: before administration, the sterile products are exposed for no more than twenty-four (24) hours at controlled room temperature, three (3) days at two (2) to eight (8) degrees centigrade, and forty-five (45) days in solid frozen state at negative twenty (–20) degrees centigrade or colder, while properly stored.

Required Testing

- All high-risk level compounded sterile products for administration by injection into the vascular and central nervous systems that are prepared in groups of more than twenty-five (25) identical individual single-dose packages (such as ampules, bags, syringes, and vials), or in multiple dose vials for administration to multiple patients, or are exposed longer than twelve (12) hours at a two (2) to eight (8) degrees centigrade and longer than six (6) hours at warmer than eight (8) degrees centigrade before they are sterilized shall be tested to ensure they are sterile, do not contain excessive bacterial endotoxins, and are of labeled potency before they are dispensed or administered as provided below.
- Sterility Testing (Bacterial and Fungal) – …The pharmacist in charge shall establish written procedures requiring daily observation of the media and requiring an immediate recall if there is any evidence of microbial growth and said procedures must be available to Board inspectors.
- Bacterial Endotoxin (Pyrogen) Testing – The USP Bacterial Endotoxin Test, or verified equivalent, shall be used to ensure compounded sterile products do not contain excessive endotoxins.
- Potency Testing – The potency of all compounded products meeting the criteria described in Board regulation 07-02-0001 (j) (5) above must be tested to verify the potency stated on the label.

Real-time Analyzer ScanRDI

- From Sampling to result within minutes
- Sensitivity down to **one microbial cell in a sample**
- Sensitivity independent from the volume filtered (large volumes can be tested)
- No cell multiplication required
- Direct detection of bacteria, yeast, molds & spores
- Direct cell count removes the need for operator calibration and interpretation
- Linear response from 1 to 105 cells for bacteria and 1 to 104 for yeast & molds
- Non-destructive test protocol permits microscopic confirmation
- Robust and easy to use
- 21 CFR 11 compliant
- Full traceability
- Accuracy: labels all viable microorganisms (bacteria, bacteria spores, yeasts, moulds, moulds spores)
- Ideal for pharmaceutical MICROBIOLOGY
- Applications: process water control, non-sterile products, environmental control, cryptosporidium giardia, etc.

taken from: http://www.aeschemunex.com/microbial-testing-solutions-for-all-labs,6/33,scan-rdi-analyzer.html

Prescriber Office Use?

(l) Compounding for a prescriber's office use:

(1) Pharmacies may prepare compounded drug products for a duly authorized prescriber's office use.

(2) An order by the duly authorized prescriber, indicating the formula and quantity ordered, will be filed in the pharmacy.

(3) The product is to be administered in the office and not dispensed to the patient. The product shall be labeled "For Office Use Only—Not for Resale".

(4) A record of the compounded drug product may be kept as a prescription record in the pharmacy computer.

(5) A label may be generated and a number assigned by the pharmacy computer for the compounded drug product.

(6) Patient specific prescriptions for controlled substances cannot be filled "for office or medical bag use".

(7) A retail pharmacy is not precluded from making more that five percent (5%) of its annual sales to licensed practitioners. The pharmacy must, however, obtain a State Wholesale Legend Drug and/or Controlled Substance Distributor Permit.

Inspections and Oversight

- Must address the actual practice of any pharmacy
- Our Compounding pharmacies usually include traditional retail practice as well
  - Retail inspection
  - Parenteral Product Inspection or Compounding Inspection

ARKANSAS STATE BOARD OF PHARMACY
INSPECTION REPORT

Date _____

PHARMACY NAME _____ PERMIT # _____

ADDRESS _____ CITY _____ ZIP _____

D.E.A. # _____ AVERAGE # RX'S PER DAY: _____

LICENSED PHARMACISTS	LICENSE #	ARE INTERNS EMPLOYED? [ ] YES [ ] NO	
PIC _____	_____	INTERNS	PERMIT #
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Number of Technicians _____

TYPE OF PHARMACY
(Check all that apply):
INDEPENDENT [ ] CHAIN [ ] LEASED DEPT [ ]
SPECIALTY (Describe) _____

Staffing at time of inspection:
Pharmacists _____ **Technicians** _____
Clerks _____ **Interns** _____

PHARMACY HOURS: Mon. through Fri. _____

Sat. _____ Sun. _____

REQUIREMENTS:

KEY: [C] Compliant [NC] Non-Compliant

General Condition/Appearance of Rx Dept./Pharmacy:

- All control & legend drugs in date & labeled, all out-of-dates isolated [ ]
- Sink clean/accessible---Hot & cold running water ____ Distilled water _____ [ ]
- Refrigerator-Biologicals & drugs organized & in date [ ]
- Work area adequate and clean [ ]
- Proper drug security while open [ ]
- Adequate space and lighting [ ]
- Compounding pharmacy with compounding area [ ]
- Hood present, expiration date _____ [ ]
- Attractive over-all store appearance [ ]

Pharmacy Services:

- Pharmacist available for after hour emergencies. If not, notice is displayed. [ ]
- Patient prescription profiles available. [ ]
- Compliant in counseling, Reg. 09-00-0001. [ ]
- Proper use of Safety Caps. [ ]

Controlled Substances:

- Proper D.E.A. inventory available dated _____ & signed [ ]
- All C-II wholesale invoices and order forms properly filed and available [ ]
- Proper information on C-II-V Rx records, signature, date & patient address [ ]
- Exempt C-V sales recorded and in compliance with regulations [ ]
- Emergency C-II prescriptions properly processed [ ]
- Sales of controlled drugs to other practitioners properly recorded [ ]
- Proper inventory & handling of out-dated D.E.A. controlled drugs [ ]
- Combat Methamphetamine Certificate current & displayed [ ]

Recordkeeping/Documentation:

- Adverse events statement & FDA telephone number [ ]
- Records readily retrievable and maintained for minimum of two years [ ]
- Written policies & procedures for technician data entry [ ]
- Law Book & required reference material available [ ]
- Pharmacist/technician/intern permits current & conspicuously displayed [ ]
- Immunization certification current [ ]
- Immunization protocol current and available for review [ ]
- CPR Certification current for applicable personnel [ ]
- Daily Log or Bound Log Book signed [ ]

YOU ARE DIRECTED TO TAKE PROMPT ACTION TO CORRECT ANY DEFICIENCIES WHICH HAVE BEEN NOTED.

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Pharmacies with no more than three (3) non-compliant deficiencies on the last inspection by the Board of Pharmacy will be designated as suitable for Intern training. Any Pharmacy non-compliant for two (2) inspections in succession may be called before the Board to show cause why the permit should not be revoked or refused.

Class A Pharmacy Y [ ] N [ ]

Remarks:

_____

_____

_____

_____

_____

_____

_____

FLAGGED FOR REINSPECTION IN APPROXIMATELY 90 DAYS DUE TO DEFICIENCIES [ ]

Pharmacist on Duty_____

Inspector_____

Common Discrepancies

- Controlled Substance Inventories
- CMEA Certificates
- Policies and Procedures
- Signage for After Hours Service
- Immunization Protocols
- Daily Log

Compounding Inspection Form

Pharmacy Name: _____ Date of Inspection: _____
License Number: _____

Products Compounded:

_____Capsules _____Topical Products _____TPN
_____Tablets _____ Injectables _____ Pain Medication
_____ Chemotherapy _____ Inhalation Products _____ Intrathecals
_____ Sterile Compounds from Bulk Product _____ Epidurals
_____ Commercially Available Products (If yes, documentation of unavailability or prescriber request ____)
If Sterile Products, type:
____low-risk ____ medium-risk ____ high-risk

Policies and Procedures available for:

____Sterile Product Compounding ____ Drug Product Compounding
_____ Annual Testing of Personnel Techniques ____Shipping
_____ Procedures for Sterility, Pyrogen, and Potency Testing (_____ Lab Used)
Is Product Released before Results are obtained? _____
____Procedures for Technician Training (ASHP Guidelines or equivalent)

Records

_____ Adequate Records of Compounded Products Maintained (Formulas, Lot/Batch, etc.)

Work Area and Equipment [Compliant (C) / Non-Compliant (NC) / Not-Applicable (NA)]

_____ Anteroom _____ Clean Room (Class _____ Environment)
_____ Laminar Flow Hood (Class _____ Environment) ____ Number of Hoods
_____ Barrier Isolator (Class _____ Environment)
_____ Chemo Hood (___ Vented to Outdoors)
_____ Daily Cleaning Procedures _____ Controlled Temperature and Humidity
_____ Adequate Space _____ Hot and Cold Water
_____ Refrigerator (___ Temp Log) _____ Freezer (___ Temp Log)

Labeling of Compounded Products [C / NC/ NA]

_____ Batch or Lot Number _____Expiration Date _____ Strength / Concentration
_____ Product Name _____ Weight or Measure _____ Route of Administration
_____ Designation of Compounded Prescription on Prescription Label

Compounding for Prescriber's Office Use (Yes / No)

_____ Office Stock Compounding _____ Invoice / Order on File indicating formula and quantity
_____ Product labeled "For Office Use Only – Not for Resale"
_____ More than 5% of Annual Sales (If yes, AR Wholesale Permit Number _____)
_____ Controlled Substances Schedule III-V
_____ Controlled Substances Schedule II (If yes, DEA Form 222 available _____)

Compounding for Veterinarians (Yes / No)

_____ Compound from Bulk Product
_____ Compound for Office Stock If yes, documentation of need _____

Out of State Compounding?

1. What products do you compound? / Do you compound from bulk?
2. Are you in compliance with Arkansas Laws and Regulations regarding compounding as well as USP 797 guidelines? Sterility, Pyrogen, Potency Testing? (Potency testing is required for Arkansas see Regulation 07-02 Compounding)
3. Do you handle any pain medications? (Intrathecals, Schedule 2's) If so, then what? How are they shipped (to patient, prescriber, other third party)?
4. Do you duplicate any commercially available products? Read Regulation 07-02
5. Do you compound any Veterinary Products?
6. Does this pharmacy compound for office stock? (For Physicians, For Veterinarians) If so, then what products?
7. Does the pharmacy receive payment from the prescriber for any product sent directly to a patient or caregiver? (This would include a shared account where the patient pays the prescriber and the pharmacy receives payment from the prescriber for medication.)
8. Does the pharmacy give any type of remuneration to the prescriber for referring patients or filling prescriptions sent by the prescriber?
9. Does the pharmacy allow prescribers to have a link to the pharmacy website on the prescriber's webpage?

What’s on the rise?

- March 18, 2014
- Huge rise in Non-sterile compounding with hardly any sterile compounders reciprocating
- Huge return on investment for ‘safer non-sterile’ compounding
- Huge percentage of our reciprocity
- Drug sampling? Unmarked containers of ketamine compounds

Staff Training and Education

- All of our inspectors are licensed pharmacists with varying experience
- 795/797 training for product preparation and testing
- Training for physical facility compliance
- Review of current standards with other state agencies and accrediting bodies
- NABP training

FDA Partnerships?

- Many Boards of Pharmacy have the people to do the job
- FDA and Boards of Pharmacy could partner to perform advanced pharmacy compounding inspections – Retail vs. CGMP?
- FDA training for appropriate guidelines
- Agree upon testing criteria for batched products

LOOKING FORWARD

- We need to standardize minimum criteria for pharmacy inspections and oversight activities
- We need to define the ability for pharmacies to fulfill needs for hospitals, clinics, prescribers and patients
- We need better transparency and partnerships with FDA with information sharing
- We need better opportunities for training

Joint Permits?

- Pharmacy permit – home state
- Wholesale Distributor – if over %
- Outsourcing FDA or some other FDA Permit
  - What does it mean
  - What does it do or allow you to do
  - How do we co-manage it
- We need to agree on standards of oversight – Board, Third party or FDA?

Questions?

John Clay Kirtley, Pharm.D.

Arkansas State Board of Pharmacy

pharmacyboard.arkansas.gov

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