

Putting the Pieces Together – Interpreting the Rules Pharmacy Law 2021

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Advancing Pharmacy for a Healthier Alabama

Conflicts of Interest

I have no potential conflicts of interest related to this program

Objectives (Technician)

Review Alabama pharmacy law with regards to technician responsibilities

Identify common pitfalls and mistakes technicians make in regard to pharmacy law

Discuss case studies involving the violations of the pharmacy practice act

Objectives (Pharmacist)

Review Alabama pharmacy law with regards to supervisor pharmacist responsibilities

Explain common mistakes pharmacists may make in regard to Alabama pharmacy law

Identify violations of the pharmacy practice act by reviewing case studies

Alabama State Board of Pharmacy (ALBOP)

Duty is to carry out the purpose and enforce Title 34, Chapter 23 of the Practice of Pharmacy Act 205 and Title 20, Chapter 2 of the Uniformed Controlled Substance Act of 1407

Primary purpose is to protect the public health, safety, and welfare of the people of Alabama

ALBOP does NOT determine the Controlled Substance List in the State of AL (This is done by Dept of Health).

ALBOP

Three governor-appointed positions

One independent pharmacy (Chris Phung)

One chain pharmacy (Christy Garmon)

One institutional (Brenda Denson)

Two at large positions (Voted upon by pharmacists within the state)

Rob Colburn and Gary Mount



ALBOP 2021

Bottom: Gary, Chris, Rob

Top: Brenda, Donna, Christy

Assessment #1

What is the purpose of the Board of Pharmacy?

- A. To promote professional organizations
- B. To enhance pharmacy practice so pharmacists and businesses can profit
- C. To protect the citizens of Alabama
- D. All of the Above

Supervising pharmacist

Rule 680-X-2-.12

Every Pharmacy is under the direct supervision and control of a Registered Pharmacist who is designated the supervising pharmacist.

A supervising pharmacist is on duty 30 hours per week or 50% of the hours a pharmacy is open, whichever is less.

The Board of Pharmacy should be notified within 10 days of a new pharmacist assuming the duties of supervising pharmacist. (This is done by completing a “Notice of Change of Supervising Pharmacist” online form on the ALBOP website).

A new supervising pharmacist is required to take an inventory of all controlled substances within 15 days.

Supervising pharmacist Responsibilities

Supervising of personnel in the prescription department to include ensuring that all licenses and registrations of pharmacists and technicians working in the pharmacy are current and in good standing with the Board.

Maintenance of accurate records of all prescription medication received and dispensed.

Maintaining the security of the prescription department and its contents.

Ensuring only registered pharmacists provide professional consultation with physicians or patients.

Ensuring that only registered pharmacists accept telephone prescriptions.

Supervising pharmacist Responsibilities

Operating the prescription department in a clean and orderly manner.

Maintenance of inspection records provided by the Board.

When discrepancies are noted in the inspection records, the supervising pharmacist has 15 days to submit (in writing) actions or steps to eliminate the discrepancy.

Ensuring that the pharmacy is operated with good pharmaceutical practices.

Ensuring compliance with the Pharmacy Practice Act, Rules of the Alabama State Board of Pharmacy, and the Controlled Substances Act.

Assessment Question #2

The supervising pharmacist is responsible for which of the following?

- A. The pharmacists that work in the pharmacy that they supervise
- B. The technicians that work in the pharmacy that they supervise
- C. The controlled substance inventory for the pharmacy
- D. All of the above
- E. None of the above

Technician Responsibilities

680-X-2-.14

Pharmacy technicians must be at least 17 years old

Pharmacy technicians shall register with the Alabama state board of pharmacy

Registration expires on the 31st of December on odd number years

Each technician registered by the board must notify the board in writing within 10 days on change of employment

Every technician must complete 6 hours of continuing education every renewal cycle and two of the 6 hours must be “live” CE

Technician Responsibilities

680-X-2-.14

Only three technicians (one must be certified) can be on duty in the prescription area of the pharmacy at one time per pharmacist.

Technicians may **NOT**:

- Document the receipt of controlled substance into inventory
- Accept by oral communication a new prescription of any nature.
- Prepare a copy of a prescription to another person.
- Provide a prescription or medication to a patient without the pharmacist's verification.
- Counsel a patient or perform a drug utilization review.
- Perform any task that requires the judgment of a pharmacist.
- Perform any task that is in violation of any federal, state or local pharmacy regulation.

Applications – Why would ALBOP refuse to issue a registration?

The applicant has willingly violated the Alabama Controlled Substance Act.

The applicant has engaged in conduct which threatens the public health, safety, or welfare.

The applicant has been convicted of a felony or a misdemeanor involving moral turpitude.

An applicant has been convicted of a felony or a misdemeanor related to a legend drug or controlled substance.

The applicant has attempted to obtain the registration by fraudulent means.

The applicant refused to appear before the Board of Pharmacy after having been ordered to do so in writing.

The applicant does not possess good moral character.

Common mistakes

Please note that the case studies are not true cases but may have some real case qualities.

Items discussed are theoretical but may seem actual because things such as these really do happen!!!!

Case 1 – Gotta go “night-night”

A pharmacy technician was paying for snacks at the register in the pharmacy when 3 Ambien tablets fell out of their pocket.

What action should be taken?

What laws were broken?

- The technician has willingly violated the Alabama Controlled Substance Act?
- The technician has violated 680-X-2-.14 violating laws regarding the sale or dispensing of narcotics?
- Anything else?





**KEEP
CALM
AND
JUST SAY
NO**

Case 2

The right to refuse

A patient filed a formal complaint to ALBOP that a pharmacy refused to fill their prescription for unknown reasons. The patient lived in a different part of the state from the pharmacy. The pharmacist stated to the board that they felt like there was evidence of “pharmacy shopping”.

What action should be taken?

Case 3

Caution!



A pharmacist was given a supervising pharmacist position in a new pharmacy. The RPh was working in the pharmacy when the ALBOP inspectors showed up to inspect the pharmacy “prior to opening”. The pharmacy had already been open for several days without a permit.

What action should be taken?

Is the supervising pharmacist responsible?

Case 4 – Not your grandma’s bath salt

An elderly patient’s son complained to ALBOP about medications for their diabetic foot ulcer. Upon investigation, ALBOP found the pharmacy to have prescriptions that have ingredients that are dispensed to make foot bath soaks. The medications included creams (that do not dissolve), high price IV antibiotics, and steroids. The prescriptions were also considered “cascade” or “waterfall” prescriptions, which are not legal in AL?

What statute or rules could the pharmacy and pharmacist be breaking?

What steps should be taken, if any?



Statute vs Rules

Code of Alabama Title 34, Chapter 23 is the Pharmacy Practice Act and contains statutes

Chapter 680 contains rules of pharmacy administrative code

Technician Training Rule

Revision of 34-23-131, Registration and supervision; rules and regulations; continuing education.

Starting January 1, 2020, all technicians receiving their initial training registration shall complete a board approved training program within the first 6 months after their registration.

The training program shall be the responsibility of the technician and the Pharmacy employing the technician.

Technician Vaccination Authorization

680-X-2-.46 was adopted on 8/18/21 and effective 10/15/21

This rule outlines immunization training for all those registered by ALBOP, including technicians.

Technicians registered and in good standing with ALBOP may immunize if:

- a 2 hour ACPE practical training program is completed
 - The technician submits the completed training program to ALBOP (and then ALBOP issues a certificate). Immunizing may start once the approved training program is completed but documentation of the training should be filed within 10 days of completion.
- A current certificate in basic CPR is obtained
- The vaccine is ordered by an Alabama licensed pharmacist or pursuant to a prescription
- The pharmacist ordering is readily and immediately available to the immunizing technician
- The vaccine is FDA authorized or FDA licensed

Immunization Training

680-X-2-.46 was adopted on 8/18/21 and effective 10/15/21

The pharmacist must complete a minimum of two hours of board-approved, immunization related continuing education for each renewal cycle.

The pharmacist is responsible for the following:

- The supervision of the intern, extern, or technician
- Reporting any adverse events to VAERS
- Ensuring the vaccine is FDA authorized or FDA licensed
- A childhood vaccination is ordered and administered according to the ACIP standard immunization schedule
- Storage, use, and administration meets USP, CDC, and Alabama Pharmacy Practice act
- An emergency epinephrine kit is available
- Proper record keeping (IMMPRINT)

Assessment Question #3

When is a technician allowed to administer immunizations?

- A. A 2 hour ACPE practical training program is completed
- B. A current certificate in basic CPR is obtained
- C. The vaccine is ordered by an Alabama licensed pharmacist or pursuant to a prescription
- D. All of the above
- E. None of the above

Pharmacist Consultants

Rule 680-X-2-.08

To align requirements with renewal cycle

Continuing education for consultants changed from 6 hours per year to 8 hours per renewal cycle.

For example, consultant pharmacists will need to obtain a total of 8 hours of consultant CE for the 2021-22 renewal cycle.

All 8 hours can be completed in one of the years or spread out among the 2 year renewal cycle.

Public Hearing 12/16/20

Effective Date 3/17/21

Parenteral Sterile Therapy

Rule 680-X-2-.19

To ensure public's safety by requiring ongoing proficiency of parenteral standards

Initial training for parenteral certificate increased from 5 hours CE to 8 hours CE; however, high risk CE is an additional 4 hours if that compounding is to be done.

There will be a 2 hours CE required per renewal cycle in which some of the activity is hands on.

NONE of the CE has to be ACPE but must be board approved.

Effective date 2/14/21

Parenteral Sterile Therapy Amendment ... Why???

- ALBOP sees sterile practice issues with pharmacies that compound sterile products.
- The goal of amending the rule is public safety.
- There have been incidences of lack of education of proper technique, BUD, sterile environment, and other USP797 issues.
- Many states have already instituted CE requirements because of the issues listed above.

How can you obtain the 2 hours for you or your staff?

Hours from professional programming at meetings or webinars (such as AISHP, Samford, AU) that are approved by ALBOP for credit are allowed.

Hours from information that you may already have access to (ASHP, Pharmacist's Letter, inhouse education, LMS, etc) can be submitted to ALBOP for approval

“Hands on” can be your annual evaluation for aseptic technique as long as approved by ALBOP.

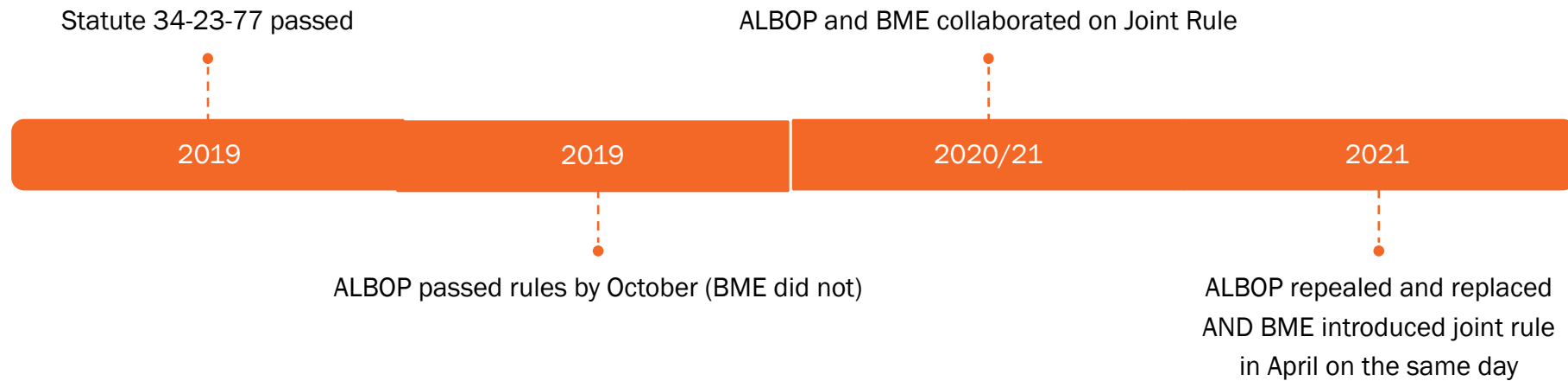
“Hands on” can be also obtained at meetings if approved.

Assessment question #4

How often does a pharmacist need to complete and send in ALBOP approved CE if they are parenterally certified and are performing any functions that require sterile technique or knowledge of sterile technique to dispense?

- A. One time only
- B. Every renewal cycle (every 2 years on even numbered years)
- C. Every 2 years on odd numbered years
- D. None of the above

Collaborative Practice



Collaborative Practice

Some updated language includes:

- Documentation and communication
 - Physician and pharmacists have to communicate within 24 hours with any therapy changes
 - Record retention – for pharmacist 2 years from the last patient contact
 - Agreements must be renewed every 2 years
- Quality Assurance
 - Quarterly review
 - Meaningful sample
 - 25% review for the first 2 years of the agreement
 - 10% review after the contract has been in effect for 2 years

Collaborative Practice

Rule 680-X-2.44

Public hearing and adoption date: 7/21/21

Rule effective date: 10/15/21

Standard formulary and protocols have been voted upon by ALBOP and reviewed by BME (awaiting for them to vote).

Examples of the draft protocols (see paper copies)

Joint committee (ALBOP and BME) will start meeting at the beginning of 2022 to review protocols submitted.



Questions????

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