

AGENDA
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
COMPOUNDING RULES COMMITTEE

JUNE 9, 2014

Embassy Suites – Lake Buena Vista
4955 Kyngs Heath Road
Kissimmee, FL 34746
(407) 597-4000

Committee Members:

Michele Weizer, PharmD, Boca Raton, Chair
Leo “Lee” Fallon, BPharm, PhD The Villages
Debra Glass, BPharm, Tallahassee
Mark Mikhael, PharmD, Orlando

Board Staff:

Patrick Kennedy, Executive Director
Tammy Collins, Program Operations Administrator
Jay Cumbie, Regulatory Specialist II

Board Counsel:

David Flynn, Assistant Attorney General
Lynette Norr, Assistant Attorney General

Participants in this public meeting should be aware that these proceedings are being recorded.

Monday, June 9, 2014 - 3:00p.m.

1. Rule 64B16-27.797
2. Annual Regulatory Plan

64B16-27.797 The Standards of Practice for Compounding Sterile Products.

The purpose of this section is to assure positive patient outcomes through the provision of standards for 1) pharmaceutical care; 2) the preparation, labeling, and distribution of sterile pharmaceuticals by pharmacies, pursuant to or in anticipation of a prescription drug order; and 3) product quality and characteristics. These standards are intended to apply to all sterile pharmaceuticals, notwithstanding the location of the patient (e.g., home, hospital, nursing home, hospice, doctor's office, or ambulatory infusion center).

(1) **Adoption of the United States Pharmacopeia:** Beginning on **October 1, 2014**, all sterile compounding shall be performed in accordance with the minimum practice and quality standards of the following chapters of the United States Pharmacopeia (USP):

- a. Chapter 797, Pharmaceutical Compounding-Sterile Preparations;
- b. Chapter 1160, Pharmaceutical Calculations in Prescription Compounding;
- c. Chapter 71, Sterility Tests;
- d. Chapter 85, Bacterial Endotoxins Test;
- e. Chapter 731, Loss on Drying; and
- f. Chapter 1231, Water for Pharmaceutical Purposes.

All referenced chapters of the USP, in subsection (1) are specifically referring to the United States Pharmacopeia, 36th revision, Second Supplement, which is hereby incorporated and adopted by reference with the effective chapter dates of December 1, 2013. A copy of the USP chapters referenced in this rule may be examined and inspected, but not copied, at the office of the Board of Pharmacy in Tallahassee, Florida. A subscription to all relevant chapters is available for purchase at www.uspnf.com.

(2) **Minimum Standards:** The minimum practice and quality standards of the USP are adopted as the minimum standards to be followed when sterile products are compounded. However, nothing in this rule shall be construed to prevent the compounding of sterile products in accordance with standards that exceed the USP.

(3) **Current Good Manufacturing Practices:** The Board deems that this rule is complied with for any sterile products that are compounded in strict accordance with ~~Federal~~ Current Good Manufacturing Practices per ~~21 C.F.R. §§ 210.1–211.3~~, 21 U.S.C. § 501 (2012), adopted and incorporated herein by reference and 21 C.F.R. Parts 210 and 211 (2011), adopted and incorporated herein by reference.

(4) **Specific Exceptions to the United States Pharmacopeia:**

- a. Although the USP requires the donning of gloves prior to entry into the clean-room, all required donning of gloves can be performed after entry into the clean-room to avoid contamination of the gloves from the door handle or access device leading into the clean-room.
- b. USP Chapter 797 requires that: “When closed-system vial-transfer devices (CSTDs)(i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 (see *Table 1*) environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable.” For purpose of said provision, a “low volume of hazardous drugs” is defined as less than 40 doses per month.

(5) ~~**Additional Exceptions:**~~—The Board encourages the use of a Petition for Rulemaking to inform the Board of a request to add an additional exception to subsection (5) of this rule. A Petition for Rulemaking is controlled by section 120.54(7), of the *Florida Statutes*.

(6) ~~**Rule Conflicts:**~~—On **October 1, 2014** this rule shall control notwithstanding any rule to the contrary located throughout the provision of Chapter 64B16, F.A.C. Upon the effective date of this rule, the board will begin the process of repealing all rules that conflict with this rule.

Approved by the Compounding Committee on 2/10/14 and approved by the Board of 2/11/14. No SERC required.

64B16-27.797 The Standards of Practice for Compounding Sterile Products.

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(1) Adoption of the United States Pharmacopeia: Beginning on October 1, 2014, all sterile compounding shall be performed in accordance with the minimum practice and quality standards of the following chapters of the United States Pharmacopeia (USP):

- (a) Chapter 797, Pharmaceutical Compounding-Sterile Preparations;
- (b) Chapter 1160, Pharmaceutical Calculations in Prescription Compounding;
- (c) Chapter 71, Sterility Tests;
- (d) Chapter 85, Bacterial Endotoxins Test;
- (e) Chapter 731, Loss on Drying; and
- (f) Chapter 1231, Water for Pharmaceutical Purposes.

All referenced chapters of the USP, in subsection (1) are specifically referring to the United States Pharmacopeia, 36th revision, Second Supplement, which is hereby incorporated and adopted by reference with the effective chapter dates of December 1, 2013. A copy of the USP chapters referenced in this rule may be examined and inspected, but not copied, at the office of the Board of Pharmacy in Tallahassee, Florida. A subscription to all relevant chapters is available for purchase at www.uspnf.com.

(2) Minimum Standards: The minimum practice and quality standards of the USP are adopted as the minimum standards to be followed when sterile products are compounded. However, nothing in this rule shall be construed to prevent the compounding of sterile products in accordance with standards that exceed the USP.

(3) Current Good Manufacturing Practices: The Board deems that this rule is complied with for any sterile products that are compounded in strict accordance with Federal Current Good Manufacturing Practices per 21 C.F.R. §§ 210.1 - 211.3.

(4) Specific Exceptions to the United States Pharmacopeia:

(a) Although the USP requires the donning of gloves prior to entry into the clean-room, all required donning of gloves can be performed after entry into the clean-room to avoid contamination of the gloves from the door handle or access device leading into the clean-room.

(b) USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 (see Table 1) environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is

acceptable.” For purpose of said provision, a “low volume of hazardous drugs” is defined as less than 40 doses per month.

(c) USP Chapter 797 provides as follows in the “Facility Design and Environmental Controls” section: “An ISO Class 7 (see Table 1) buffer area and ante-area supplied with HEPA-filtered air shall receive an ACPH of not less than 30. The PEC is a good augmentation to generating air changes in the air supply of an area but cannot be the sole source of HEPA-filtered air. If the area has an ISO Class 5 (see Table 1) recirculating device, a minimum of 15 ACPHs through the area supply HEPA filters is adequate, providing the combined ACPH is not less than 30. More air changes may be required, depending on the number of personnel and processes. HEPA-filtered supply air shall be introduced at the ceiling, and returns should be mounted low on the wall, creating a general top-down dilution of area air with HEPA-filtered make-up air. Ceiling-mounted returns are not recommended.” Notwithstanding the quoted provision, pharmacies that meet the standards set forth in the section quoted above as of the effective date of this rule are not required to change the location of supply air or return filters or ducts so long as the ISO standards are maintained.

(5) Additional Exceptions: The Board encourages the use of a Petition for Rulemaking to inform the Board of a request to add an additional exception to subsection (5) of this rule. A Petition for Rulemaking is controlled by Section 120.54(7) of the Florida Statutes.

(6) Rule Conflicts: On October 1, 2014 this rule shall control notwithstanding any rule to the contrary located throughout the provision of Chapter 64B16, F.A.C. Upon the effective date of this rule, the board will begin the process of repealing all rules that conflict with this rule.

THIS RULE SHALL TAKE EFFECT OCTOBER 1, 2014.

DON GAETZ
President



Senator Rene Garcia, Chair
Representative James W. "J.W." Grant, Vice Chair
Senator Dwight Bullard
Senator Nancy C. Detert
Senator Miguel Diaz de la Portilla
Senator Geraldine F. "Geri" Thompson
Representative Douglas Vaughn "Doug" Broxson
Representative Charles David "Dave" Hood, Jr.
Representative Dave Kerner
Representative George R. Moraitis, Jr.
Representative Hazelle P. "Hazel" Rogers

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THE FLORIDA LEGISLATURE
**JOINT ADMINISTRATIVE
PROCEDURES COMMITTEE**

May 20, 2014

Mr. David Flynn
Assistant Attorney General
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Tallahassee, Florida 32399-1050

**Re: Department of Health: Board of Pharmacy
Rule 64B16-27.700, F.A.C.**

Dear Mr. Flynn:

I have reviewed proposed rule 64B16-27.700, "Definition of Compounding," which was advertised in the Florida Administrative Register on May 2, 2014. I have the following comments.

64B16-27.700(3)(a)-(f): It appears that these paragraphs authorize a compounding pharmacy to prepare compounded drug(s) for office use, without the name of an identifiable patient. Notwithstanding the board's letter of February 21, 2013 ("board's letter"), these rule paragraphs appear to be contrary to state and federal law, which the board is charged with enforcing, and which chapter 465 licensees are charged with following. For example, section 465.003(8) defines "medicinal drugs" or "drugs" to mean "'prescription' or 'legend' drugs which are required by federal or state law to be dispensed only on a prescription, but shall not include patents or proprietary preparations." Section 465.003(9) defines "patent or proprietary preparation" to mean "a medicine in its unbroken, original package which is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof and which is not misbranded under the provisions of the Florida Drug and Cosmetic Act [chapter 499, Florida Statutes]." Section 465.016(1)(e) provides grounds for denial of a license or disciplinary action against chapter

465 licensees for violating chapters 499 or 893, Florida Statutes, or the Federal Food, Drug and Cosmetic Act (including 21 U.S.C. section 353a, discussed *infra*), or the Federal Comprehensive Drug Abuse Prevention and Control Act. Similarly, section 465.023(1)(c) provides grounds for the revocation or suspension or other disciplinary action against a pharmacy permittee, or any affiliated person, partner, officer, director or agent of the permittee for violating any requirements of chapters 465, 499, or 893, Florida Statutes, the Federal Food, Drug, and Cosmetic Act, or the Federal Comprehensive Drug Abuse Prevention and Control Act. Section 465.022(11)(a) requires the prescription department manager of a permittee to maintain drug records required “by any state or federal law to be obtained by a pharmacy,” including chapters 465, 499, or 893, Florida Statutes, and requires the prescription department manager to ensure compliance with “all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.” Section 465.026(6) authorizes the “transfer of a prescription for medicinal drugs listed in Schedules III, IV, and V appearing in chapter 893 for the purpose of refill dispensing,” subject to the requirements of federal law. Thus, it appears that chapter 465 is replete with requirements that its licensees abide by the requirements of other state statutes, as well as federal law.

Moreover, any standards of practice adopted by the board must be consistent with the provisions of chapter 465:

Consistent with the provisions of this act, the board shall adopt by rule standards of practice relating to the practice of pharmacy which shall be binding on every state agency and shall be applied by such agencies when enforcing or implementing any authority granted by any applicable statute, rule, or regulation, whether federal or state.

§ 465.0155, Fla. Stat. (Emphasis added). If a rule and statute conflict, the statute controls. *See One Beacon Ins. v. Agency for Health Care Admin.*, 958 So. 2d 1127, 1129 (Fla. 1st DCA 2007) (“In cases of conflict, a statute takes precedence over an administrative rule.”). It appears that these rule paragraphs may be inconsistent with, and may conflict with, provisions of chapter 465, and other applicable Florida and federal laws.

Florida Law

The word “dispense” is defined in section 465.003(6), Florida Statutes, and means, “the transfer of possession of one or more doses of a

medical drug by a *pharmacist to the ultimate consumer or her or his agent.*” (Emphasis added). *See also* § 465.003(1), Fla. Stat. (defining “administration” as “the obtaining and giving of a single dose of medicinal drugs by a legally authorized person *to a patient for her or his consumption.*”) (emphasis added). These rule paragraphs appear to authorize a pharmacist to provide compounded drug(s) to the practitioner, who will administer the compounded drug(s) to patient(s). Although the board’s letter indicated that it interprets the words “agent” and “consumer” in the definition of “dispense” as including the patient’s health care provider, such an interpretation appears to conflict with the plain intent of the statute when read *in pari materia* with chapter 465. *See Fla. Dep’t of State, Div. of Elections v. Martin*, 916 So. 2d 763, 768 (Fla. 2005) (“The doctrine of *in pari materia* is a principle of statutory construction that requires that statutes relating to the same subject or object be construed together to harmonize the statutes and to give effect to the Legislature’s intent.”).

Further, it is appropriate to consult a dictionary to ascertain the range of possible interpretations of words not defined in the statute. *See Debarry Real Estate Holdings, LLC v. Dep’t of Bus. and Prof. Reg., Div. of Pari-mutuel Wagering*, 112 So. 3d 157, 166 (Fla. 1st DCA 2013) (utilizing the dictionary to determine the plain meaning of the statute when considering the agency’s interpretation). “Agent” is defined as “[o]ne who is authorized to act for or in place of another; a representative.” *Black’s Law Dictionary* 64 (7th ed. 1999). “Ultimate” is defined as “completed, last, final,” and “consumer” is defined as “one that consumes.” *Webster’s Third New International Dictionary (Unabridged)* 490, 2479 (1976). Consumer is also defined as “[a] person who buys goods or services for personal, family or household use, with no intention of resale; a natural person who uses products for personal rather than business purposes.” *Black’s* at 311.

Accordingly, it appears that the “ultimate consumer” is the intended patient. It does not appear there can be an agent for the ultimate consumer if the consumer is not identified at the time the drug is compounded. *See Fla. State Oriental Med. Ass’n, Inc. v. Slepkin*, 971 So. 2d 141 (Fla. 1st DCA 2007) (providing a discussion of the elements of actual and apparent authority necessary to create an agency relationship). As the court in *Randol Mill Pharmacy v. Miller*, 413 S.W.3d 844, 849-51 (Tex. App. 2013), *petition for review filed*, No. 13-1014 (Tex. Dec. 20, 2013), concluded, when a pharmacy provided a compounded drug pursuant to a “bulk phone order” for a physician’s office use, and not for any specific person, individual, or identifiable patient, the physician was not the

“agent” of some yet to be determined user of the compounded drug. Also, the physician who ordered the drug for office use could not be the ultimate user of the drug because he did not obtain the compounded drug to use on himself.

It appears that these rule paragraphs, which specifically authorize a pharmacist to “dispense and deliver a quantity of a compounded drug to a practitioner for office use by the practitioner,” enlarge and modify the provisions of sections 456.003 and 456.0155, and are therefore an invalid exercise of delegated legislative authority. *See* § 120.52(8)(c), Fla. Stat.

The statutory definition of “dispensing” also mandates that, as an element of dispensing:

[T]he pharmacist *shall*, prior to the actual physical transfer, interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment, and the pharmacist shall certify that the medicinal drug called for by the prescription is ready for transfer. The pharmacist *shall* also provide counseling on proper drug usage, either orally or in writing, if in the exercise of her or his professional judgment counseling is necessary.

§ 465.003(6), Fla. Stat. (Emphasis added).

Without requiring a prescription for an identified patient for whom the drug is compounded, it appears that the board may be authorizing a pharmacist to abdicate the exercise of her or his professional judgment. This appears to impermissibly modify the pharmacist’s duties prescribed by section 465.003(6). *See* § 120.52(8)(c), Fla. Stat.

Further, it appears that rule paragraphs (3)(a), (b), (c), (d), (e), and (f) contravene provisions of chapters 465 and 499, Florida Statutes. Paragraphs (3)(a), (b), and (c) authorize a pharmacist to deliver compounded drugs to a practitioner for office use provided:

(a) The quantity of compounded drug does not exceed the amount a practitioner anticipates may be used in the practitioner’s office before the expiration date of the drug;

(b) The quantity of compounded drug is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice;

(c) The quantity of compounded drug for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.

Rule paragraph (3)(d) requires the pharmacy and practitioner to enter into a written agreement and specifies what must be contained in the agreement. Rule paragraph (3)(e) states the records that must be maintained of all compounded drugs ordered by practitioners for office use. Paragraph (3)(f) contains certain labeling requirements for any compounded drug provided for office use, and does not require the name of the patient who will ultimately consume the product. None of these paragraphs requires the name of an identifiable patient to be provided to the compounding pharmacist.

If a compounded drug is ordered for office use without providing the pharmacist with the name of an identifiable patient, there does not appear to be a valid agency relationship between the ultimate consumer (the patient) and the practitioner for whom the compounded drug was prepared by the pharmacist. As stated in *Randol Mill Pharmacy*, if a drug was not compounded and prescribed for any particular person, pharmacy employees could not be compounding the drug for any particular person, and the ordering practitioner "cannot be the 'agent' of some yet be determined user." *Randol Mill Pharmacy*, 413 S.W.3d at 851.

Section 465.015(2)(c) provides, "[i]t is unlawful for any person: . . . [t]o sell or dispense drugs as defined in s. 465.003(8) without first being furnished with a prescription." Section 465.023(1)(h) further provides that:

(1) The department [of health] or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on probation, or otherwise discipline any pharmacy permittee if the permittee, or any affiliated person, partner, officer,

director, or agent of the permittee, including a person fingerprinted under s. 465.022(3), has:

* * *

(h) Dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the *pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed* and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

(Emphasis added). *See also* Fla. Admin. Code R. 64B16-30.001(2)(e)1.f.(I) and (II) (providing disciplinary guidelines of a \$1,500 fine to possible revocation upon licensees and permittees for violating section 465.015(2)(c), Fla. Stat.).

Instead of dispensing the drug to the ultimate consumer or her or his agent, it appears the pharmacy selling and delivering a compounded drug to the practitioner for office use is distributing the drug to a person other than the consumer or the consumer's agent. The selling of compounded prescription drugs to a practitioner for office use appears to constitute the wholesale distribution of a prescription drug. *See* § 499.003(54), Fla. Stat. It appears that a pharmacy selling compounded prescription drugs for administration to patients may be a wholesale distributor, which is defined in section 499.003(55) as:

[A]ny person engaged in wholesale distribution of prescription drugs *in or into* this state, including, but not limited to, manufacturers; repackagers; own-label distributors; jobbers; private-label distributors; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; exporters; *retail pharmacies*; and the agents thereof that conduct wholesale distributions.

(Emphasis added). *See also* § 499.01(1)(d) and (2)(d), Fla. Stat. Generally, "wholesale distribution" is defined in section

499.003(54) as the “distribution of prescription drugs to persons other than a consumer or patient.”

The term “distribution” is defined in section 499.003(17) as follows:

“Distribute” or “distribution” means to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver. The term does not mean to administer or dispense and does not include the billing and invoicing activities that commonly follow a wholesale distribution transaction.

It does not appear that the exception to the definition of “wholesale distribution” contained in section 499.003(54)(e) for the “lawful dispensing of a prescription drug in accordance with chapter 465” applies to this rule, because, as previously discussed, these rule paragraphs do not provide for the lawful dispensing of compounded drugs to the ultimate consumer or to her or his agent. *See* § 465.003(6), Fla. Stat. *Cf. Randol Mill Pharmacy.*

Notwithstanding the board’s letter, the legislature did not define “wholesale distribution” as the “production in mass for the transfer of goods to a retailer.” *See State v. Bodden*, 877 So. 2d 680, 685 (Fla. 2004) (“The legislature is presumed to know the meaning of words and the rules of grammar, and the only way the court is advised of what the legislature intends is by giving the generally accepted construction, not only to the phraseology of an act, but to the manner in which it is punctuated.”) (quoting *Florida State Racing Comm’n v. Bourquardez*, 42 So. 2d 87, 88 (Fla. 1949).

Therefore, it appears that pharmacies selling compounded drugs for office use which are not prepared pursuant to a specific patient prescription must obtain a prescription drug wholesale distributor permit from the Department of Business and Professional Regulation, pursuant to sections 499.01(1)(d) and (2)(d) and rule 61N-1.015(7)(e), Florida Administrative Code. Alternatively, it appears that these pharmacies could obtain a retail pharmacy drug wholesale distributor permit pursuant to sections 499.01(1)(f) and (2)(f), and rule 61N-1.015(7)(f), Florida Administrative Code, which would authorize transfers between a retail pharmacy and a health care practitioner licensed in this state and authorized by law to dispense or prescribe prescription drugs. *See* § 499.01(2)(f)4., Fla. Stat.

Please explain how this rule authorizing a pharmacy to provide a non-patient specific compounded drug to a practitioner without the appropriate permit is not an invalid exercise of delegated legislative authority because it enlarges, modifies, and contravenes chapters 465 and 499, and exceeds the board's rulemaking authority. *See* § 120.52(8)(b) and (c), Fla. Stat.

Unless the pharmacy that is compounding drugs for office use (without the name of an identified patient) obtains the appropriate permit, it appears it is unlawful for a practitioner to administer compounded drugs that are not prepared for an identifiable patient or pursuant to a valid patient prescription. Section 499.005 states in part:

It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

* * *

(4) The sale, distribution, purchase, trade, holding, or offering of any drug, device, or cosmetic in violation of this part.

* * *

(14) The purchase or receipt of a prescription drug from a person that is not authorized under this chapter to distribute prescription drugs to that purchaser or recipient.

(15) The sale or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess prescription drugs from the person selling or transferring the prescription drug.

* * *

(22) Failure to obtain a permit or registration, or operating without a valid permit when a permit or registration is required by this part for that activity.

Additionally, section 499.005 provides that it is unlawful for a person to perform or cause the following acts in this state:

(2) The adulteration or misbranding of any drug, device, or cosmetic.

(3) The receipt of any drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery of such drug, device, or cosmetic, for pay or otherwise.

A prescription drug is considered adulterated, if, among other reasons, it “has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so.” *See* § 499.006(10), Fla. Stat. *Cf.* § 499.0051(12)(a), Fla. Stat. (stating any person who sells, delivers, or holds or offers for sale any drug that is adulterated or misbranded commits a misdemeanor).

Please explain how a pharmacy providing a compounded drug for office use without the name of an identified patient pursuant to the provisions of these rule paragraphs is not providing adulterated or misbranded drugs to be administered by the practitioner in violation of Florida law.

Federal Law

It not only appears that there is no statutory authority for paragraphs (3)(a)-(f), it appears that these rule paragraphs may be preempted and expressly prohibited by federal law. *See Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 372 (2000).

The board is amending this rule to add paragraph (3)(g), which provides:

In the case of compounded sterile products intended for human use, the pharmacy must be in full compliance with 21 U.S.C. § 353b, including being registered as an Outsourcing Facility. 21 U.S.C. § 353b (eff. Nov. 27, 2013) is hereby adopted and incorporated by reference.

With this rule amendment, it appears that the board acknowledges that the Food, Drug, and Cosmetic Act (FDCA), as amended by the Drug Quality and Security Act (DQSA), Pub L. No. 113-54, governs human drug compounding in the United States. The DQSA, among other things, removed the advertising provisions in 21 U.S.C. section 353a(c) of the FDCA, which were held to be unconstitutional in *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002). As such, any ambiguity pertaining to the validity of section 353a has been removed.

As the Supreme Court explained in *Thompson*, 21 U.S.C. section 353a:

[E]xempts compounded drugs from the FDCA's "new drug" requirements and other requirements provided the drugs satisfy a number of restrictions. First, they must be compounded by a licensed pharmacist or physician *in response to a valid prescription for an identified individual patient, or, if prepared before the receipt of such a prescription, they must be made only in "limited quantities" and in response to a history of the licensed pharmacist's or physician's receipt of valid prescription orders for that drug product within an established relationship between the pharmacist, the patient, and the prescriber. . . .* Fifth, in States that have not entered into a "memorandum of understanding" with the FDA addressing the distribution of "inordinate amounts" of compounded drugs in interstate commerce, *the pharmacy, pharmacist, or physician compounding the drug may not distribute compounded drugs out of State in quantities exceeding five percent of that entity's total prescription orders.*

Id. at 364 (emphasis added) (citations omitted). It appears that rule paragraphs (3)(a), (b), and (c) are contrary to federal law, not only because they authorize "office use compounding" for patients who are not identified, but also because the quantities authorized therein appear to exceed the quantities authorized by 21 U.S.C. section 353a. Please explain.

If pharmacies compounding for office use are not provided with the name of an identified patient for whom the drug is compounded, please explain how the board can comply with the requirements of 21 U.S.C. section 353a-1. requiring the Secretary of Health and Human Services to receive submissions from State boards of pharmacy expressing concerns that a compounding pharmacy may be acting contrary to 21 U.S.C. section 353a.

It does not appear that these rule paragraphs provide any prohibition against providing these compounded drugs for office use in interstate commerce. Please explain how pharmacies that compound drugs for office use for unidentified patients pursuant to paragraphs (3)(a) through (f) comply with section 499.023, which states:

A person may not sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug unless an approved application has become effective under s. 505 of the federal act [21 U.S.C. section 355] or unless otherwise permitted by the Secretary of the United States Department of Health and Human Services for shipment in interstate commerce.

21 U.S.C. section 355(a) provides that, “No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.” *See also Thompson*, 535 U.S. at 364 (summarizing the 1997 amendments to the FDCA, exempting compounded drugs from the FDCA’s “new drug” requirements if certain restrictions, discussed *supra*, are met).

Please explain why this rule does not violate the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. sections 301-392. *See Fla. Admin. Code R. 64B16-30.001(2)(e)5.* (providing disciplinary guidelines of a \$2,500 fine to possible revocation for violating 21 U.S.C. sections 301-392).

CS/HB 7077, effective October 1, 2014

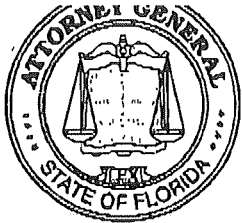
Please note CS/HB 7077 passed in the 2014 legislative session. This bill, if it becomes law, may further affect the validity of this rule. For example, it appears that the definition of “compounding” in the unnumbered introductory paragraph differs from the definition of “compounding” which is contained in section 1 of this bill. If the bill becomes law, please revise this rule to comport with its provisions by October 1, 2014.

As always, please let me know if you have any questions. Otherwise, I look forward to your response.

Sincerely,



Marjorie C. Holladay
Chief Attorney



PAM BONDI
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May 21, 2014

Marjorie Holladay, Senior Attorney
Joint Administrative Procedures Committee
Room 680, Pepper Building
Tallahassee, FL 32399-1400

Re: Board of Pharmacy
Fla. Admin. Code R. 64B16-27.700

Dear Ms. Holladay:

After a careful review of your correspondence, and with the acknowledgement that the Committee (JAPC) has authority to review even an existing rule, I note that you have highlighted some state and federal law concerns aimed primarily at portions of the rule that are currently in effect. There does not appear to be any concerns with the Board's current proposed amendment which will add paragraph (g) to subsection (3). As you are aware, this proposed amendment makes clear that compliance with 21 U.S.C. § 353b, must be complied with when drugs are compounded for office-use if the drug product is a sterile compounded drug intended for human use. The proposed amendment portion is critical to further defining the parameters of compounding in Florida.

Therefore, the Board intends to proceed forward, as soon as permissible under the provision of the APA, with this one portion of the proposed amendment. In the interim, I will add the entirety of this rule to the Annual Regulatory Plan for a comprehensive review of the entire rule by the Board. I will also forward a copy of your correspondence to the Board for review and consideration. Therefore, it is respectfully requested that the Committee certify this rule amendment for adoption when presented with such a request by the Board.

I thank you for your time and consideration. Please feel free to contact me directly if you have any further questions or concerns.

Sincerely,

David D. Flynn, Esquire
Assistant Attorney General
Attorney for the Board

cc: Patrick Kennedy, Executive Director
Ed Tellechea, Bureau Chief
Angela Southwell, Paralegal Specialist

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