PHARMACY LAW UPDATE 2020

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FLORIDA STATUTES: FLORIDA LEGISLATURE


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NEW FLORIDA STATUTES OVERVIEW: TOOK EFFECT JULY 1, 2020

- Collaborative pharmacy practice agreement (CPPA) for chronic health conditions– Fla. Stat. § 465.1865
- Testing or screening for and treatment of minor, nonchronic health conditions–Fla. Stat. § 465.1895
- Consultant Pharmacists license, application, renewal, fees, responsibilities– Fla. Stat. § 465.0125
- Automated Pharmacy Systems– Fla. Stat. § 465.0235
- Prescription Drug Donation Repository Program Act– Fla. Stat. § 465.1902
- Institutional formularies established by nursing home facilities–Fla. Stat. § 400.143
- Keep Our Graduates Working Act of 2020– Fla. Stat. § 120.82
- Autonomous practice by an advanced practice registered nurse – Fla. Stat. § 464.0123

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COLLABORATIVE PHARMACY PRACTICE FOR CHRONIC HEALTH CONDITIONS
FLA. STAT. §465.1865(1)

A "collaborative pharmacy practice agreement" means a written agreement between a pharmacist who meets the qualifications of this section and a physician (MD or DO only) in which a collaborating physician authorizes a pharmacist to provide specified patient care services to the collaborating physician's patients.

"Chronic health condition" means:

1) Arthritis;
2) Asthma;
3) Chronic obstructive pulmonary diseases;
4) Type 2 diabetes;
5) Human immunodeficiency virus or acquired immune deficiency syndrome;
6) Obesity; or
7) Any other chronic condition adopted in rule by the board, in consultation with the Board of Medicine and Board of Osteopathic Medicine.

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COLLABORATIVE PHARMACY PRACTICE FOR CHRONIC HEALTH CONDITIONS
FLA. STAT. §465.1865(2)

To provide services under a collaborative pharmacy practice agreement, a pharmacist must be certified by the board, according to the rules adopted by the board in consultation with the Board of Medicine and the Board of Osteopathic Medicine. To be certified, a pharmacist must, at a minimum:

a) Hold an active and unencumbered license to practice pharmacy in this state

b) Have earned a degree of doctor of pharmacy or have completed 5 years of experience as a licensed pharmacist

c) Have completed an initial 20-hour course approved by the board, in consultation with the Board of Medicine and Board of Osteopathic Medicine, that includes, at a minimum, instruction on the following:

   1. Performance of patient assessments
   2. Ordering, performing, and interpreting clinical and laboratory tests related to collaborative pharmacy practice
   3. Evaluating and managing diseases and health conditions in collaboration with other health care practitioners
   4. Any other area required by board

d) Maintain at least $250,000 of professional liability insurance coverage. However, a pharmacist who maintains professional liability insurance coverage pursuant to s. 465.1895 (the test and treat statute) satisfies this requirement.

e) Have established a system to maintain records of all patients receiving services under a collaborative pharmacy practice agreement for a period of 5 years from each patient's most recent provision of service

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COLLABORATIVE PHARMACY PRACTICE FOR CHRONIC HEALTH CONDITIONS
FLA. STAT. §465.1865(3)

The terms and conditions of the collaborative pharmacy practice agreement must be appropriate to the pharmacist's training and the services delegated to the pharmacist must be within the collaborating physician's scope of practice. A copy of the certification issued under subsection (2) must be included as an attachment to the collaborative pharmacy practice agreement.

a) A collaborative pharmacy practice agreement must include the following:

   1. Name of the collaborating physician's patient or patients for whom a pharmacist may provide services.
   2. Each chronic health condition to be collaboratively managed.
   3. Specific medicinal drug or drugs to be managed by the pharmacist for each patient.
   4. Circumstances under which the pharmacist may order or perform and evaluate laboratory or clinical tests.
   5. Conditions and events upon which the pharmacist must notify the collaborating physician and the manner and timeframe in which such notification must occur.
   6. Beginning and ending dates for the collaborative pharmacy practice agreement and termination procedures, including procedures for patient notification and medical records transfers.
   7. A statement that the collaborative pharmacy practice agreement may be terminated, in writing, by either party at any time.

b) A collaborative pharmacy practice agreement shall automatically terminate 2 years after execution if not renewed.

c) The pharmacist, along with the collaborating physician, must maintain on file the collaborative pharmacy practice agreement at his or her practice location, and must make such agreements available to the department or board upon request or inspection.

d) A pharmacist who enters into a collaborative pharmacy practice agreement must submit a copy of the signed agreement to the board before the agreement may be implemented.

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COLLABORATIVE PHARMACY PRACTICE FOR CHRONIC HEALTH CONDITIONS
FLA. STAT. §465.1865(4)-(7)

A pharmacist may not:

a) Modify or discontinue medicinal drugs prescribed by a health care practitioner with whom he or she does not have a collaborative pharmacy practice agreement.

b) Enter into a collaborative pharmacy practice agreement while acting as an employee without the written approval of the owner of the pharmacy.

A physician may not delegate the authority to initiate or prescribe a controlled substance to a pharmacist.

A pharmacist who practices under a collaborative pharmacy practice agreement must complete an 8-hour continuing education course approved by the board that addresses issues related to collaborative pharmacy practice each biennial licensure renewal in addition to the general continuing education requirements (under s. 465.009). A pharmacist must submit confirmation of having completed such course when applying for licensure renewal. A pharmacist who fails to comply with this subsection shall be prohibited from practicing under a collaborative pharmacy practice agreement under this section.

The board, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, shall adopt rules to implement this section.

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TESTING OR SCREENING FOR AND TREATMENT OF MINOR, NONCHRONIC HEALTH CONDITIONS
FLA. STAT. §465.1895(1)

(1) A pharmacist may test or screen for and treat minor, nonchronic health conditions within the framework of an established written protocol with a supervising physician (MD or DO only). For purposes of this section, a minor, nonchronic health condition is typically a short-term condition that is generally managed with minimal treatment or self-care, and includes:

(a) Influenza.

(b) Streptococcus.

(c) Lice.

(d) Skin conditions, such as ringworm and athlete's foot.

(e) Minor, uncomplicated infections.

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TESTING OR SCREENING FOR AND TREATMENT OF MINOR, NONCHRONIC HEALTH CONDITIONS
FLA. STAT. §465.1895(2)

(2) A pharmacist who tests or screens for and treats minor, nonchronic health conditions under this section must:

a) Hold an active and unencumbered license to practice pharmacy in the state.

b) Hold a certification issued by the board to test and screen for and treat minor, nonchronic health conditions, in accordance with requirements established by the board in rule in consultation with the Board of Medicine and Board of Osteopathic Medicine. The certification must require a pharmacist to complete, on a one-time basis, a 20-hour education course approved by the board in consultation with the Board of Medicine and the Board of Osteopathic Medicine. The course, at a minimum, must address patient assessments; point-of-care testing procedures; safe and effective treatment of minor, nonchronic health conditions; and identification of contraindications.

c) Maintain at least $250,000 of liability coverage. A pharmacist who maintains liability coverage pursuant to s. 465.1865 satisfies this requirement.

d) Report a diagnosis or suspected existence of a disease of public health significance to the department pursuant to s. 381.0031.

e) Upon request of a patient, furnish patient records to a health care practitioner designated by the patient.

f) Maintain records of all patients receiving services under this section for a period of 5 years from each patient's most recent provision of service.

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TESTING OR SCREENING FOR AND TREATMENT OF MINOR, NONCHRONIC HEALTH CONDITIONS
FLA. STAT. §465.1895(3) & (4)

- (3) The board shall adopt, by rule, a formulary of medicinal drugs that a pharmacist may prescribe for the minor, nonchronic health conditions approved under subsection (1). The formulary must include medicinal drugs approved by the United States Food and Drug Administration which are indicated for treatment of the minor, nonchronic health condition. The formulary may not include any controlled substance as described in s. 893.03 or 21 U.S.C. s. 812.
- (4) A pharmacist who tests or screens for and treats minor, nonchronic health conditions under this section may use any tests that may guide diagnosis or clinical decisionmaking which the Centers for Medicare and Medicaid Services has determined qualifies for a waiver under the federal Clinical Laboratory Improvement Amendments of 1988, or the federal rules adopted thereunder, or any established screening procedures that can safely be performed by a pharmacist.

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TESTING OR SCREENING FOR AND TREATMENT OF MINOR, NONCHRONIC HEALTH CONDITIONS
FLA. STAT. §465.1895(5)

(5) The written protocol between a pharmacist and supervising physician under this subsection must include particular terms and conditions imposed by the supervising physician relating to the testing and screening for and treatment of minor, nonchronic health conditions under this section. The terms and conditions must be appropriate to the pharmacist's training. A pharmacist who enters into such a protocol with a supervising physician must submit the protocol to the board.

(a) At a minimum, the protocol shall include:

1. Specific categories of patients who the pharmacist is authorized to test or screen for and treat minor, nonchronic health conditions.

2. The physician's instructions for obtaining relevant patient medical history for the purpose of identifying disqualifying health conditions, adverse reactions, and contraindications to the approved course of treatment.

3. The physician's instructions for the treatment of minor, nonchronic health conditions based on the patient's age, symptoms, and test results, including negative results.

4. A process and schedule for the physician to review the pharmacist's actions under the protocol.

5. A process and schedule for the pharmacist to notify the physician of the patient's condition, tests administered, test results, and course of treatment.

6. Any other requirements as established by the board in consultation with the Board of Medicine and the Board of Osteopathic Medicine.

(b) A pharmacist authorized to test and screen for and treat minor, nonchronic conditions under a protocol shall provide evidence of current certification by the board to the supervising physician. A supervising physician shall review the pharmacist's actions in accordance with the protocol.

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TESTING OR SCREENING FOR AND TREATMENT OF MINOR, NONCHRONIC HEALTH CONDITIONS
FLA. STAT. §465.1895(6)-(11)

(6) A pharmacist providing services under this section may not perform such services while acting as an employee without the written approval of the owner of the pharmacy.

(7) A pharmacist providing services under this section must complete a 3-hour continuing education course approved by the board addressing issues related to minor, nonchronic health conditions each biennial licensure renewal in addition to the continuing education requirements under s. 465.009. Each pharmacist must submit confirmation of having completed the course when applying for licensure renewal. A pharmacist who fails to comply with this subsection may not provide testing, screening, or treatment services.

(8) A pharmacist providing services under this section must provide a patient with written information to advise the patient to seek followup care from his or her primary care physician. The board, by rule, shall adopt guidelines for the circumstances under which the information required under this subsection shall be provided.

(9) The pharmacy in which a pharmacist tests and screens for and treats minor, nonchronic health conditions must prominently display signage indicating that any patient receiving testing, screening, or treatment services under this section is advised to seek followup care from his or her primary care physician.

(10) A pharmacist providing services under this section must comply with applicable state and federal laws and regulations.

(11) The requirements of the section do not apply with respect to minor, nonchronic health conditions when treated with over-the-counter products.

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AUTOMATED PHARMACY SYSTEMS USED BY LONG-TERM CARE FACILITIES, HOSPICES, OR STATE CORRECTIONAL INSTITUTIONS, OR FOR OUTPATIENT DISPENSING
FLA. STAT. §465.0235(2)

(2) A community pharmacy licensed in this state may provide pharmacy services for outpatient dispensing through the use of an automated pharmacy system that need not be located at the same location as the community pharmacy if:

a) The automated pharmacy system is under the supervision and control of the community pharmacy.

b) The automated pharmacy system is housed in an indoor environment area and in a location to increase patients' access to their prescriptions, including, but not limited to, medical facilities or places of business where essential goods and commodities are sold or large employer workplaces or locations where access to a community pharmacy is limited.

c) The community pharmacy providing services through the automated pharmacy system notifies the board of the location of the automated pharmacy system and any changes in such location.

d) The automated pharmacy system has a mechanism that provides live, real-time patient counseling by a pharmacist and licensed in this state, before the dispensing of any medicinal drug.

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AUTOMATED PHARMACY SYSTEMS USED BY LONG-TERM CARE FACILITIES, HOSPICES, OR STATE CORRECTIONAL INSTITUTIONS, OR FOR OUTPATIENT DISPENSING
FLA. STAT. §465.0235(2) CONTINUED

(2) A community pharmacy licensed in this state may provide pharmacy services for outpatient dispensing through the use of an automated pharmacy system that need not be located at the same location as the community pharmacy if:

e) The automated pharmacy system does not contain or dispense any controlled substance listed in s. 893.03 or 21 U.S.C. s. 812.

f) The community pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.

g) The automated pharmacy system ensures the confidentiality of personal health information.

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AUTOMATED PHARMACY SYSTEMS USED BY LONG-TERM CARE FACILITIES, HOSPICES, OR STATE CORRECTIONAL INSTITUTIONS, OR FOR OUTPATIENT DISPENSING
FLA. STAT. §465.0235(2) CONTINUED

(2) A community pharmacy licensed in this state may provide pharmacy services for outpatient dispensing through the use of an automated pharmacy system that need not be located at the same location as the community pharmacy if:

(h) The community pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system. The community pharmacy shall annually review the policies and procedures and maintain a record of such policies and procedures for a minimum of 4 years. The annual review must be documented in the community pharmacy's records and must be made available to the board upon request. The policies and procedures must, at a minimum, address all of the following:

1. Maintaining the automated pharmacy system and any accompanying electronic verification process in good working order.
2. Ensuring the integrity of the automated pharmacy system's drug identifier database and its ability to identify the person responsible for making database entries.
3. Ensuring the accurate filling, stocking, restocking, and verification of the automated pharmacy system.
4. Ensuring the sanitary operation of the automated pharmacy system and the prevention of cross-contamination of cells, cartridges, containers, cassettes, or packages.
5. Testing the accuracy of the automated pharmacy system and any accompanying electronic verification process. The automated pharmacy system and accompanying electronic verification process must, at a minimum, be tested before the first use of the system, upon restarting the system, and after a modification cation of the system or electronic verification process which alters the filling, stocking, or restocking of the system or the electronic verification process.
6. Training of persons authorized to access, stock, restock, or use the system.
7. Conducting routine and preventative maintenance of the automated pharmacy system, including calibration of the system, if applicable.
8. Removing expired, adulterated, misbranded, or recalled medicinal drugs from the automated pharmacy system.
9. Preventing unauthorized persons from accessing the automated pharmacy system, including assigning, discontinuing, or modifying security access.
10. Identifying and recording persons responsible for filling, stocking, and restocking the automated pharmacy system.
11. Ensuring compliance with state and federal law, including, but not limited to, all applicable labeling, storage, and security requirements.
12. Maintaining an ongoing quality assurance program that monitors and records performance of the automated pharmacy system and any accompanying electronic verification process to ensure proper and accurate functioning, including tracking and documenting system errors. A community pharmacy must maintain such records for a minimum of 4 years and must make such records available to the board upon request.

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AUTOMATED PHARMACY SYSTEMS USED BY LONG-TERM CARE FACILITIES, HOSPICES, OR STATE CORRECTIONAL INSTITUTIONS, OR FOR OUTPATIENT DISPENSING
FLA. STAT. §465.0235(2) CONTINUED

(3) Medicinal drugs stored in bulk or unit of use in an automated pharmacy system servicing a long-term care facility, hospice, or correctional institution, or for outpatient dispensing, are part of the inventory of the pharmacy providing pharmacy services to that facility, hospice, or institution, or for outpatient dispensing, and medicinal drugs delivered by the automated pharmacy system are considered to have been dispensed by that pharmacy.

(4) The operation of an automated pharmacy system must be under the supervision of a pharmacist licensed in this state. To qualify as a supervisor for an automated pharmacy system, the pharmacist need not be physically present at the site of the automated pharmacy system and may supervise the system electronically. The pharmacist shall be required to develop and implement policies and procedures designed to verify that the medicinal drugs delivered by the automated pharmacy system are accurate and valid and that the machine is properly restocked.

(5) The Legislature does not intend for this section to limit the current practice of pharmacy in this state. This section is intended to allow automated pharmacy systems to enhance the ability of a pharmacist to provide pharmacy services in locations that do not employ a full-time pharmacist. This section does not limit or replace the use of a consultant pharmacist.

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AUTOMATED PHARMACY SYSTEMS USED BY LONG-TERM CARE FACILITIES, HOSPICES, OR STATE CORRECTIONAL INSTITUTIONS, OR FOR OUTPATIENT DISPENSING
FLA. STAT. §465.0235(2) CONTINUED

(6) The board may adopt rules governing the use of an automated pharmacy systems. If adopted, such rules must include all of the following:

a) Recordkeeping requirements;
b) Security requirements; and
c) Labeling requirements that permit the use of unit-dose medications if the facility, hospice, or institution maintains medication-administration records that include directions for use of the medication and the automated pharmacy system identifies:
    1. The dispensing pharmacy;
    2. The prescription number;
    3. The name of the patient; and
    4. The name of the prescribing practitioner

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PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM
FLA. STAT. §465.1902

- (2) DEFINITIONS.--As used in this section, the term:
- (a) "Closed drug delivery system" means a system in which the actual control of the unit-dose medication package is maintained by the facility, rather than by the individual patient.
- (b) "Controlled substance" means any substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03.
- (c) "Dispenser" means a health care practitioner who, within the scope of his or her practice act, is authorized to dispense medicinal drugs and who does so under this act.
- (d) "Free clinic" means a clinic that delivers only medical diagnostic services or nonsurgical medical treatment free of charge to low-income recipients.
- (e) "Health care practitioner" or "practitioner" means a practitioner licensed under this chapter, chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.
- (f) "Indigent" means having a family income during the 12 months preceding the determination of income that is below 200 percent of the federal poverty level as defined by the most recently revised poverty income guidelines published by the United States Department of Health and Human Services.
- (g) "Nonprofit health clinic" means a nonprofit legal entity that provides medical care to patients who are indigent, uninsured, or underinsured. The term includes, but is not limited to, a federally qualified health center as defined in 42 U.S.C. s. 1396d(l)(2)(B) and a rural health clinic as defined in
- (h) "Nursing home facility" has the same meaning as in s. 400.021.
- (i) "Prescriber" means a health care practitioner who, within the scope of his or her practice act, is authorized to prescribe medicinal drugs.
- (j) "Prescription drug" has the same meaning as the term "medicinal drugs" or "drugs," as those terms are defined in s. 465.003(8), but does not include controlled substances, cancer drugs donated under s. 499.029, or drugs with an approved United States Food and Drug Administration risk evaluation and mitigation strategy that includes elements to assure safe use.
- (k) "Program" means the Prescription Drug Donation Repository Program created by this section.

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PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM
FLA. STAT. §465.1902

- (2) DEFINITIONS.—As used in this section, the term:
- (l) "Supply" means a material or an instrument used to administer a prescription drug.
- (m) "Tamper-evident packaging" means a package that has one or more indicators or barriers to access which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. The term includes, but is not limited to, unopened unit-dose packaging, multiple-dose packaging, and medications with a seal on their immediate, outer, secondary, or tertiary packaging.
- (n) "Underinsured" means having health care coverage or prescription drug coverage, but having exhausted these benefits or not having prescription drug coverage for the drug prescribed.
- (o) "Uninsured" means not having health care coverage and being ineligible for prescription drug coverage under a program funded in whole or in part by the Federal Government.

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PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM
FLA. STAT. §465.1902

(3) PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM; CREATION; PURPOSE.—The Prescription Drug Donation Repository Program is created within the department to facilitate the donation of prescription drugs and supplies to eligible patients.

(4) REPOSITORIES

a) A repository may accept and dispense eligible donations to eligible patients under the program. The repository must inspect, store, and dispense donations and report to the department in accordance with this section.

b) The following entities may participate as a repository:

1. A health care practitioner's office.
2. A pharmacy.
3. A hospital with a closed drug delivery system.
4. A nursing home facility with a closed drug delivery system.
5. A free clinic or nonprofit health clinic that is licensed or permitted to dispense medicinal drugs in the state.

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PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM
FLA. STAT. §465.1902

(4) REPOSITORIES

(c) An eligible entity must notify the department of its intent to participate in the program as a repository before accepting or dispensing any donations under the program. The notification must be made on a physical or an electronic form prescribed by the department in rule and must, at a minimum, include:

1. The name, street address, website, and telephone number of the intended repository and any license or registration number issued by the state to the intended repository, including the name of the issuing agency.

2. The name and telephone number of the pharmacist employed by or under contract with the intended repository who is responsible for th inspection of donated prescription drugs and supplies.

3. A signed and dated statement by the responsible pharmacist affirming that the intended repository meets the eligibility requirements of this subsection.

(d) A repository may withdraw from participation in the program at any time by providing written notice to the department, as appropriate, on a physical or an electronic form prescribed by the department in rule. The department shall adopt rules addressing the disposition of prescription drugs and supplies in the possession of the withdrawing repository.

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PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM

FLA. STAT. §465.1902

(5) ELIGIBLE DONORS.—The following entities may donate prescription drugs or supplies to a repository under the program:

a) Nursing home facilities with closed drug delivery systems.

b) Hospices that have maintained control of a patient's prescription drugs

c) Hospitals with closed drug delivery systems.

d) Pharmacies.

e) Drug manufacturers or wholesale distributors.

f) Medical device manufacturers or suppliers.

g) Prescribers who receive prescription drugs or supplies directly from a drug manufacturer, wholesale distributor, or pharmacy.

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PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM

FLA. STAT. §465.1902

(6) ELIGIBLE DONATIONS; DONATION REQUIREMENTS; PROHIBITED DONATIONS.—

(a) An eligible donor may only donate a prescription drug to a repository if:

1. The drug is approved for medical use in the United States.
2. The drug is in unopened, tamper-evident packaging.
3. The drug requires storage at normal room temperature per the manufacturer or federal storage requirements.
4. The drug has been stored according to manufacturer or federal storage requirements.
5. The drug does not have any physical signs of tampering or adulteration and there is no reason to believe that the drug is adulterated.
6. The packaging does not have any physical signs of tampering, misbranding, deterioration, compromised integrity, or adulteration.
7. The packaging indicates the expiration date of the drug. If the lot number is not retrievable, all specified medications must be destroyed in the event of a recall.
8. The drug has an expiration date that is more than 3 months after the date on which the drug was donated.

(b) An eligible donor may donate a prescription drug or supply to a repository only if it is in unopened, tamper-evident packaging.

(c) Donations must be made on the premises of a repository to a person designated by the repository. A drop box may not be used to accept donations.

(d) A prescription drug or supply may not be donated to a specific patient.

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PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM

FLA. STAT. §465.1902

(7) INSPECTION AND STORAGE.—

(a) Upon receipt of a proposed donation, a licensed pharmacist employed by or under contract with a repository shall inspect the donation to determine whether it meets the requirements of subsections (5) and (6). The repository shall quarantine a donation until such inspection is complete and the donation is approved for dispensing.

(b) The inspecting pharmacist must sign an inspection record on a physical or an electronic form prescribed by the department in rule which verifies that the prescription drug or supply meets the criteria of subsections (5) and (6) and must attach the record to the inventory required in paragraph

(d). A repository that receives prescription drugs and supplies from another repository is not required to reinspect such drugs and supplies.

(c) A repository shall store donations in a secure storage area under the environmental conditions specified by the manufacturer or federal storage requirements. Donations may not be stored with other inventory.

(d) A repository shall maintain an inventory of the name, strength, available quantity, and expiration date of donations; the transaction date; and the name, street address, and telephone number of the donor. The repository shall record such inventory on a physical or an electronic form prescribed by the department in rule.

(e) By the 5th day of each month, a repository shall submit to the department its inventory records of donations received during the previous month.

(f) The department may facilitate the redistribution of donations between repositories. A repository that receives donations may, after notifying the department, distribute the donations to another repository.

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PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM
FLA. STAT. §465.1902

(8) ELIGIBLE PATIENTS; DISPENSING REQUIREMENTS; PATIENT NOTICE; PROHIBITIONS.–

(a) A repository may dispense an eligible donation to a state resident who is indigent, uninsured, or underinsured, and who has a valid prescription for such donation, as applicable.

(b) Each new eligible patient must submit an intake collection form to a repository to receive a donation using a physical or an electronic form prescribed by the department in rule. Such form shall, at a minimum, include:

1. The name, street address, and telephone number of the eligible patient.

2. The basis for the patient's eligibility, which must specify that the patient is indigent, uninsured, or underinsured.

3. A statement physically or electronically signed and dated by the patient affirming that the patient meets the eligibility requirements of this section and will inform the repository if the patient's eligibility changes.

4. Notice that the prescription drug or supply was donated to the program, that the donors and participants in the program are immune from civil or criminal liability or disciplinary action, and that the eligible patient is not required to pay for the prescription drug or supply.

5. A statement physically or electronically signed and dated by the eligible patient acknowledging receipt of notice required under this paragraph.

(c) By the 5th day of each month, a repository shall submit to the department a summary of each intake collection form obtained during the previous month.

(d) A dispenser may dispense donations, if available, only to an eligible patient who has submitted a completed intake collection form.

(e) A dispenser may provide dispensing and consulting services to an eligible patient.

(f) Donations may not be sold or resold.

(g) A dispenser may not submit a claim or otherwise seek reimbursement from any public or private third-party payor for donations.

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PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM
FLA. STAT. §465.1902

(9) RECALLED PRESCRIPTION DRUGS

(a) Each repository shall establish and follow a protocol for notifying recipients in the event that a prescription drug donated under the program is recalled.

(b) A repository shall destroy all donated prescription drugs that are recalled, expired, or unsuitable for dispensing. A repository must complete a destruction form for all such drugs using a physical or an electronic form prescribed by the department in rule.

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PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM
FLA. STAT. §465.1902

(10) RECORDKEEPING.–

(a) A repository shall maintain records of prescription drugs and supplies that are accepted, donated, dispensed, distributed, or destroyed under the program using a physical or an electronic form prescribed by the department in rule.

(b) All required records must be maintained in accordance with any applicable practice act. A repository shall submit these records monthly to the department for data collection.

(11) REGISTRIES; PUBLICATION OF FORMS.–

(a) The department shall establish and maintain registries of all repositories and prescription drugs and supplies available under the program. The registry of repositories must include each repository's name, street address, website, and telephone number. The registry of available prescription drugs and supplies must include the name, strength, available quantity, and expiration date of the prescription drugs or supplies and the name and contact information of each repository where such drugs or supplies are available. The department shall publish the registries on its website.

(b) The department shall publish all forms required by this section on its website.

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PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM
FLA. STAT. §465.1902

(12) IMMUNITY FROM LIABILITY; DISCIPLINARY ACTION.–

(a) Any donor of prescription drugs or supplies and any participant in the program who exercises reasonable care in donating, accepting, distributing, or dispensing prescription drugs or supplies under the program is immune from civil or criminal liability and professional disciplinary action by the state for any injury, death, or loss to person or property relating to such activities.

(b) A pharmaceutical manufacturer who exercises reasonable care is not liable for any claim or injury arising from the donation of any prescription drug or supply under this section, including, but not limited to, liability for failure to transfer or communicate product or consumer information regarding the donated prescription drug or supply, including its expiration date.

(13) RULEMAKING.–The department shall adopt rules necessary to administer this section.

252.36 Emergency management powers of the Governor.–

(5) In addition to any other powers conferred upon the Governor by law,

she or he may: (o) Waive the patient eligibility requirements of s. 465.1902.

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INSTITUTIONAL FORMULARIES ESTABLISHED BY NURSING HOME FACILITIES
FLA. STAT. §400.143

(1) For purposes of this section, the term:

(a) "Institutional formulary" means a list of medicinal drugs established by a nursing home facility under this section for which a pharmacist may use a therapeutic substitution for a medicinal drug prescribed to a resident of the facility.

(b) "Medicinal drug" has the same meaning as provided in s. 465.003(8)

(c) "Prescriber" has the same meaning as provided in s. 465.025(1)

(d) "Therapeutic substitution" means the practice of replacing a nursing home facility resident's prescribed medicinal drug with another chemically different medicinal drug that is expected to have the same clinical effect.

(2) A nursing home facility may establish and implement an institutional formulary in accordance with the requirements of this section

(3) A nursing home facility that implements an institutional formulary under this section must:

(a) Establish a committee to develop the institutional formulary and written guidelines or procedures for such institutional formulary. The committee must consist of, at a minimum: 1. The facility's medical director. 2. The facility's director of nursing services. 3. A consultant pharmacist licensed by the Department of Health and certified under s. 465.0125.

(b) Establish methods and criteria for selecting and objectively evaluating all available pharmaceutical products that may be used as therapeutic substitutes.

(c) Establish policies and procedures for developing and maintaining the institutional formulary and for approving, disseminating, and notifying prescribers of the institutional formulary.

(d) Perform quarterly monitoring to ensure compliance with the policies and procedures established under paragraph (c) and monitor the clinical outcomes in circumstances in which a therapeutic substitution has occurred.

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INSTITUTIONAL FORMULARIES ESTABLISHED BY NURSING HOME FACILITIES
FLA. STAT. §400.143

(4) The nursing home facility shall maintain all written policies and procedures for the institutional formulary established under this section. Each nursing home facility shall make available such policies and procedures to the agency, upon request.

(5)(a) A prescriber who uses the institutional formulary must authorize such use for each patient. A nursing home facility must obtain the prescriber's approval for any subsequent change made to a nursing home facility's institutional formulary. A prescriber may opt out of the nursing home facility's institutional formulary with respect to a medicinal drug or class of medicinal drugs for any resident. A nursing home facility may not take adverse action against a prescriber for declining to use the facility's institutional formulary.

(b) A nursing home facility must notify the prescriber before each therapeutic substitution using a method of communication designated by the prescriber. A nursing home facility must document the therapeutic substitution in the resident's medical records.

(c) A prescriber may prevent a therapeutic substitution for a specific prescription by indicating "NO THERAPEUTIC SUBSTITUTION" on the prescription. If the prescription is provided orally, the prescriber must make an overt action to opt out of the therapeutic substitution.

(6) The nursing home facility must obtain informed consent from a resident or a resident's legal representative, or his or her designee, to the use of the institutional formulary for the resident. The nursing home facility must clearly inform the resident or the resident's legal representative, or his or her designee, of the right to refuse to participate in the use of the institutional formulary and may not take any adverse action against the resident who refuses to participate in the use of the institutional formulary.

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SUBSTITUTION OF DRUGS
(INSTITUTIONAL FORMULARY)
FLA. STAT. §465.025 (9)

- A pharmacist may therapeutically substitute medicinal drugs in accordance with an institutional formulary for the resident of a nursing home facility if the prescriber has agreed to the use of such institutional formulary for the patient. The pharmacist may not therapeutically substitute a medicinal drug pursuant to the facility's institutional formulary if the prescriber indicates on the prescription "NO THERAPEUTIC SUBSTITUTION" or overtly indicates that therapeutic substitution is prohibited.

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KEEP OUR GRADUATES WORKING ACT
FLA. STAT. §120.82

- The purpose of this act is to ensure that Floridians who graduate from an accredited college or university can maintain their occupational licenses and remain in the workforce while they attempt to pay off their student loan debt
- A state authority may not deny a license, refuse to renew a license, or suspend or revoke a license that it has issued to a person who is in default on or delinquent in the payment of his or her student loans solely on the basis of such default or delinquency
- If the graduate is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities solely based on a default or delinquency on a student loan, the Board of Pharmacy is no longer required to deny their licensure, certification, registration or admission to an examination

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KEEP OUR GRADUATES WORKING ACT
FLA. STAT. §120.82

- Section 456.072 has been amended so that failing to pay student loans is no longer grounds for discipline
  - Failing to repay a student loan issued or guaranteed by the state or the Federal Government in accordance with the terms of the loan is not considered a failure to perform a statutory or legal obligation
- Section 456.0721 is now repealed, so the Department of Health will no longer investigate and prosecute health care practitioners who fail to repay a student loans or comply with scholarship service obligations
- Section 456.074 has now been removed, so failing to pay your student loans will no longer result in an emergency order to immediately suspend the practitioner's license

33

EPIDEMIOLOGICAL RESEARCH; REPORT OF DISEASES OF PUBLIC HEALTH SIGNIFICANCE TO DEPARTMENT
FLA. STAT. §381.0031(2)

- Pharmacists authorized to perform test and treat and those practicing under a collaborative pharmacy practice agreement are required to report the existence of a disease of public health significance to the Department of Health, both if the disease is diagnosed or suspected

- Fla. Stat. § 381.0031(2): Any practitioner licensed in this state to practice medicine, osteopathic medicine, chiropractic medicine, naturopathy, or veterinary medicine; **any licensed pharmacist authorized under a protocol with a supervising physician under s. 465.1895, or a collaborative pharmacy practice agreement, as defined in s. 465.1865, to perform or order and evaluate laboratory and clinical tests**; any hospital licensed under part I of chapter 395; or any laboratory appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder which diagnoses or suspects the existence of a disease of public health significance shall immediately report the fact to the Department of Health.

34

AUTONOMOUS NURSE PRACTITIONER PRACTICE
FLA. STAT. §464.0123

(5) "Autonomous practice" means advanced nursing practice by an advanced practice registered nurse who is registered under s. 464.0123 and who is not subject to supervision by a physician or a supervisory protocol.

Autonomous practice by an advanced practice registered nurse

(1) REGISTRATION.—The board shall register an advanced practice registered nurse as an autonomous advanced practice registered nurse if the applicant demonstrates that he or she:

(a) Holds an active, unencumbered license to practice advanced nursing

(b) (b) Has not been subject to any disciplinary action or any similar disciplinary action in another state or other territory or jurisdiction within the 5 years immediately preceding the registration request.

(c) Has completed, in any state, jurisdiction, or territory of the United States, at least 3,000 clinical practice hours, which may include clinical instructional hours provided by the applicant, within the 5 years immediately preceding the registration request while practicing as an advanced practice registered nurse under the supervision of an allopathic or osteopathic physician who held an active, unencumbered license issued by any state, jurisdiction, or territory of the United States during the period of such supervision. For purposes of this paragraph, "clinical instruction" means education provided by faculty in a clinical setting in a graduate program leading to a master's or doctoral degree in a clinical nursing specialty area.

(d) Has completed within the past 5 years 3 graduate-level semester hours, or the equivalent, in differential diagnosis and 3 graduate-level semester hours, or the equivalent, in pharmacology. (e) The board may provide additional registration requirements by rule.

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AUTONOMOUS NURSE PRACTITIONER PRACTICE
FLA. STAT. §464.0123

PRACTICE REQUIREMENTS

(a) An advanced practice registered nurse who is registered under this section may:

1. Engage in autonomous practice only in primary care practice, including family medicine, general pediatrics, and general internal medicine, as defined by board rule.

2. For certified nurse midwives, engage in autonomous practice in the performance of the acts listed in s. 464.012(4)(c).

3. Perform the general functions of an advanced practice registered nurse related to primary care.

4. For a patient who requires the services of a health care facility: a. Admit the patient to the facility. b. Manage the care received by the patient in the facility. c. Discharge the patient from the facility, unless prohibited by federal law or rule.

5. Provide a signature, certification, stamp, verification, affidavit, or endorsement that is otherwise required by law to be provided by a physician, except an advanced practice registered nurse registered under this section may not issue a physician certification

b) A certified nurse midwife must have a written patient transfer agreement with a hospital and a written referral agreement with a physician licensed under chapter 458 or chapter 459 to engage in nurse midwifery

c) An advanced practice registered nurse engaging in autonomous practice under this section may not perform any surgical procedure other than a subcutaneous procedure

d) The board shall adopt rules, in consultation with the council created in subsection (4), establishing standards of practice, for an advanced practice registered nurse registered under this section.

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AUTONOMOUS NURSE PRACTITIONER PRACTICE
FLA. STAT. §464.0123

PRACTITIONER PROFILE.—The department shall conspicuously distinguish an advanced practice registered nurse's license if he or she is registered with the board under this section and include the registration in the advanced practice registered nurse's practitioner profile

DISCLOSURES.—When engaging in autonomous practice, an advanced practice registered nurse registered under this section must provide information in writing to a new patient about his or her qualifications and the nature of autonomous practice before or during the initial patient encounter.

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RELATIVELY RECENT STATUTES

38

MANDATORY ELECTRONIC PRESCRIBING REQUIREMENT
FLA. STAT. §456.42(3)

- A health care practitioner licensed by law to prescribe who maintains a system of electronic health records or who prescribes as an owner, employee, or contractor of a licensed health care facility or practice that maintains electronic health records and who is prescribing in his or her capacity as such an owner, an employee, or a contractor, may only electronically transmit prescriptions
- After January 1, 2020, health care practitioners are required to electronically prescribe upon renewal of their license or by July 1, 2021, whichever is earlier.
- Exceptions to the law:
  - The practitioner and the dispenser are the same entity
  - The prescription cannot be transmitted electronically under the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT Standard
  - The practitioner has been issued a waiver by the department (cannot be more than 1 year in duration) due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the practitioner, or another exceptional circumstance demonstrated by the practitioner
  - The practitioner reasonably determines that it would be impractical for the patient in question to obtain a medicinal drug prescribed by electronic prescription in a timely manner and such delay would adversely impact the patient's medical condition
  - The practitioner is prescribing a drug under a research protocol
  - The prescription is for a drug for which the federal Food and Drug Administration requires the prescription to contain elements that may not be included in electronic prescribing
  - The prescription is issued to an individual receiving hospice care or who is a resident of a nursing home facility, or
  - The practitioner determines that it is in the best interest of the patient, or the patient determines that it is in his or her own best interest, to compare prescription drug prices among area pharmacies. The practitioner must document such determination in the patient's medical record.

39

NONOPIOID ALTERNATIVES
FLA. STAT. §456.44(7)

- The Legislature finds that every competent adult has the fundamental right of self-determination regarding decisions pertaining to his or her own health, including the right to refuse an opioid drug listed as a Schedule II controlled substance
- DOH shall develop and publish on its website an educational pamphlet regarding the use of nonopioid alternatives for the treatment of pain. The pamphlet shall, at a minimum, include:
  - Information on available nonopioid alternatives for the treatment of pain, including nonopioid medicinal drugs or drug products and nonpharmacological therapies.
  - The advantages and disadvantages of the use of nonopioid alternatives.
- Here is the link to access the DOH pamphlet: http://www.floridahealth.gov/programs-and-services/non-opioid-pain-management/_documents/alternatives-facts-8.5x11-eng.pdf
- Except in the provision of emergency services and care, before providing anesthesia or prescribing, ordering, dispensing, or administering an opioid drug listed as a Schedule II controlled substance for the treatment of pain, a health care practitioner, **excluding pharmacists**, must:
  - Inform the patient of available nonopioid alternatives for the treatment of pain, which may include nonopioid medicinal drugs or drug products, interventional procedures or treatments, acupuncture, chiropractic treatments, massage therapy, physical therapy, occupational therapy, or any other appropriate therapy as determined by the health care practitioner.
  - Discuss the advantages and disadvantages of the use of nonopioid alternatives, including whether the patient is at a high risk of, or has a history of, controlled substance abuse or misuse and the patient's personal preferences.
  - Provide the patient with the educational pamphlet from DOH
  - Document the nonopioid alternatives considered in the patient's record.

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USE OF TELEHEALTH TO PROVIDE SERVICES
FLA. STAT. §456.47(1) DEFINITION

- Definition of telehealth
  - the use of synchronous or asynchronous telecommunications technology by a telehealth provider to provide health care services, including, but not limited to:
    - assessment, diagnosis, consultation, treatment, and monitoring of a patient
    - transfer of medical data
    - patient and professional health-related education
    - public health services, and
    - health administration
  - The term does not include:
    - audio-only telephone calls
    - e-mail messages, or
    - facsimile transmissions

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USE OF TELEHEALTH TO PROVIDE SERVICES
FLA. STAT. §456.47(1) DEFINITION OF PROVIDERS

- Telehealth Provider
  - any individual who provides health care and related services using telehealth and who is licensed or certified as:
    - a behavior analyst; in emergency medical services (technicians); acupuncturist; medical doctor(MD)/physician; doctor of osteopathy(DO)/physician; chiropractor; podiatrist; optometrist; nurse; pharmacist; dentist; midwife; speech pathologist or audiologist, occupational therapist, radiological personnel, respiratory therapist, dietician or nutritionist, athletic trainer, orthotist or prosthetist or pedorthotist; electrolysist; massage therapist, licensed in multiphasic health testing services, clinical laboratory personnel, a dispenser of optical devices and hearing aids, physical therapist, psychologist, clinical social workers/marriage and family therapist/mental health counselors
    - any individual who provides health care and related services using telehealth who is licensed under a multistate health care licensure compact of which Florida is a member state
    - or an out-of-state telehealth provider who is registered and in compliance with Florida law

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USE OF TELEHEALTH TO PROVIDE SERVICES
FLA. STAT. §456.47(2) PRACTICE STANDARDS & FLA. STAT. §456.47 (3)RECORDS

- PRACTICE STANDARDS
  - A telehealth provider has the duty to practice in a manner consistent with his or her scope of practice and the prevailing professional standard of practice for a health care professional who provides in-person health care services to patients in this state
  - A telehealth provider may use telehealth to perform a patient evaluation
    - If a telehealth provider conducts a patient evaluation sufficient to diagnose and treat the patient, the telehealth provider is not required to research a patient's medical history or conduct a physical examination of the patient before using telehealth to provide health care services to the patient.
  - A telehealth provider may not use telehealth to prescribe a controlled substance unless the controlled substance is prescribed for the following:
    - The treatment of a psychiatric disorder;
    - Inpatient treatment at a hospital
    - The treatment of a patient receiving hospice services
    - The treatment of a resident of a nursing home facility

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USE OF TELEHEALTH TO PROVIDE SERVICES
FLA. STAT. §456.47(2) PRACTICE STANDARDS & FLA. STAT. §456.47 (3)RECORDS

- PRACTICE STANDARDS continued
  - A telehealth provider and a patient may be in separate locations when telehealth is used to provide health care services to a patient.
  - A nonphysician telehealth provider using telehealth and acting within his or her relevant scope of practice, as established by Florida law or rule, is not in violation of the practice of medicine or the practice of osteopathic medicine without a license
- RECORDS
  - A telehealth provider shall document in the patient's medical record the health care services rendered using telehealth according to the same standard as used for in-person services.
  - Medical records, including video, audio, electronic, or other records generated as a result of providing such services, are confidential.

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USE OF TELEHEALTH TO PROVIDE SERVICES
FLA. STAT. §456.47(4) REGISTRATION OF OUT-OF-STATE TELEHEALTH PROVIDERS

- A health care professional not licensed in this state may provide health care services to a patient located in this state using telehealth if the health care professional registers with the applicable board, or the department if there is no board, and provides health care services within the applicable scope of practice established by Florida law or rule.
- The board, or the department if there is no board, shall register a health care professional not licensed in this state as a telehealth provider if the health care professional:
  - Completes an application in the format prescribed by the department;
  - Is licensed with an active, unencumbered license that is issued by another state, the District of Columbia, or a possession or territory of the United States and that is substantially similar to a license issued to a Florida-licensed provider
  - Has not been the subject of disciplinary action relating to his or her license during the 5-year period immediately prior to the submission of the application
  - Designates a duly appointed registered agent for service of process in this state on a form prescribed by the department; and
  - Demonstrates to the board, or the department if there is no board, that he or she maintains liability insurance requirements
- The department shall use the National Practitioner Data Bank to verify the information submitted under this paragraph, as applicable.
- The website of a registered out of state telehealth provider must prominently display a hyperlink to the department's website containing information on their credentials as required under the statute

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USE OF TELEHEALTH TO PROVIDE SERVICES
FLA. STAT. §456.47(4) REGISTRATION OF OUT-OF-STATE TELEHEALTH PROVIDERS

- A health care professional may not register under this subsection if his or her license to provide health care services is subject to a pending disciplinary investigation or action, or has been revoked in any state or jurisdiction.
  - A health care professional registered under this subsection must notify the appropriate board, or the department if there is no board, of restrictions placed on his or her license to practice, or any disciplinary action taken or pending against him or her, in any state or jurisdiction
  - The notification must be provided within 5 business days after the restriction is placed or disciplinary action is initiated or taken.
- A provider registered under this subsection shall maintain professional liability coverage or financial responsibility, that includes coverage or financial responsibility for telehealth services provided to patients not located in the provider's home state, in an amount equal to or greater than the requirements for a licensed practitioner
- A health care professional registered under this subsection may not open an office in this state and may not provide in-person health care services to patients located in this state.
- A pharmacist registered under this subsection may only use a Florida pharmacy with a Florida permit, a nonresident pharmacy registered in Florida, or a nonresident pharmacy or outsourcing facility holding an active Florida permit to dispense medicinal drugs to patients located in this state

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USE OF TELEHEALTH TO PROVIDE SERVICES
FLA. STAT. §456.47(4) REGISTRATION OF OUT-OF-STATE TELEHEALTH PROVIDERS

- The department shall publish on its website a list of all registrants and include, to the extent applicable, each registrant's:
  - Name; Health care occupation; Completed health care training and education, including completion dates and any certificates or degrees obtained; Out-of-state health care license with the license number; Florida telehealth provider registration number; Specialty; Board certification; Five-year disciplinary history, including sanctions and board actions; Medical malpractice insurance provider and policy limits, including whether the policy covers claims that arise in this state; The name and address of the registered agent designated for service of process in this state.
- The board, or the department if there is no board, may take disciplinary action against an out-of-state telehealth provider registered under this subsection if the registrant:
  - Fails to notify the applicable board, or DOH if there is no board, of any adverse actions taken against his or her license as required
  - Has restrictions placed on or disciplinary action taken against his or her license in any state or jurisdiction.
  - Violates any of the requirements of this section.
  - Commits any act that constitutes grounds for disciplinary action under Florida general healthcare practitioner disciplinary statutes or the applicable practice act for Florida-licensed providers.
- The applicable Board or DOH if there is no applicable Board may suspend or revoke the provider's registration or issue a reprimand or letter of concern.
- A suspension may be accompanied by a corrective action plan determined by the Board or DOH, the completion of which may lead to the suspended registration being reinstated according to rules adopted by the board or DOH.

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USE OF TELEHEALTH TO PROVIDE SERVICES
FLA. STAT. §456.47(5) VENUE & (6) EXEMPTIONS

- VENUE (location of the court for a lawsuit)
  - Any act that constitutes the delivery of health care services is deemed to occur at the place where the patient is located at the time the act is performed or in the patient's county of residence.
  - Venue for a civil or administrative action initiated by the department, the appropriate board, or a patient who receives telehealth services from an out-of-state telehealth provider may be located in the patient's county of residence or in Leon County.
- TWO EXEMPTIONS
  - A health care professional who is not licensed to provide health care services in this state but who holds an active license to provide health care services in another state or jurisdiction, and who provides health care services using telehealth to a patient located in this state, is not subject to the registration requirement under this section if the services are provided:
    - 1) In response to an emergency medical condition
      - a medical condition manifesting itself by acute symptoms of sufficient severity, which may include severe pain, such that the absence of immediate medical attention could reasonably be expected to result in any of the following:
        - Serious jeopardy to patient health, including a pregnant woman or fetus.
        - Serious impairment to bodily functions.
        - Serious dysfunction of any bodily organ or part.
      - With respect to a pregnant woman:
        - That there is inadequate time to effect safe transfer to another hospital prior to delivery;
        - That a transfer may pose a threat to the health and safety of the patient or fetus; or
        - That there is evidence of the onset and persistence of uterine contractions or rupture of the membranes.
    - 2) In consultation with a health care professional licensed in this state who has ultimate authority over the diagnosis and care of the patient.

48

INTERNATIONAL EXPORT PHARMACY PERMITS

- Federal approval was required to create the programs
  - Effective date for the law was July 1, 2019, but it required federal approval first
  - Federal approval was obtained on December 18, 2019
- Florida will create 2 programs to import FDA approved prescription drugs into Florida:
  - The Canadian Drug Importation Program and
  - The International Drug Importation Program
- The Canadian Prescription Drug Importation Program will focus on the importation of drugs for programs such as Medicaid, the Department of Corrections and county health departments.
- The International Prescription Drug Importation Program will allow prescription drug importation from other countries in addition to Canada through the creation of two new permit types and a registration process.
  - The Department of Business and Professional Regulation will be responsible for implementing a new international prescription drug wholesaler permit and The Florida Department of Health (Board of Pharmacy) will be responsible for creating a new international export pharmacy permit.
  - In addition, a registration process for participating importers and exporters will be created by the Department of Business and Professional Regulation

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PRESCRIPTION DRUG IMPORTATION PROGRAM
FLA. STAT. §499.0285

- The department shall establish a program for the importation of safe and effective prescription drugs from foreign nations with which the United States has current mutual recognition agreements, cooperation agreements, memoranda of understanding, or other federal mechanisms recognizing their adherence to current good manufacturing practices for pharmaceutical products.
- ELIGIBLE PRESCRIPTION DRUGS - An eligible importer may import a prescription drug from an eligible exporter if:
  - The drug meets the United States Food and Drug Administration's standards related to safety, effectiveness, misbranding, and adulteration;
  - Importing the drug would not violate the patent laws of the United States; and
  - The drug is not (CANNOT IMPORT ANY OF THESE):
    - A controlled substance
    - A biological product
    - An infused drug
    - An intravenously injected drug
    - A drug that is inhaled during surgery, or
    - A drug that is a parenteral drug, the importation of which is determined by the United States Secretary of Health and Human Services to pose a threat to the public health.

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PRESCRIPTION DRUG IMPORTATION PROGRAM
FLA. STAT. §499.0285

EXPORTERS - defined in law as "an international prescription drug wholesale distributor, a nonresident prescription drug manufacturer registered to participate in the program, or an international export pharmacy that exports prescription drugs into this state under the program"

The following entities may export prescription drugs into this state under the program:
- An international prescription drug wholesale distributor
- A nonresident prescription drug manufacturer
- An international export pharmacy

- An eligible exporter must register with the department before exporting prescription drugs into this state under the program.
- An exporter may not distribute, sell, or dispense prescription drugs imported under the program to any person residing outside of the state.

IMPORTERS – defined in the law as a "wholesale distributor, pharmacy, or pharmacist importing prescription drugs into this state under the program"

The following entities may import prescription drugs under the program:
- A wholesale distributor
- A Florida permitted pharmacy
- A Florida licensed pharmacist

- An eligible importer must register with the department before importing prescription drugs into this state under the program.
- An importer may not distribute, sell, or dispense prescription drugs imported under the program to any person residing outside of the state.

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PRESCRIPTION DRUG IMPORTATION PROGRAM
FLA. STAT. §499.0285

PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION –

A participating importer must submit the following information and documentation to the department:

1. The name and quantity of the active ingredient of the prescription drug.
2. A description of the dosage form of the prescription drug.
3. The date on which the prescription drug is shipped.
4. The quantity of the prescription drug that is shipped.
5. The point of origin and destination of the prescription drug.
6. The price paid by the importer for the prescription drug.
7. Documentation from the exporter specifying: the original source of the prescription drug; and the quantity of each lot of the prescription drug originally received by the seller from that source.
8. The lot or control number assigned to the prescription drug by the manufacturer.
9. The name, address, telephone number, and professional license or permit number of the importer.
10. In the case of a prescription drug that is shipped directly by the first foreign recipient from the manufacturer:

- Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.
- Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into this state is not more than the quantity that was received by the first foreign recipient.
- For an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.

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PRESCRIPTION DRUG IMPORTATION PROGRAM
FLA. STAT. §499.0285

PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION – A participating importer must submit the following information and documentation to the department (continued)

11. In the case of a prescription drug that is not shipped directly from the first foreign recipient, documentation demonstrating that each batch in each shipment offered for importation into this state was statistically sampled and tested for authenticity and degradation.

12. For an initial imported shipment of a specific drug by an importer, the department shall ensure that each batch of the drug in the shipment is statistically sampled and tested for authenticity and degradation in a manner consistent with the federal act. The agency may contract with a vendor for these functions.

13. For every subsequent imported shipment of that drug by that importer, the department shall ensure that a statistically valid sample of the shipment was tested for authenticity and degradation in a manner consistent with the federal act.

14. Certify that the drug: Is approved for marketing in the United States and is not adulterated or misbranded; and meets all of the labeling requirements under 21 U.S.C. s. 352.

15. Maintain qualified laboratory records, including complete data derived from all tests necessary to ensure that the drug is in compliance with the requirements of this section.

16. Maintain documentation demonstrating that the testing required by this section was conducted at a qualified laboratory in accordance with the federal act and any other applicable federal and state laws and regulations governing laboratory qualifications.

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PRESCRIPTION DRUG IMPORTATION PROGRAM
FLA. STAT. §499.0285

PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION –

(a) A participating importer must submit the following information and documentation to the department (from previous slides)

(b) All testing required by this section must be conducted in a qualified laboratory that meets the standards under the federal act and any other applicable federal and state laws and regulations governing laboratory qualifications for drug testing.

(c) The vendor shall maintain information and documentation submitted under this section for a period of at least 7 years.

(d) A participating importer must submit all of the following information to the department:

The name and quantity of the active ingredient of the drug; A description of the dosage form of the drug; The date on which the drug is received; The quantity of the drug that is received; The point of origin and destination of the drug; The price paid by the importer for the drug

(e) A participating International Importation Drug supplier must submit the following information and documentation to the agency or the agency's designated vendor specifying all of the following:

The original source of the drug, including: The name of the manufacturer of the drug; The date on which the drug was manufactured; The location (country, state or province, and city) where the drug was manufactured; The date on which the drug is shipped; The quantity of the drug that is shipped; The quantity of each lot of the drug originally received and from which source; The lot or control number and the batch number assigned to the drug by the manufacturer; The name, address, and telephone number, and professional license or permit number of the importer.

(f) The department may require any other information necessary to ensure the protection of the public health.

IMMEDIATE SUSPENSION.–The department shall immediately suspend the importation of a specific prescription drug or the importation of prescription drugs by a specific importer if it discovers that any prescription drug or activity is in violation of this section. The department may revoke the suspension if, after conducting an investigation, it determines that the public is adequately protected from counterfeit or unsafe prescription drugs being imported into this state.

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INTERNATIONAL EXPORT PHARMACY PERMIT
FLA. STAT. §465.0157

- To participate as an exporter of prescription drugs into this state under the International Prescription Drug Importation Program, a pharmacy located outside of the United States must hold an international export pharmacy permit
- An international export pharmacy shall maintain at all times an active and unencumbered license or permit to operate the pharmacy in compliance with the laws of the jurisdiction in which the dispensing facility is located and from which the prescription drugs will be exported. Such jurisdiction must be in a country with which the United States has a current mutual recognition agreement, cooperation agreement, memorandum of understanding, or other federal mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products.
- An application for an international export pharmacy permit must be submitted on a form developed and provided by the board. The board may require an applicant to provide any information it deems reasonably necessary to carry out the purposes of this section.
- An applicant shall submit the following to the board to obtain an initial permit, or to the department to renew a permit:
  - Proof of an active and unencumbered license or permit to operate the pharmacy in compliance with the laws of the jurisdiction in which the dispensing facility is located and from which the prescription drugs will be exported.
  - Documentation demonstrating that the country in which the pharmacy operates has a current mutual recognition agreement, cooperation agreement, memorandum of understanding, or other federal mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products.
  - The location, names, and titles of all principal corporate officers and the pharmacist who serves as the prescription department manager for prescription drugs exported into this state under the International Prescription Drug Importation Program.
  - Written attestation by an owner or officer of the applicant, and by the applicant's prescription department manager, that:
    - The attestor has read and understands the laws and rules governing the manufacture, distribution, and dispensing of prescription drugs in this state.
    - A prescription drug shipped, mailed, or delivered into this state meets or exceeds this state's standards for safety and efficacy.
    - A prescription drug product shipped, mailed, or delivered into this state must not have been, and may not be, manufactured or distributed in violation of the laws and rules of the jurisdiction in which the applicant is located and from which the prescription drugs shall be exported.

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INTERNATIONAL EXPORT PHARMACY PERMIT
FLA. STAT. §465.0157

- An applicant shall submit the following to the board to obtain an initial permit, or to the department to renew a permit (continued):
  - A current inspection report from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which the applicant is located. The inspection report must reflect compliance with this section. An inspection report is current if the inspection was conducted within 6 months before the date of submitting the application for the initial permit or within 1 year before the date of submitting an application for permit renewal. If the applicant is unable to submit a current inspection report conducted by the regulatory or licensing agency of the jurisdiction in which the applicant is located and from which the prescription drugs will be exported, due to acceptable circumstances, as established by rule, or if an inspection has not been performed, the department must:
    - Conduct, or contract with an entity to conduct, an onsite inspection, with all related costs borne by the applicant;
    - Accept a current and satisfactory inspection report, as determined by rule, from an entity approved by the board; or
    - Accept a current inspection report from the United States Food and Drug Administration conducted pursuant to the federal Drug Quality and Security Act
- The department shall adopt rules governing the financial responsibility of the pharmacy permittee. The rules must establish, at a minimum, financial reporting requirements, standards for financial capability to perform the functions governed by the permit, and requirements for ensuring permittees and their contractors can be held accountable for the financial consequences of any act of malfeasance or misfeasance or fraudulent or dishonest act or acts committed by the permittee or its contractors.
- The permit will need to be renewed biennially (every 2 years) in accordance with the general permit requirements (465.022(14))

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CONTINUING EDUCATION REQUIREMENT
FLA. STAT. §456.0341 REQUIREMENTS FOR INSTRUCTION ON HUMAN TRAFFICKING

- One hour Human Trafficking CE required for these professions:
  - Acupuncture, Medicine, Osteopathic Medicine, Chiropractic Medicine, Podiatric Medicine, Optometry, **Pharmacy**, Dentistry, Nursing Home Administration, Occupational Therapy, Dietetics and Nutrition, Respiratory Care, Massage Therapy, and Physical Therapy.
  - The course must address both sex trafficking and labor trafficking, how to identify individuals who may be victims of human trafficking, how to report cases of human trafficking, and resources available to victims.
- Healthcare professionals licensed by these Boards must complete one hour of continuing education (CE) on human trafficking and post a sign about human trafficking in their office by January 1, 2021.

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CONTINUING EDUCATION REQUIREMENT
FLA. STAT. §456.0341 REQUIREMENTS FOR INSTRUCTION ON HUMAN TRAFFICKING

- Sign regarding human trafficking must be posted in a conspicuous place accessible to employees by January 1, 2021. The sign must be at least 11 x 15 inches and in at least 32-point type. The sign must contain statutorily required language and be posted in English and Spanish which is:
  - "If you or someone you know is being forced to engage in an activity and cannot leave, whether it is prostitution, housework, farm work, factory work, retail work, restaurant work, or any other activity, call the National Human Trafficking Resource Center at 888-373-7888 or text INFO or HELP to 233-733 to access help and services. Victims of slavery and human trafficking are protected under United States and Florida law."

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CONTINUING EDUCATION REQUIREMENT
FLA. STAT. §456.0341 REQUIREMENTS FOR INSTRUCTION ON HUMAN TRAFFICKING

- The Department has also provided Mandarin translations of these signs for use in offices where those languages are spoken. Here is a link to the English Spanish example sign provided by DOH that meets the statutory requirements when printed at the listed size: http://www.flhealthsource.gov/humantrafficking/docs/HumanTraffickingPoster-Eng-Span.pdf
- The course must be completed by January 1, 2021 and will count towards the required CE for renewal. The continuing education (CE) course on human trafficking must be specifically approved by their Board. Acceptable courses: https://courses.cebroker.com/search
- I contacted the DOH for clarification and this course will be required for each renewal similar to medication errors and controlled substances, but is not required for the initial renewal. It is required for renewals after the initial renewal.

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PHARMACIST CE REQUIREMENTS

Required CE Subject Area	Required Number of Hours	Important Information
General Hours	25	Can be ACPE or Board Approved
Controlled Substance (CS)	2	Board Approved
Medication Error (ME)	2	Board Approved
Human Trafficking (HT)	1	Board Approved

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TECHNICIAN CE REQUIREMENTS

REQUIRED SUBJECT AREA	REQUIRED NUMBER OF HOURS	IMPORTANT INFORMATION
General Hours	18	General hours can be either ACPE or Board approved, 4 of the 20 must be live.
Medication Errors CE	2	Medication Errors Must be Board Approved
Human Trafficking CE	1	Each licensee or certificate holder shall complete a board-approved, 1 hour continuing education course on human trafficking. The course may be included in the total general hours required and must be completed by January 1, 2021. Required in accordance with Section 456.0341, Florida Statutes.*Note: The 1 hour of Human Trafficking is included in the required general hours.

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FLORIDA RULES: FL BOARD OF PHARMACY

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SUBJECT MATTER FOR CONSULTANT PHARMACIST LICENSURE RENEWAL CONTINUING EDUCATION

FLA. RULE 64B16-26.302

A Consultant Pharmacist License Renewal Continuing Education Program must contain at least three (3) hours of training in any of the subjects specified below. Duplicate courses are not acceptable.

(1) Drug Therapy – Disease State. Patient Drug Therapy – management and monitoring.
- a) Drug, Disease State Information – In-depth disclosure of the drug or therapeutic class of drugs or disease state including pharmacology, side effects and interaction.
- b) New Therapeutic Modalities: Expansion of current drug therapy or treatment.
- c) Patient Assessment: Assessment techniques by consultant pharmacist to determine the need and effectiveness of indicated drug therapy along with identification and assessment of side effects on patient's well-being.
- d) Pertinent Laboratory Tests.
- e) Therapeutic Dosing.

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SUBJECT MATTER FOR CONSULTANT PHARMACIST LICENSURE RENEWAL CONTINUING EDUCATION
FLA. RULE 64B16-26.302

(2) Administrative Responsibilities.

a) Update on Administrative Responsibilities.
1. Legal requirements including statutes, rules and regulation (Federal and State).
2. The Joint Commission on the Accreditation of Healthcare Organizations.
3. Personnel requirements.
4. Health Insurance Portability and Accountability.

b) Focus on Consultant Pharmacist Practice Issues/Concerns.
1. How to get things accomplished in complex organizations.
2. Key contacts to be effective as a consultant pharmacist.
3. Considerations and preparation for site inspections.

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SUBJECT MATTER FOR CONSULTANT PHARMACIST LICENSURE RENEWAL CONTINUING EDUCATION
FLA. RULE 64B16-26.302

(3) Consultant Pharmacist Facility Responsibilities. This segment details the requirements in one of the facility types for which a consultant pharmacist is required. Only one practice setting may be included in each program.

a) Pharmacist-Medication Responsibilities – Assessment mechanism for delivery system, review procedures and monitoring processes.
b) Pharmacist-Patient Responsibilities – Patient assessment, laboratory test monitoring and therapeutic dosing.
c) Committee Responsibilities – Make-up and responsibilities for various facility committees.
d) Reporting requirements.

(4) Compounding sterile or nonsterile human drugs, or both.

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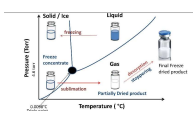

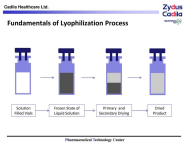

WHAT IS LYOPHILIZATION?

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THE STANDARDS OF PRACTICE FOR COMPOUNDING STERILE PRODUCTS: LYOPHILIZATION

64B16-27.797

- Sterile compounded products prepared using a process that includes lyophilization shall, in addition to all applicable provisions of USP Chapter 797, be subject to the following additional requirements:
  - **Compounded sterile products prepared for lyophilization shall be maintained in ISO 5 unidirectional laminar flow air** throughout sterilization, filling, and transport from the Primary Engineering Control ("PEC") into the lyophilizer. **Smoke studies shall be conducted** to demonstrate that transport from the PEC to the lyophilizer can be accomplished while maintaining ISO 5 laminar flow air at all times. **The smoke study shall be recorded and available for inspection**.
  - The **pharmacy shall establish, maintain, and follow policies and procedures for the high-level disinfection of the chamber, piping, and all other areas of the lyophilizer which pose a potential risk of contamination to the product.**
  - **The pharmacy shall, initially and after any change to the cleaning process or agents, validate a high-level disinfection process for the lyophilizer**. For the purposes of this rule, **validation means that the high-level disinfection process shall be proven with validation studies performed with the 5 aerobic bacterial and fungal ATCC organisms referenced in USP Chapter 71. The validation studies must be performed by an external vendor or by an internal laboratory. A pharmacy with an internal laboratory shall be separated from the compounding area and the work area to prevent contamination in the pharmacy. Documentation of validation shall be readily available for inspection**.
  - **A policy and procedure for cleaning the lyophilizer prior to high level disinfection to include cleaning agents and schedules shall be established. Documentation of cleaning shall be maintained and readily available for inspection**.

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THE STANDARDS OF PRACTICE FOR COMPOUNDING STERILE PRODUCTS: LYOPHILIZATION

64B16-27.797

- Sterile compounded products prepared using a process that includes lyophilization shall, in addition to all applicable provisions of USP Chapter 797, be subject to the following additional requirements:
  - The **pharmacy shall establish policies and procedures** as well as a **schedule for the maintenance of the lyophilizer**, which **shall be, at a minimum, based on the manufacturer's recommendations**. As leakage into the vacuum chamber poses a risk of contamination to the product, the **maintenance schedule shall include provisions for periodically testing for leaks** along with all recommended procedures described by the equipment manufacturer. **Documentation of routine maintenance shall be available for inspection**.
  - **The pharmacy shall develop standard operating procedures (SOPs) and a quality assurance program** to include validation of the filling process, container closure integrity, the frequent monitoring of fill volumes, training and assessment of personnel involved in all aspects of compounding sterile products for lyophilization, identification of overfills and underfills, equipment qualification, formula verification, and evaluation of the finished product for conformance to specifications.
  - **The pharmacy shall establish provisions for sterilizing the inert gas or air used for backfilling during the vacuum release phase. Filters shall be used to sterilize the gas or air and shall undergo manufacturer's recommended integrity testing.**
  - **Media fills shall be conducted using maximum batch sizes. The media fills shall demonstrate the filling, transportation to the lyophilizer, loading, and stoppering operations. Media shall not be frozen as part of the media fill as freezing of the media could reduce the ability of the media to support growth.**

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THE STANDARDS OF PRACTICE FOR COMPOUNDING STERILE PRODUCTS: LYOPHILIZATION

64B16-27.797

- Sterile compounded products prepared using a process that includes lyophilization shall, in addition to all applicable provisions of USP Chapter 797, be subject to the following additional requirements:
  - Personnel preparing sterile compounds for lyophilization shall **wear sterile Personal Protective Equipment (PPE)** that allows all exposed skin to be covered.
  - Personnel shall perform **Glove Fingertip Sampling with each batch after the fill and transport of the vials**. This sampling shall be **documented** and **incorporated into the batch record**.
  - **In-process acceptance criteria for each lyophilized product shall be established** and **may include criteria such as color, moisture limits and visual appearance. A one hundred percent (100%) visual examination of the finished product shall be conducted** to determine that the product conforms to the established visual criteria. This examination shall be **documented and incorporated in the batch record**.

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THE STANDARDS OF PRACTICE FOR COMPOUNDING STERILE PRODUCTS: LYOPHILIZATION
64B16-27.797

- Sterile compounded products prepared using a process that includes lyophilization shall, in addition to all applicable provisions of USP Chapter 797, be subject to the following additional requirements:
  - Laboratory testing
    - **Finished product testing shall be conducted on all batches.** Procedures for selecting samples from the batch for testing shall be written and followed. Procedures may include location of vials in the lyophilizer (e.g. select from each corner and the middle of each shelf) and position in the fill line (e.g. beginning, middle, and end of fill.)
    - **Finished product testing for all batches shall include sterility testing with methods described in USP Chapter 71 unless an alternative method has been validated** and shown to be equivalent or better. Diluents for reconstituting the vials for testing shall be preservative free. Lyophilized products released with beyond use dates within USP Chapter 797 guidelines shall, in lieu of sterility testing, conduct viable air, surface, and personnel (gloves and sleeves) sampling for each batch.
    - **Endotoxin limits shall be established for every lyophilized product.**
    - **Endotoxin testing for all lyophilized batches shall be performed in accordance with USP Chapter 85** and confirmed to fall within the set limits. This shall be **documented on the batch record**.
    - **Potency, radiochemical purity or applicable test to assure label claim shall be conducted on every batch** and **documented in the batch record**. In lieu of potency testing, weight-based verification may occur based on formula verification. Weight based verification will be based on ninety to one hundred ten percent (90% – 110%) theoretical yield. **Potency testing shall be based on USP monograph if one is available**; if not, it shall be based on ninety to one hundred ten percent (90% – 110%) theoretical yield. Initial potency testing shall be established based on worst case scenario.

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STANDARDS OF PRACTICE – DRUG THERAPY MANAGEMENT
64B16-27.830

(1) "Prescriber Care Plan" means an individualized assessment of a patient and orders for specific drugs, laboratory tests, and other pharmaceutical services intended to be dispensed or executed by a pharmacist. **The Prescriber Care Plan shall be written by a physician or physician assistant licensed pursuant to Chapter 458 or 459, F.S., a podiatric physician licensed under Chapter 461, F.S., or a dentist licensed under Chapter 466, F.S., or similar statutory provision in another jurisdiction, and may be transmitted by any means of communication.** The Prescriber Care Plan shall specify the conditions under which a pharmacist shall order laboratory tests, interpret laboratory values ordered for a patient, execute drug therapy orders for a patient, and notify the prescriber.

(2) "Drug Therapy Management" means any act or service by a pharmacist in compliance with orders in a Prescriber Care Plan.

(3) A pharmacist may provide Drug Therapy Management services for a patient, incidental to the dispensing of medicinal drugs or as a part of consulting concerning therapeutic values of medicinal drugs or as part of managing and monitoring the patient's drug therapy. A pharmacist who provides Drug Therapy Management services for a patient shall comply with orders in a Prescriber Care Plan, insofar as they specify:

a) Drug therapy to be initially dispensed to the patient by the pharmacist, or

b) Laboratory values or tests to be ordered, monitored and interpreted by the pharmacist, or

c) The conditions under which the duly licensed practitioner authorizes the execution of subsequent orders concerning the drug therapy for the patient, or

d) The conditions under which the pharmacist shall contact or notify the prescriber.

(4) A pharmacist who provides Drug Therapy Management services shall do so only under the auspices of a pharmacy permit that provides the following:

a) A transferable patient care record that includes:

1. A Prescriber Care Plan that includes a section noted as "orders" from a duly licensed prescriber for each patient for whom a pharmacist provides Drug Therapy Management services,
2. Progress notes; and,

b) A pharmaceutical care area that is private, distinct, and partitioned from any area in which activities other than patient care activities occur, and in which the pharmacist and patient may sit down during the provision of Drug Therapy Management services; and,

c) A continuous quality improvement program that includes standards and procedures to identify, evaluate, and constantly improve Drug Therapy Management services provided by a pharmacist.

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ALL PERMITS - DELIVERY OF MEDICINAL DRUGS
64B16-28.10801

- Neither a pharmacy nor a pharmacist shall dispense or deliver any adulterated medicinal drugs.
- All pharmacies must have and follow policies and procedures to ensure medicinal drugs are not adulterated at the time of reciept by the patient or their agent.
- The policies and procedures must include providing instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.

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OUTDATED PHARMACEUTICALS
64B16-28.110

- Under no circumstances may prescription drugs, pharmaceuticals or devices which bear upon the container an expiration or beyond use date which has been reached be sold or dispensed to the public.
- Accordingly, all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs and pharmaceuticals shall be removed or quarantined from active stock.

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FEDERAL STATUTES: US CONGRESS

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THE CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY (CARES) ACT OF 2020
THE OVER-THE-COUNTER MONOGRAPH SAFETY, INNOVATION, AND REFORM ACT (OTC MONOGRAPH REFORM ACT)

New OTC Monograph Approval Drug Review Process (Sections 3851-3853)

- Section 3851 of the Cares Act adds section 505G to the Federal Food, Drug, and Cosmetic Act (FDCA)
- These sections remove the current rulemaking procedures for over-the-counter (OTC) drugs, and institute an Administrative Order process.
  - Does not apply to homeopathic drugs, a category of drugs that were excluded from the original OTC drug review.
  - A nonprescription drug that does not comply with section 505G is "misbranded."
  - A drug would also be misbranded if it was "manufactured, prepared, propagated, compounded, or processed in a facility" that does not pay the user fees required under the new act.
- The OTC Monograph Reform Act makes significant changes to the slow notice-and-comment rulemaking process that has governed the development of OTC drug monographs by introducing administrative orders to replace rulemaking for the development of OTC monographs
- Article summarizing new changes:
  - https://www.arnoldporter.com/-/media/files/perspectives/publications/2020/04/otc-monograph-safety-innovation-reform-act-enacted.pdf?

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THE CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY (CARES) ACT OF 2020
THE OVER-THE-COUNTER MONOGRAPH SAFETY, INNOVATION, AND REFORM ACT (OTC MONOGRAPH REFORM ACT)

OTC Drug User Fees (Sections 3861-3862):

- **FDA can now collect user fees from the OTC drug industry to fund its monograph modernization activities.**
- FDA will begin collecting fees for Fiscal Year 2021 (Oct. 1, 2020), to be paid on July 1, 2020
- **There are two types of fees: 1) Facility Fees and 2) OTC Monograph Order Request Fees**

1) FACILITY FEES

- Two types of manufacturing facility fees will be assessed annually:
  - OTC monograph drug facility – Each foreign or domestic facility engaged in manufacturing or processing the finished dosage form of an OTC monograph drug will pay a "full" facility fee.
  - Contract manufacturing organization facility – Each foreign or domestic facility, where neither the owner nor any affiliate sells the finished OTC drug produced at the facility directly to US wholesalers, retailers, or consumers, will pay two-thirds of a facility fee.
- FDA will establish the fees to be paid by each category of manufacturer by May 11, 2020, and the fees will be based on a total facility fee revenue amount of approximately $8 million plus certain economic adjustments. The OTC drug manufacturing facilities that are subject to these fees shall be identified as part of each facility's drug establishment registration requirement.

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THE CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY (CARES) ACT OF 2020
THE OVER-THE-COUNTER MONOGRAPH SAFETY, INNOVATION, AND REFORM ACT (OTC MONOGRAPH REFORM ACT)

OTC Drug User Fees (Sections 3861-3862):

- FDA can now collect user fees from the OTC drug industry to fund its monograph modernization activities.

2) OTC Monograph Order Request Fees

- Paid by entities submitting industry-initiated administrative orders (except for certain changes in safety labeling)
- The fees are due on date of submission of an OTC monograph order request

Two types of OTC Monograph Order Request Fees

- A **Tier 2** request has a $100,000 fee and involves a request for information/wording changes to the Drug Facts Label of an OTC drug.
- A **Tier 1** request involves all other changes, including for new ingredients, new dosage forms, and Rx-to-OTC switches, and triggers a $500,000 fee (to be adjusted for inflation in future years).

- Non-payment of these user fees subjects the manufacturer or requestor to several potential penalties, such as inclusion on a public "arrears" list, drugs being deemed misbranded, order requests being refused, and ineligibility for meetings with FDA.
- The user fees have to be reauthorized by Congress after Fiscal Year 2025.

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HIPAA, TELEHEALTH, & CORONAVIRUS
MARCH 2020

- OCR allows good faith provision of telehealth during the COVID-19 nationwide public health emergency, so they will not penalize healthcare providers for using some technology platforms that would not normally be considered HIPAA compliant
  - This applies to both COVID-19 and non COVID-19 related treatment – so basically any healthcare service provided via telehealth
- As of March 19, 2020, OCR announced that covered health care providers may in good faith use popular applications for video chats, including Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, or Skype, to provide telehealth without risk of penalty (these platforms would not normally be considered compliant)
  - They do say, however, even with the emergency waiver, that you cannot use Facebook Live, Twitch, or TikTok to provide telehealth services (lol)
- Providers are encouraged to notify patients that these third-party applications potentially introduce privacy risks, and providers should enable all available encryption and privacy modes when using such applications;
- OCR suggested to use these vendors that claim to provide HIPAA-compliant video communication products that can enter into a HIPAA business associate agreement:
  - Skype for Business / Microsoft Teams
  - Updox
  - VSee
  - Zoom for Healthcare
  - Doxy.me
  - Google G Suite Hangouts Meet

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FEDERAL LAW FOR ELECTRONIC PRESCRIBING FOR CONTROLLED SUBSTANCES SUPPORT FOR PATIENTS AND COMMUNITIES ACT (H.R. 6) OCTOBER 2019

- Does many things including deterring prescription fraud and the diversion of opioids through the use of e-prescribing for opioids
- Prescriptions for a Schedule II, III, IV, or V controlled substance covered under a Part D prescription drug plan or Medicare Advantage Prescription Drug Plan (MA-PD) are required to be electronically prescribed starting January 1, 2021.
- The Secretary may waive this requirement in certain defined cases, such as reasonable technological limitations
  - The reasons for waiver (the exceptions) have been adopted into Florida law, so they are the same
  - These exceptions are listed on the previous slide under the Florida law
- Drug Enforcement Administration required to update its regulations pertaining to how prescribers authenticate prescriptions using biometrics (e.g. fingerprint scan, facial recognition technology) to keep up with changing technology
- Under the federal law, pharmacists are not required to verify that a practitioner has a waiver. The law is also not to be interpreted as affecting the pharmacists' ability to continue to dispense covered part D drugs from otherwise valid written, oral, or fax prescriptions that are consistent with laws and regulations. Also nothing in the law shall be interpreted as affecting the ability of an individual who is being prescribed a covered part D drug to designate a particular pharmacy to dispense the covered part D drug to the extent consistent with the requirements of the law.

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FEDERAL RULES: DEA & FDA

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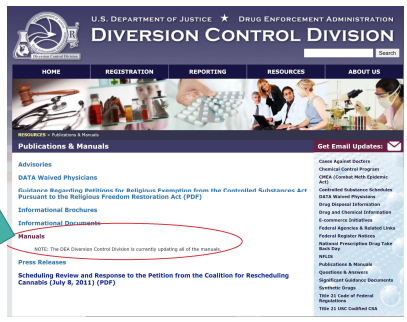
THE DEA IS CURRENTLY UPDATING THE DEA PHARMACIST'S MANUAL

NO ESTIMATED TIME OF COMPLETION



81

§1305.05 POWER OF ATTORNEY CHANGE
SEPTEMBER 2019

- Any person registered by DEA may legally authorize one or more individuals to sign Form 222 on his/her behalf
- May revoke authorization at any time by executing a notice of revocation
- Suggested format at 21 CFR 1305.05
  - http://www.deadiversion.usdoj.gov/21cfr/cfr/1305/1305_05.htm
- Granting of power of attorney and revocation of power of attorney requires two witnesses
  - **To grant power of attorney, need:**
    - **the signature of the registrant, if an individual; a partner of the registrant, if a partnership; or an officer of the registrant, if a corporation, corporate division, association, trust or other entity (does not expand this provision to include the person who signed the most recent application for registration)**
    - **the signature of the person being granted power of attorney and**
    - **the signatures of the 2 witnesses**
  - **To revoke, need signature of the person who signed the most recent DEA registration/reregistration and two witnesses**
- A power of attorney executed under this section may be signed electronically, by any or all of the persons required to sign

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DEA FORM 222 NEW SINGLE SHEET FORMAT
OCTOBER 2019

- The DEA is implementing a new single-sheet format for the DEA Form 222 used to order schedules I and II controlled substances – it will no longer be the traditional triplicate form
  - The rule provides for a two-year transition period, during which the existing triplicate version of the forms may continue to be used until their stock runs out or until Oct 30, 2021
- The new form will include 20 order lines, double the previous number, and will fit on a standard 8.5" x 11" sheet
  - The DEA is aware of the FDA's pending changes to the NDC format (FDA is running out of 5-digit manufacturer codes and needs to come up with something new), and, although no changes are being made to the NDC field on the new Form 222, the DEA will be monitoring the FDA's rulemaking on the matter, and will update the Form 222 as necessary in the future
- DEA Forms 222 are issued in mailing envelopes containing a predetermined number of forms based on the business activity of the registrant, each form consisting of one single-sheet
  - Additional forms can be specifically requested and a reasonable need for such additional forms must be shown
- A purchaser must make a copy of the original DEA Form 222 for its records and then submit the original to the supplier
  - The copy retained by the purchaser may be in paper or electronic form

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DEA FORM 222 NEW SINGLE SHEET FORMAT
§1305.11 PROCEDURE FOR OBTAINING DEA FORMS 222

- DEA Forms 222 are issued in mailing envelopes containing a predetermined number of forms based on the business activity of the registrant, each form consisting of one single-sheet. A limit, which is based on the business activity of the registrant, will be imposed on the number of DEA Forms 222 that will be furnished upon a requisition for order forms unless additional forms are specifically requested and a reasonable need for such additional forms is shown.
- Any person with an active registration that is authorized to order Schedule I and II controlled substances is entitled to obtain a DEA Form 222, which will be supplied at any time after the DEA registration is granted.
- Any person holding a registration authorizing the person to obtain a DEA Form 222 may requisition the forms through a DEA secured network connection or by contacting any Division Office or the Registration Section of the Administration through the customer service center.
- Each requisition must show the name, address, and registration number of the registrant and the number of DEA Forms 222 desired.
- DEA Forms 222 will have an order form number and be issued with the name, address and registration number of the registrant, the authorized activity, and schedules of the registrant.
- This information cannot be altered or changed by the registrant; the registrant must report any errors to the local Division Office or the Registration Section of the Administration to modify the registration.

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DEA FORM 222 NEW SINGLE SHEET FORMAT
§1305.12 PROCEDURE FOR EXECUTING DEA FORMS 222

- A purchaser must prepare and execute a DEA Form 222 by use of a typewriter, computer printer, pen, or indelible pencil.
- Only one item may be entered on each numbered line.
- An item must consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance.
- The number of lines completed must be noted on that form at the bottom of the form, in the space provided.
- DEA Forms 222 for carfentanil, etorphine hydrochloride, and diprenorphine must contain only these substances.
- The name and address of the supplier from whom the controlled substances are being ordered must be entered on the form. Only one supplier may be listed on any form.
- Each DEA Form 222 must be signed and dated by a person authorized to sign an application for registration or a person granted power of attorney to sign a Form 222. The name of the purchaser, if different from the individual signing the DEA Form 222, must also be inserted in the signature space.
- Unexecuted DEA Forms 222 may be kept and may be executed at a location other than the registered location printed on the form, provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of the location by any officer authorized to make inspections, or to enforce, any Federal, State, or local law regarding controlled substances.

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DEA FORM 222 NEW SINGLE SHEET FORMAT
§1305.13 PROCEDURE FOR FILLING DEA FORMS 222

- A purchaser must make a copy of the original DEA Form 222 for its records and then submit the original to the supplier. The copy retained by the purchaser may be in paper or electronic form.
- A supplier may fill the order, if possible and if the supplier desires to do so, and must record on the original DEA Form 222 its DEA registration number and the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser.
- **Suppliers can partially fill orders up to 60 days** - If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the DEA Form 222.
- **No DEA Form 222 is valid more than 60 days after its execution by the purchaser**
- The controlled substances must be shipped only to the purchaser and the location printed by the Administration on the DEA Form 222

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DEA FORM 222 NEW SINGLE SHEET FORMAT
§1305.13 PROCEDURE FOR FILLING DEA FORMS 222

- **The supplier must retain the original DEA Form 222 for the supplier's files.**
- Any supplier who is not required to report acquisition/disposition transactions to the Automation of Reports and Consolidated Orders System (ARCOS)(such as a practitioner) must make and submit a copy of the original DEA Form 222 to DEA, either by mail to the Registration Section, or by email to DEA.Orderforms@usdoj.gov.
- The copy must be forwarded at the close of the month during which the order is filled.
- If an order is filled by partial shipments, the copy must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires.
- The purchaser must record on its copy of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser.
- DEA Forms 222 submitted by registered procurement officers of the Defense Supply Center of the Defense Logistics Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the DEA Form 222, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

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DEA FORM 222 NEW SINGLE SHEET FORMAT
§1305.14 PROCEDURE FOR ENDORSING DEA FORMS 222

- A DEA Form 222, made out to any supplier who cannot fill all or a part of the order within the time limitation set forth (60 days) , may be endorsed to another supplier for filling.
- The endorsement must be made only by the supplier to whom the DEA Form 222 was first made, must state (in the spaces provided in Part 3 on the original DEA Form 222) the DEA number of the second supplier, and must be signed and dated by a person authorized to obtain and execute DEA Forms 222 on behalf of the first supplier.
- The first supplier may not fill any part of an order on an endorsed form. The second supplier may fill the order, if possible and if the supplier desires to do so, including shipping all substances directly to the purchaser.
- Distributions made on endorsed DEA Forms 222 must be reported by the second supplier in the same manner as all other distributions.

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DEA FORM 222 NEW SINGLE SHEET FORMAT
§1305.15 UNACCEPTED AND DEFECTIVE DEA FORMS 222

- A DEA Form 222 must not be filled if either of the following apply:

  (1) The order is not complete, legible, or properly prepared, executed, or endorsed.

  (2) The order shows any alteration, erasure, or change of any description.
- If a DEA Form 222 cannot be filled for any reason under this section, the supplier must return the original DEA Form 222 to the purchaser with a statement as to the reason (e.g., illegible or altered).
- A supplier may for any reason refuse to accept any order and if a supplier refuses to accept the order, a statement that the order is not accepted is sufficient for purposes of this paragraph.
- When a purchaser receives an unaccepted order, the original DEA Form 222 and the statement must be retained in the files of the purchaser in accordance with §1305.17.
- A defective DEA Form 222 may not be corrected; it must be replaced by a new DEA Form 222 for the order to be filled.

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DEA FORM 222 NEW SINGLE SHEET FORMAT
§1305.16 LOST AND STOLEN DEA FORMS 222

- If a purchaser ascertains that an unfilled DEA Form 222 has been lost, the purchaser must execute another and attach a statement containing the order form number and date of the lost form, and stating that the goods covered by the first DEA Form 222 were not received through loss of that DEA Form 222.
- A copy of the second form and a copy of the statement must be retained with a copy of the DEA Form 222 first executed.
- A copy of the statement must be attached to a copy of the second DEA Form 222 sent to the supplier.
- If the first DEA Form 222 is subsequently received by the supplier to whom it was directed, the supplier must mark upon the face "Not accepted" and return the original DEA Form 222 to the purchaser, who must attach it to the statement.
- Whenever any used or unused DEA Forms 222 are stolen or lost (other than in the course of transmission) by any purchaser or supplier, the purchaser or supplier must immediately upon discovery of the theft or loss, report the theft or loss to the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located, stating the serial number of each form stolen or lost.

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DEA FORM 222 NEW SINGLE SHEET FORMAT
§1305.16 LOST AND STOLEN DEA FORMS 222

- If the theft or loss includes any original DEA Forms 222 received from purchasers and the supplier is unable to state the serial numbers of the DEA Forms 222, the supplier must report the date or approximate date of receipt and the names and addresses of the purchasers.
- If any DEA Forms 222 are lost or stolen, and the purchaser is unable to state the order form numbers of the DEA Forms 222, the purchaser must report, in lieu of numbers of the forms, the date or approximate date of issuance.
- If any unused DEA Form 222 reported stolen or lost is subsequently recovered or found, the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located must immediately be notified.

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DEA FORM 222 NEW SINGLE SHEET FORMAT
§1305.17 PRESERVATION OF DEA FORMS 222

- The purchaser must retain a copy of each executed DEA Form 222 and all copies of unaccepted or defective forms with each statement attached.
- The supplier must retain the original of each DEA Form 222 that it has filled.
- DEA Forms 222 must be maintained separately from all other records of the registrant.
- DEA Forms 222 are required to be kept available for inspection for a period of two years.
- If a purchaser has several registered locations, the purchaser must retain a copy of the executed DEA Form 222 and any attached statements or other related documents (not including unexecuted DEA Forms 222, which may be kept elsewhere under §1305.12 at the registered location printed on the DEA Form 222.
- The supplier of thiafentanil, carfentanil, etorphine hydrochloride, and diprenorphine must maintain DEA Forms 222 for these substances separately from all other DEA Forms 222 and records required to be maintained by the registrant.
- Electronic copies of DEA Forms 222 will be deemed to be maintained separately from all other records of the registrant, for the purposes of this section, if such copies are readily retrievable separately from all other records.
- Electronic copies of DEA Forms 222 may be stored on a system at a location different from the registered location, provided such copies are readily retrievable at the registered location.

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DEA FORM 222 RULE UPDATE
§1305.18 RETURN OF UNUSED DEA FORMS 222

- If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes the name or address as shown on the purchaser's registration) or is suspended or revoked for all Schedule I and II controlled substances for which the purchaser is registered, the purchaser must return all unused DEA Forms 222 to the Registration Section.

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DEA FORM 222 RULE UPDATE
§1305.19 CANCELLATION AND VOIDING OF DEA FORMS 222

- A purchaser may cancel part or all of an order on a DEA Form 222 by notifying the supplier in writing of the cancellation.
  - The supplier must indicate the cancellation on the original DEA Form 222 sent by the purchaser by drawing a line through the canceled items and printing "canceled" in the space provided for the number of items shipped.
- A supplier may void part or all of an order on a DEA Form 222 by notifying the purchaser in writing of the voiding.
  - The supplier must indicate the voiding in the manner prescribed for cancellation.

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DEA FORM 222 NEW SINGLE SHEET FORMAT
§1305.20 TRANSITION PROVISIONS ALLOWING CONTINUED USE OF EXISTING STOCKS OF TRIPLICATE DEA FORMS 222

- Registrants may continue to use existing stocks of the triplicate DEA Form 222 until October 30, 2021.
- In any case, as soon as a registrant's supply of triplicate DEA Forms 222 is exhausted, the registrant must use the new single-sheet DEA Form 222.
- The provisions of this part are applicable to the use of triplicate forms, except for the specific rules as provided in this section.
- *Procedure for obtaining triplicate DEA Forms 222*. The DEA will no longer issue triplicate forms. Triplicate DEA Forms 222 will not be accepted after October 30, 2021.

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DEA FORM 222 NEW SINGLE SHEET FORMAT
§1305.20 TRANSITION PROVISIONS ALLOWING CONTINUED USE OF EXISTING STOCKS OF TRIPLICATE DEA FORMS 222

*Procedure for **executing** triplicate DEA Forms 222*

A purchaser must prepare and execute a triplicate DEA Form 222 simultaneously by means of interleaved carbon sheets that are part of the triplicate DEA Form 222. Triplicate DEA Form 222 must be prepared by use of a typewriter, pen, or indelible pencil.

Only one item may be entered on each numbered line. An item must consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance. The number of lines completed must be noted on that form at the bottom of the form, in the space provided. Triplicate DEA Forms 222 for carfentanil, etorphine hydrochloride, and diprenorphine must contain only these substances.

The name and address of the supplier from whom the controlled substances are being ordered must be entered on the form. Only one supplier may be listed on any form.

Each triplicate DEA Form 222 must be signed and dated by a person authorized to sign an application for registration or a person granted power of attorney to sign a DEA Form 222 under §1305.05. The name of the purchaser, if different from the individual signing the DEA Form 222, must also be inserted in the signature space.

Unexecuted DEA Forms 222 may be kept and may be executed at a location other than the registered location printed on the form, provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of the location by any officer authorized to make inspections, or to enforce, any Federal, State, or local law regarding controlled substances.

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DEA FORM 222 NEW SINGLE SHEET FORMAT
§1305.20 TRANSITION PROVISIONS ALLOWING CONTINUED USE OF EXISTING STOCKS OF TRIPLICATE DEA FORMS 222

- *Procedure for **filling** triplicate DEA Forms 222*
  - A purchaser must submit Copy 1 and Copy 2 of the triplicate DEA Form 222 to the supplier and retain Copy 3 in the purchaser's files.
  - A supplier may fill the order, if possible and if the supplier desires to do so, and must record on Copies 1 and 2 the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the triplicate DEA Form 222. No triplicate DEA Form 222 is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (c)(6) of this section.
  - The controlled substances must be shipped only to the purchaser and the location printed by the Administration on the triplicate DEA Form 222, except as specified in paragraph (c)(6) of this section.
  - The supplier must retain Copy 1 of the triplicate DEA Form 222 for his or her files in accordance with paragraph (g)(3) of this section and forward Copy 2 to the Special Agent in Charge of the Drug Enforcement Administration in the area in which the supplier is located. Copy 2 must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, Copy 2 must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires.
  - The purchaser must record on Copy 3 of the triplicate DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser.
  - DEA triplicate Forms 222 submitted by registered procurement officers of the Defense Supply Center of the Defense Logistics Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the triplicate DEA Form 222, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

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DEA FORM 222 NEW SINGLE SHEET FORMAT
§1305.20 TRANSITION PROVISIONS ALLOWING CONTINUED USE OF EXISTING STOCKS OF TRIPLICATE DEA FORMS 222

- *Procedure for endorsing triplicate DEA Forms 222*
  - A triplicate DEA Form 222, made out to any supplier who cannot fill all or a part of the order within the time limitation set forth in paragraph (c) of this section, may be endorsed to another supplier for filling.
  - The endorsement must be made only by the supplier to whom the triplicate DEA Form 222 was first made, must state (in the spaces provided on the reverse sides of Copies 1 and 2 of the triplicate DEA Form 222) the name and address of the second supplier, and must be signed by a person authorized to obtain and execute triplicate DEA Forms 222 on behalf of the first supplier.
  - The first supplier may not fill any part of an order on an endorsed form.
  - The second supplier may fill the order, if possible and if the supplier desires to do so, in accordance with paragraphs (c)(2) through (4) of this section, including shipping all substances directly to the purchaser.
  - Distributions made on endorsed triplicate DEA Forms 222 must be reported by the second supplier in the same manner as all other distributions.

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DEA FORM 222 NEW SINGLE SHEET FORMAT
§1305.20 TRANSITION PROVISIONS ALLOWING CONTINUED USE OF EXISTING STOCKS OF TRIPLICATE DEA FORMS 222

- *Unaccepted and defective triplicate DEA Forms 222*
- (1) A triplicate DEA Form 222 must not be filled if either of the following apply:
  - (i) The order is not complete, legible, or properly prepared, executed, or endorsed.
  - (ii) The order shows any alteration, erasure, or change of any description.
- (2) If a triplicate DEA Form 222 cannot be filled for any reason under this section, the supplier must return Copies 1 and 2 to the purchaser with a statement as to the reason (e.g. illegible or altered).
- (3) A supplier may for any reason refuse to accept any order and if a supplier refuses to accept the order, a statement that the order is not accepted is sufficient for purposes of this paragraph.
- (4) When a purchaser receives an unaccepted order, Copies 1 and 2 of the triplicate DEA Form 222 and the statement must be attached to Copy 3 and retained in the files of the purchaser in accordance with paragraph (g) of this section. A defective triplicate DEA Form 222 may not be corrected; it must be replaced by a new triplicate DEA Form 222 for the order to be filled.

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DEA FORM 222 NEW SINGLE SHEET FORMAT
§1305.20 TRANSITION PROVISIONS ALLOWING CONTINUED USE OF EXISTING STOCKS OF TRIPLICATE DEA FORMS 222

Lost and stolen triplicate DEA Forms 222.

- (1) If a purchaser ascertains that an unfilled triplicate DEA Form 222 has been lost, the purchaser must execute another in triplicate and attach a statement containing the serial number and date of the lost form, and stating that the goods covered by the first triplicate DEA Form 222 were not received through loss of that triplicate DEA Form 222. Copy 3 of the second form and a copy of the statement must be retained with Copy 3 of the triplicate DEA Form 222 first executed. A copy of the statement must be attached to Copies 1 and 2 of the second triplicate DEA Form 222 sent to the supplier. If the first triplicate DEA Form 222 is subsequently received by the supplier to whom it was directed, the supplier must mark upon the face "Not accepted" and return Copies 1 and 2 to the purchaser, who must attach it to Copy 3 and the statement. However, if the registrant no longer can use triplicate forms, then the registrant shall proceed by issuing a new single-sheet form in accordance with §1305.16.
- (2) Whenever any used or unused triplicate DEA Forms 222 are stolen or lost (other than in the course of transmission) by any purchaser or supplier, the purchaser or supplier must immediately upon discovery of the theft or loss, report the theft or loss to the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located, stating the serial number of each form stolen or lost.
- (3) If the theft or loss includes any original triplicate DEA Forms 222 received from purchasers and the supplier is unable to state the serial numbers of the triplicate DEA Forms 222, the supplier must report the date or approximate date of receipt and the names and addresses of the purchasers.
- (4) If an entire book of triplicate DEA Forms 222 is lost or stolen, and the purchaser is unable to state the serial numbers of the triplicate DEA Forms 222 in the book, the purchaser must report, in lieu of the numbers of the forms contained in the book, the date or approximate date of issuance.
- (5) If any unused triplicate DEA Form 222 reported stolen or lost is subsequently recovered or found, the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located must immediately be notified.

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DEA FORM 222 NEW SINGLE SHEET FORMAT
§1305.20 TRANSITION PROVISIONS ALLOWING CONTINUED USE OF EXISTING STOCKS OF TRIPLICATE DEA FORMS 222

Preservation of triplicate DEA Forms 222

- (1) The purchaser must retain Copy 3 of each executed triplicate DEA Form 222 and all copies of unaccepted or defective forms with each statement attached.
- (2) The supplier must retain Copy 1 of each triplicate DEA Form 222 that it has filled.
- (3) Triplicate DEA Forms 222 must be maintained separately from all other records of the registrant. Triplicate DEA Forms 222 are required to be kept available for inspection for a period of two years. If a purchaser has several registered locations, the purchaser must retain Copy 3 of the executed triplicate DEA Form 222 and any attached statements or other related documents (not including unexecuted triplicate DEA Forms 222, which may be kept elsewhere under paragraph (b)(5) of this section), at the registered location printed on the triplicate DEA Form 222.
- (4) The supplier of thiafentanil, carfentanil, etorphine hydrochloride, and diprenorphine must maintain triplicate DEA Forms 222 for these substances separately from all other DEA triplicate Forms 222 and records required to be maintained by the registrant.

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DEA FORM 222 NEW SINGLE SHEET FORMAT
§1305.20 TRANSITION PROVISIONS ALLOWING CONTINUED USE OF EXISTING STOCKS OF TRIPLICATE DEA FORMS 222

- *Return of unused triplicate DEA Forms 222.*
  - If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes the name or address as shown on the purchaser's registration) or is suspended or revoked under §1301.36 of this chapter for all schedule I and II controlled substances for which the purchaser is registered, the purchaser must return all unused triplicate DEA Forms 222 to the Registration Section.
- *Cancellation and voiding of triplicate DEA Forms 222.*
  - A purchaser may cancel part or all of an order on a triplicate DEA Form 222 by notifying the supplier in writing of the cancellation. The supplier must indicate the cancellation on Copies 1 and 2 of the triplicate DEA Form 222 by drawing a line through the canceled items and printing "canceled" in the space provided for the number of items shipped.
  - A supplier may void part or all of an order on a triplicate DEA Form 222 by notifying the purchaser in writing of the voiding. The supplier must indicate the voiding in the manner prescribed for cancellation in paragraph (i)(1) of this section.

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FEDERAL AGE TO PURCHASE TOBACCO PRODUCTS RAISED TO 21 DECEMBER 2019

- Federal law passed in December 2019, amending the Federal Food, Drug, and Cosmetic Act to raise the federal legal age to purchase tobacco products to 21 from 18

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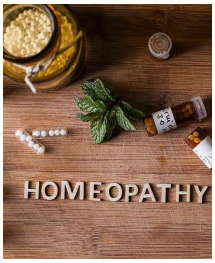
FDA REGULATION OF HOMEOPATHIC DRUGS OCTOBER 2019

- In October 2019, FDA withdrew its previous homeopathic "Compliance Policy Guidance" and proposed a new draft the "Revised Homeopathic Draft Guidance" which they were accepting comments on up until January 23, 2020.
- The Revised Homeopathic Draft Guidance explains that, in the absence of a safe harbor, all unapproved homeopathic drugs are "being marketed illegally and subject to FDA enforcement at any time."
- FDA is prioritizing for enforcement those homeopathic products that the agency determines pose the highest risks to consumers. Specifically, FDA is prioritizing *for enforcement* the following types of homeopathic drug products:
  - Products with reports of injury that, after evaluation, raise potential safety concerns;
  - Products that contain or purport to contain ingredients associated with potentially significant safety concerns;
  - Products for routes of administration other than oral and topical;
  - Products intended to be used for the prevention or treatment of serious and/or life-threatening diseases or conditions;
  - Products for vulnerable populations; and
  - Products with significant quality issues
- FDA is going after the above listed categories of homeopathic drugs first and can enforce against any others at any time.



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US SUPREME COURT

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RUTLEDGE V. PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

ORAL ARGUMENTS IN THE CASE WILL BE HEARD ON OCTOBER 6, 2020

Facts of the case

- In 2015, the legislature of Arkansas passed a law regulating the conduct of pharmacy benefits managers ("PBMs")–the entities that serve as intermediaries between health plans and pharmacies–in an attempt to address the trend in that state of significantly fewer independent and rural-serving pharmacies. PBMs perform numerous functions in this rule, including creating a maximum allowable cost ("MAC") list which sets reimbursement rates to pharmacies dispensing generic drugs. As a result of contracts between PBMs and some pharmacies, some other pharmacies might actually lose money on a particular prescription transaction. The Act sought to address this and other situations where the conduct of PBMs could cause harm to pharmacies.
- Pharmaceutical Care Management Association (PCMA), a pharmacy trade association, filed a lawsuit on behalf of its members claiming, among other arguments, that Arkansas Act 900 is preempted by both ERISA and Medicare Part D. The district court found that ERISA did preempt some portions of the Act but that Medicare Part D did not preempt the Act.
- On appeal, the U.S. Court of Appeals for the Eighth Circuit affirmed in part and reversed in part, finding that Act 900 was preempted by both ERISA and Medicare Part D. The appellate court noted that ERISA broadly preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plans." Because Act 900 "both relates to and has a connection with employee benefit plans," ERISA preempts it.

Question for the Court

- Does ERISA preempt an Arkansas law regulating pharmacy benefit managers' drug-reimbursement rates?

Citation from: https://www.oyez.org/cases/2020/18-540

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EXECUTIVE ORDERS

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EXECUTIVE ORDERS
AUGUST 3, 2020

- **Extends Telehealth Beyond the COVID Emergency** - Propose a Centers for Medicare & Medicaid Services (CMS) rule to extend parts of Medicare's broader coverage of telehealth beyond the end of the current public health emergency.
- **Improve Rural Healthcare** - Propose a payment model to improve rural healthcare through the Center for Medicare and Medicaid Innovation.

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EXECUTIVE ORDERS
JULY 24, 2020

- **Access to Affordable Life-saving Medications**: directs federally qualified health centers (FQHCs) to pass along discounts on insulin and epinephrine received from drug companies to certain low-income Americans
- **Increasing Drug Importation to Lower Prices for American Patients**: allows for individual state plans for the safe importation of certain drugs, authorizes the re-importation of insulin products made in the United States, and creates a pathway for widespread use of personal importation waivers at authorized pharmacies throughout the United States
- **Lowering Prices for Patients by Eliminating Kickbacks to Middlemen (PBMs):** prohibits secret deals between drug manufacturers and pharmacy benefit manager middlemen, ensuring patients directly benefit from available discounts at the pharmacy counter

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EXECUTIVE ORDERS
MARCH 16, 2020

- Prioritizing and Allocating Health and Medical Resources to Respond to the Spread of COVID-19
- Preventing Hoarding of Health and Medical Resources To Respond to the Spread of COVID-19

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