



Pharmacy Law Update

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2014 Legislative Session

- **HB 323/SB 278** Relating to Pharmacy Technicians
- **HB 7077/SB 662** Relating to Nonresident Pharmacies
- **HB 859/SB 962** Relating to Medical Use of Cannabis
- **SB 7016** Relating to Prescription Drug Monitoring
- **HQS1** Relating to Sterile Compounding



Disclosure

- I do not have a vested interest in or affiliation with any corporate organization offering financial support or grant monies for this continuing education activity, or any affiliation with an organization whose philosophy could potentially bias my presentation



Florida Pharmacy Laws(Statutes)

- Chapter 465 "Florida Pharmacy Act"
- Chapter 893 "Florida Comprehensive Drug Abuse Prevention and Control Act"
- Chapter 120 "Administrative Procedures Act"
- Chapter 499 "Florida Drug, Device and Cosmetics Act"
- Chapter 456 "Health Professions and Occupations"



Objectives

- The participant will become familiar with issues centered on patient safety involved with recently enacted FL legislation related to the Chapter 465 of the Florida Statutes (Pharmacy Practice Act).
- The pharmacist technician attendee will review Board of Pharmacy revised rules pertaining to initial training program, FL registration, background screening and continuing education requirements.
- The participant will become familiar with key bills related to pharmacy technicians as presented for consideration to the FL House and Senate during the 2014 legislative session.
- The attendee will become familiar with evolving practice regulations related to sterile compounding as per the FL Board of Pharmacy.



465.014 (1) Pharmacy Technician

- A person other than a licensed pharmacist or pharmacy intern may not engage in the practice of the profession of pharmacy, except that a licensed pharmacist may delegate to pharmacy technicians who are registered pursuant to this section those duties, tasks, and functions that do not fall within the purview of s. [465.003](#)(13). All such delegated acts shall be performed under the direct supervision of a licensed pharmacist who shall be responsible for all such acts performed by persons under his or her supervision.



465.014 Pharmacy Technician (Continued)

- A pharmacy registered technician, under the supervision of a pharmacist, may initiate or receive communications with a practitioner or his or her agent, on behalf of a patient, regarding refill authorization requests.

465.014 (6) Pharmacy Technician

- As a condition of registration renewal, a registered pharmacy technician shall complete 20 hours biennially of continuing education courses approved by the board or the Accreditation Council for Pharmacy Education
- 4 hours must be via live presentation
- 2 hours must be related to the prevention of medication errors and pharmacy law.

465.014 Pharmacy Technician (Continued)

- A licensed pharmacist may not supervise more than one registered pharmacy technician unless otherwise permitted by the guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise more than one but not more than three pharmacy technicians.

465.014 (7) Pharmacy Technician

- The board shall adopt rules that require each registration issued by the board under this section to be displayed in such a manner as to make it available to the public and to facilitate inspection by the department. The board may adopt other rules as necessary to administer this section.

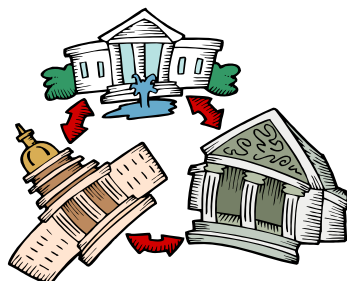
465.014 (2) Pharmacy Technician

- Any person who wishes to work as a pharmacy technician in this state must register by filing an application with the board on a form adopted by rule of the board. The board shall register each applicant who has remitted a registration fee set by the board, not to exceed \$50 biennially; has completed the application form and remitted a nonrefundable application fee set by the board, not to exceed \$50; is at least 17 years of age; and has completed a pharmacy technician training program approved by the Board of Pharmacy.

465.014 (8) Pharmacy Technician

- If the board finds that an applicant for registration as a pharmacy technician or that a registered pharmacy technician has committed an act that constitutes grounds for discipline as set forth in s. [456.072\(1\)](#) or has committed an act that constitutes grounds for denial of a license or disciplinary action as set forth in this chapter, including an act that constitutes a substantial violation of s. [456.072\(1\)](#) or a violation of this chapter which occurred before the applicant or registrant was registered as a pharmacy technician, the board may enter an order imposing any of the penalties specified in s. [456.072\(2\)](#) against the applicant or registrant.

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Regulations !!!

BOP Regulations (continued)

- 64B16-26.600 – Tripartite Continuing Education Committee
- 64B16-26.6012 – Guidelines for Board Ordered Disciplinary Continuing Education Courses
- 64B16-26.603 – Continuing Education Records Requirements
- 64B16-26.351 – Standards for Approval of Registered Pharmacy Technician Training Programs
- 64B16-26.350 – Requirements for Pharmacy Technician Registration

Florida Pharmacy Regulations(Rules)

- Chapter 64B-16 “Board of Pharmacy”
 - Florida Administrative Code
- Chapter 61N-1 “Drugs, Devices and Cosmetics Program”
 - 61N-1.011 (e-f) Wholesale distribution of prescription drugs – Exceptions and Specific Distribution Authorized
- Chapter 64K-1 “Prescription Drug Monitoring Program”

BOP Regulations (continued)

- 64B16-27.410 – Registered Pharmacy Technician to Pharmacist Ratio
- 64B16-27.420 – Registered Pharmacy Technician Responsibilities
- 64B16-27.430 – Responsibilities of the Pharmacist
- 64B16-27.440 – Policies and Procedures

Board of Pharmacy Regulations

- 64B16-27.1001 – Practice of Pharmacy
- 64B16-27.100 – Display of Current License
- 64B16-26.103 – Cont. Education Credits; Renewal
- 64B16-26.104 – Exemptions for Members of the Armed Forces
- 64B16-26.355 – Subject Matter for Registered Pharmacy Technician Continuing Education
- 64B16-26.601 – Standards for Approval of Courses and Providers

64B16-27.420 - Registered Pharmacy Technician Responsibilities

- (l) Registered pharmacy technicians may assist the pharmacist in performing the following tasks:
- (a) Retrieval of prescription files, patient files and profiles and other such records pertaining to the practice of pharmacy;
 - (b) Data Entry;
 - (c) Label preparation;
 - (d) The counting, weighing, measuring, pouring and compounding of prescription medication or stock legend drugs and controlled substances, including the filling of an automated medication system;
 - (e) Initiate communication to a prescribing practitioner or their medical staffs (or agents) regarding patient prescription refill authorization requests. For the purposes of this section “prescription refill” means the dispensing of medications pursuant to a prescriber’s authorization provided on the original prescription;
 - (f) Initiate communication to confirm the patient’s name, medication, strength, quantity, directions and date of last refill;
 - (g) Initiate communication to a prescribing practitioner or their medical staff (or agents) to obtain clarification on missing or illegible dates, prescriber name, brand/generic preference, quantity, DEA registration number or license numbers; and
 - (h) May accept authorization for a prescription renewal. For the purposes of this section, “prescription renewal” means the dispensing of medications pursuant to a practitioner’s authorization to fill an existing prescription that has no refill remaining.

64B16-27.420 - Registered Pharmacy Technician Responsibilities

- (2) Registered Pharmacy technicians shall not:
- (a) Receive new verbal prescriptions or any change in the medication, strength or directions;
 - (b) Interpret a prescription or medication order for therapeutic acceptability and appropriateness;
 - (c) Conduct a final verification of dosage and directions;
 - (d) Engage in prospective drug review;
 - (e) Provide patient counseling;
 - (f) Monitor prescription usage; and
 - (g) Override clinical alerts without first notifying the pharmacist.

Registered Pharmacy Technician Continuing Education Information (cont.)

- FLBOP uses the CEBroker database to determine a registrant's compliance with the requirements for continuing education.
 - Two method of data entry:
 - FLBOP-approved CE providers (FSHP)
 - Self-reporting (instruction on CEBroker website)
- Caution: It is the registrant's responsibility to provide proof of compliance with CE requirements (not the employer)

64B16-27.420 - Registered Pharmacy Technician Responsibilities

(3) Nuclear pharmacy permits allow the registered pharmacy technician to receive diagnostic orders only. The pharmacist must receive therapy or blood product procedure orders.

(4)(a) All registered pharmacy technicians shall identify themselves as registered pharmacy technicians by wearing a type of identification badge that is clearly visible which specifically identifies the employee by name and by status as a "registered pharmacy technician"; and

(b) All registered pharmacy technicians shall state their names and verbally identify themselves as registered pharmacy technicians in the context of telephone or other forms of communication.

SB 278 – Pharmacy Technician Supervision

- SB278
 - Authorizes BOP to approve increases in technician ratio 1:1 on a case by case basis
 - This is pursuant to BOP established guidelines
 - Removes the 3:1 statutory limit
 - Increases the number of institutional and community pharmacists which must be appointed from 1 in each category to two.
 - Current BOP members not meeting the above criteria will be permitted to serve out their term.

Registered Pharmacy Technician Continuing Education Information

- For renewal 20 hours C.E. of which 4 must be LIVE continuing education.
- 1 hour HIV/AIDS course must be taken from a Florida approved provider (First time renewal only)
- All courses must be approved by the FLBOP or ACPE
- All courses must be appropriate for pharmacy technicians

SB 278 – Pharmacy Technician Supervision (cont)

- SB 278
 - Authorizes pharmacists to administer meningococcal vaccine under physician protocol
 - Removes requirement for Rx from a physician to administer shingles vaccine
 - 456.42 & 893.04(2)(D), F.S.
 - Amended to permit the date on a Rx for a CS to be in numeric month/day/year format or for the month to be written out in whole and must be legible
 - Removes requirement that the date required under 456.42 and the written quantity and date under 893.04(2), F.S. must be on the face of the prescription

HB 323 – Pharmacy Technician Supervision

- HB 323
 - Removes statutory 3:1 limit on the number of technicians that may be supervised by a pharmacist
 - Makes no increase in the number of institutional and community pharmacists which must be appointed to the BOP
 - Automatic approval of requests to increase technician ratio for an automated pharmacy system or within a pharmacy performing or contracting for performance of centralized prescription filling.



SB702/HB745 – Pharmacy Audit Bill of Rights

- SB702/HB745 establish standards that PBM's must follow in regard to pharmacy audits
- Modeled after Florida Medicaid Pharmacy Audit Standards
 - Pharmacy must receive minimum of seven days notice of intent to audit
 - Required audit is scheduled after the first five calendar days of a month, unless pharmacist consents
 - Requires audit be conducted by or in consultation with a Florida licensed pharmacist
 - Requires reimbursement for a claim that is retroactively denied for clerical or typographical error
 - Unless a pattern of errors exists or fraudulent billing is alleged



SB662/HB7077 – Sterile Compounding

- Require out-of-state pharmacies that compound medications to obtain a sterile compounding permit if they wish to ship their products into the state of Florida.
- Insure that non-resident pharmacies meet or exceed the standards for sterile compounding required of Florida pharmacies.
- Improve enforcement by authorizing inspection of the non-resident pharmacies by Florida inspectors.
- Subject non-resident pharmacies to the same disciplinary standards as resident pharmacies.



SB702/HB745 – Pharmacy Audit Bill of Rights

- Requires receipt of preliminary audit report within 90 days of audit completion
- Allows pharmacist to produce documentation to address a discrepancy in an audit finding within 10 days of preliminary audit report
- Provides for recoupment or penalties based on actual overpayments
 - Not based upon extrapolation
- Limits audit period to 24 months
- If PBM willfully violates the provisions of this bill, the pharmacy has cause of action for civil damages.



SB702/HB745 – Pharmacy Audit Bill of Rights

- Florida's pharmacies support the right of a pharmacy benefit manager (PBM) to conduct audits to prevent fraud and abuse.
- There are no uniform audit standards in place to govern the auditing process.
- This has led to unreasonable demands and abuses
 - PBM's have sought recoupment of otherwise valid prescriptions due to minor clerical mistakes or misspellings by a pharmacist.
- Survey of 250 independent Florida pharmacies revealed
 - Average pharmacy faces four to six audits / month
 - Every month of the year



SB1384 – Mail Order Medications

- Currently some insurance and managed care companies mandate that their members obtain prescription medications exclusively from mail order pharmacies.
- This bill would prohibit that practice.
- Requires both mail order and non-mail order pharmacies be subject to the same terms and conditions
 - Any willing pharmacy



Sterile Compounding

- What is sterile compounding?
 - Sterile compounding is the preparation of custom medications for patients in a sterile environment to prevent contamination and maintain patient safety.
 - Pharmacies that offer this service are known as compounding pharmacies.
 - A compounding pharmacy may use pharmacists or technicians to prepare medications. In both cases, they work in a “sterile” environment.



SB1646/HB7113 - Telehealth

- SB1646
 - Narrower approach to “telemedicine” bill
 - Limits providers to physicians, pharmacists, physician assistants, and ARNPs.
- Both the House and Senate appear committed to pass some form of telehealth/telemedicine bill this session



SB1646/HB7113 - Telehealth

- HB7113
 - Broad
 - “Telehealth” defined to mean use of synchronous or asynchronous telecommunication’s technology by a telehealth provider to provide healthcare services including, but not limited to patient assessment, diagnosis, consultation, treatment, monitoring, and transfer of medical data



SB862/HB1381 Prescription Drug Monitoring Program

- Both bills deal with issues of access to the PDMP database
- FSHP & FPA have agreed to support funding of the PDMP from surplus money in the Pharmacy Account in the MQA Trust Fund
- PCB SAC 14-05 sponsored by the House State Affairs Committee passed
 - Renewing various exemptions to the public records law applicable to the PDMP database



SB1646/HB7113 - Telehealth

- HB7113
 - Audio only telephone calls, email messages, and facsimile transmissions are expressly excluded from this definition
 - Includes virtually all health care practitioners licensed by state of Florida
 - Standards of care for telehealth indential to standards of care for providers providing in-person health care services



Sterile Compounding (cont.)

- The Florida Board of Pharmacy has published notice that USP <797> and associated chapters have been officially noticed for adoption as the rules for sterile compounding in Florida but with exceptions pertaining to facility design and workplace cleaning.
- All pharmacies engaged in sterile compounding will have until March 21, 2014 to obtain a Special Sterile Compounding Permit.
- New USP chapter <800>
 - Hazardous drugs



SB1030/HB843 Medical Marijuana

- These bills would “legalize” Charlotte’s web
 - Derivative of the cannabis plant for treatment of autism and epilepsy
 - No additional action on these bills at this time
 - House and Senate sponsors have publicly expressed optimism that the bills would be enacted this session

