AGENDA

Florida Board of Pharmacy
Rules Committee Meeting
April 3, 2018 – 9:00 a.m.

Residence Inn Tallahassee Universities at the Capitol
600 West Gaines Street
Tallahassee, Florida 32304
850-329-9080

Committee Members:
Jeffrey Mesaros, PharmD, JD – Chair
David Bisaillon
Jonathan Hickman, PharmD
Jeenu Philip, BPharm
Blanca Rivera, BPharm, MBA

Board Staff
C. Erica White, MBA, JD - Executive Director
Savada Knight, Regulatory Supervisor

Board Counsel:
David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

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

1. **Rule 64B16-28.141, F.A.C. -** Requirements for an Automated Pharmacy System in a Community Pharmacy

2. **Rule 64B16-26.351, F.A.C.** - Standards for Approval of Registered Pharmacy Technician Training Programs and Review/Update of Technician Duties Research

3. **Rule 64B16-27.410, F.A.C. -** Registered Pharmacy Technician to Pharmacist Ratio (pg. 5)

4. **Rule 64B16-27.450, F.A.C.** – Prescription Department Managers (pg. 18)

5. **Rule 64B16-28.501, F.A.C.** – Institutional Permit – Consultant Pharmacist of Record (pg. 21)

6. **Rule 64B16-27.630, F.A.C. -** Additional Immunizations or Vaccines Which May Be Administered

7. **Rule 64B16-28.100 F.A.C.** – Pharmacy Permits – Applications and Permitting (pg. 25)

8. **Rule 64B16-28.100, F.A.C., and Amendments to Pharmacy Permit Applications:**
   - Community Pharmacy Permit – DH MQA 1214 (pg. 31)
   - Institutional Pharmacy Permit – DH MQA 1215 (pg. 49)
   - Internet Pharmacy Permit – DH MQA 1216 (pg. 71)
   - Nuclear Pharmacy Permit – DH MQA 1218 (pg. 89)
   - Special Pharmacy Permit – DH MQA 1220 (pg. 109)
   - Special Sterile Compounding Pharmacy Permit – DH MQA 1270 (pg. 129)
   - Change in Prescription Department Manager - DH-PH10 (pg. 150)
   - Change in Consultant Pharmacist of Record - DH-MQA 1184 (pg. 151)

9. **Rule 64B16-30.001, F.A.C.** - Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances (pg. 152)

10. **Rule 64B16-30.002, F.A.C.** - Minor Violations (pg. 168)

11. **2018 Legislation: Required Rulemaking**
    - HB 21 (pg. 171)
    - HB 675 (pg. 376)

12. **Old Business / New Business**

14. **Public Comment**

15. **Adjourn**

TAB #1

TAB #2

TAB #3

Notice of Proposed Rule

DEPARTMENT OF HEALTH
Board of Pharmacy
RULE NO.: RULE TITLE:
64B16-27.410 Registered Pharmacy Technician to Pharmacist Ratio
PURPOSE AND EFFECT: The Board proposes the rule amendment to update the ratios of registered pharmacy technicians to pharmacists and to add language regarding determination of the appropriate pharmacist-technician supervision ratio.
SUMMARY: The ratios of registered pharmacy technicians to pharmacists will be updated and language regarding determination of the appropriate pharmacist-technician supervision ratio will be added.
SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION:
The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of $200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.
The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: During discussion of the economic impact of this rule at its Board meeting, the Board, based upon the expertise and experience of its members, determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. No person or interested party submitted additional information regarding the economic impact at that time.
Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.
RULEMAKING AUTHORITY: 456.069(1), 465.005, 465.014, 465.017, 465.022 FS.
LAW IMPLEMENTED: 465.014, 465.022 FS.
IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: C. Erica White, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254.

THE FULL TEXT OF THE PROPOSED RULE IS:

64B16-27.410 Registered Pharmacy Technician to Pharmacist Ratio.

(1) through (4) No change.

(5) Six ~~Four~~ to One (6~~4~~:1) Ratio: Any pharmacy or any pharmacist may allow a supervision ratio of up to six (6) ~~four (4)~~ registered pharmacy technicians to one (1) pharmacist (6 ~~4~~:1), as long as the pharmacist or pharmacy is not engaged in sterile compounding.

(6) Eight ~~Six~~ to One (8~~6~~:1) Ratio:

(a) Non-dispensing pharmacies. Any pharmacy which does not dispense medicinal drugs, and the pharmacist(s) employed by such pharmacy, may allow a supervision ratio of up to eight ~~six~~ (8~~6~~) registered pharmacy technicians to one (1) pharmacist (8~~6~~:1), as long as the pharmacy or pharmacist is not engaged ~~involved~~ in sterile compounding.

(b) Dispensing pharmacies. A pharmacy which dispenses medicinal drugs may utilize a eight ~~six~~ to one (8~~6~~:1) ratio in any physically separate area of the pharmacy from which medicinal drugs are not dispensed. A "physically separate area" is a part of the pharmacy which is separated by a permanent wall or other barrier which restricts access between the two areas.

(7) The determination of the appropriate pharmacist-technician supervision ratio shall be made by the Prescription Department Manager or Consultant Pharmacist of Record. No other person, permitee, or licensee shall interfere with the exercise of the Prescription Department Manager or Consultant Pharmacist of Record's independent professional judgement in setting the pharmacist to technician ratio(s).

Rulemaking Authority 465.005, 456.069(1), 465.014, 465.017, 465.022 FS. Law Implemented 465.014, 465.022 FS. History–

New 2-14-77, Amended 3-31-81, Formerly 21S-4.02, Amended 8-31-87, Formerly 21S-4.002, Amended 9-9-92, Formerly 21S-27.410, 61F10-27.410, Amended 1-30-96, Formerly 59X-27.410, Amended 2-23-98, 10-15-01, 1-1-10, 1-7-15, 7-6-15,_____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy
NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Pharmacy
DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 12, 2017
DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: January 11, 2018

JOE NEGRON
President

RICHARD CORCORAN
Speaker

THE FLORIDA LEGISLATURE

JOINT ADMINISTRATIVE PROCEDURES COMMITTEE

Senator Kevin Rader, Chair
Representative George R. Moraitis, Jr., Vice Chair
Senator Daphne Campbell
Senator George B. Gainer
Senator Rene Garcia
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Representative Barrington A. "Barry" Russell

KENNETH J. PLANTE
COORDINATOR
Room 680, Pepper Building
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www.japc.state.fl.us
joint.admin.procedures@leg.state.fl.us

February 22, 2018

Mr. David Flynn
Assistant Attorney General
Department of Legal Affairs
PL-01, The Capitol
Tallahassee, Florida 32399-1050

Re: Department of Health: Board of Pharmacy
Proposed Rule 64B16-27.410

Dear Mr. Flynn:

I have reviewed proposed rule 64B16-27.410, "Registered Pharmacy Technician to Pharmacist Ratio," which was advertised in the Florida Administrative Register on February 6, 2018. I have the following comments.

64B16-27.410(4): This subsection states that any pharmacy or any pharmacist engaged in sterile compounding shall not exceed a ratio of up to three registered pharmacy technicians to one pharmacist. Section 465.014(1) states in part: "A licensed pharmacist may not supervise more than one registered pharmacy technician unless otherwise permitted by the guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise more than one pharmacy technician." Please explain how this rule provision establishes guidelines that explain the circumstances under which a pharmacist may supervise more than one pharmacy technician. *See* § 120.52(8)(c), Fla. Stat.

64B16-27.410(5): This subsection states that any pharmacy or any pharmacist may allow a supervision ratio of up to six registered pharmacy technicians to one pharmacist, as long as the pharmacist or pharmacy is not engaged in sterile compounding. Section 465.014(1) states in part: "A licensed pharmacist may not supervise more than one registered pharmacy technician unless otherwise permitted by the guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise more than one pharmacy technician." Please explain how this rule provision establishes guidelines that explain the circumstances under which a pharmacist may supervise more than one pharmacy technician. *See* § 120.52(8)(c), Fla. Stat.

64B16-27.410(6)(a): This paragraph states that any pharmacy that does not dispense medicinal drugs, and the pharmacy is employed by that pharmacy, may allow a supervision ratio of up to eight registered pharmacy technicians to one pharmacist, as long as the pharmacy or pharmacist is not engaged in sterile compounding. Section 465.014(1) states in part: "A licensed pharmacist may not supervise more than one registered pharmacy technician unless otherwise permitted by the guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise more than one pharmacy technician." Please explain how this rule provision establishes guidelines that explain the circumstances under which a pharmacist may supervise more than one pharmacy technician. *See* § 120.52(8)(c), Fla. Stat.

64B16-27.410(6)(b): This paragraph states that a pharmacy that dispenses medicinal drugs, may utilize an eight to one ratio in any physically separate area of the pharmacy from which medical drugs are not dispensed.

"[A] eight to one" should be "an eight to one."

Section 465.014(1) states in part: "A licensed pharmacist may not supervise more than one registered pharmacy technician unless otherwise permitted by the guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise more than one pharmacy technician." Please explain how this rule provision establishes guidelines that explain the circumstances under which a pharmacist may supervise more than one pharmacy technician. *See* § 120.52(8)(c), Fla. Stat.

64B16-27.410(7): This subsection states:

> The determination of the appropriate pharmacist-technician supervision ratio shall be made by the Prescription Department Manager or Consultant Pharmacist of Record. No other person, permitee [sic], or licensee shall interfere with the exercise of the Prescription Department Manager or Consultant Pharmacist of Record's independent professional judgement in setting the pharmacist to technician ratio(s).

Please correct the spelling of "permittee." Also, please consider changing "judgement" to "judgment."

Please explain what the board means by "appropriate" pharmacist-technician supervision ratio. *See* § 120.52(8)(d), Fla. Stat.

Section 465.014(1) requires the board to establish guidelines to be following in determining the circumstances under which a licensed pharmacist may supervise more than on pharmacy technician. Please explain why this rule provision does not delegate the board's legislatively prescribed responsibility to establish those guidelines. *See Procacci v. Dep't of Health & Rehabilitative Serv.*, 603 So. 2d 1299, 1300 (Fla. 1st DCA 1992) ("An agency may not delegate to a hearing officer its legislatively prescribed responsibilities."); *Booker Creek Pres., Inc. v. Sw. Fla. Water Mgmt. Dist.*, 534 So. 2d 419, 424 (Fla. 5th DCA 1988) ("The District cannot delegate its statutory duty to other state agencies.").

Please explain whether this rule provision will prohibit the Department of Health or the Board of Pharmacy from "interfer[ing] with" the judgment of the Prescription Department Manager or Consultant Pharmacist of Record in setting the pharmacist to technician ratios.

Please explain whether, upon inspection of the pharmacy, the department or the board may initiate disciplinary proceedings or otherwise decide that the determination of ratios by the Prescription Department Manager or the Consultant Pharmacist of Record is incorrect.

Please explain how the pharmacists and registered pharmacy technicians will be aware of the ratio established by either the Prescription Department Manager or the Consultant Pharmacist of Record.

Please explain whether this rule paragraph would allow the Prescription Department Manager or Consultant Pharmacist of Record to exceed the ratios established in rule subsections (4), (5), and (6). *See* § 120.545(1)(i), Fla. Stat.

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

Sincerely,

Marjorie C. Holladay
Chief Attorney

cc: Mr. Edward A. Tellechea, Chief Assistant Attorney General
Mr. Lawrence Harris, Assistant Attorney General

MCH:DF WORD/MARJORIE/64B16_27.410LS022218_164251

PAM BONDI
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Administrative Law Bureau

Lawrence D Harris
Assistant Attorney General
PL-01 The Capitol
Tallahassee, FL 32399-1050
Phone (850) 414-3771 Fax (850) 922-6425
Lawrence Harris@myfloridalegal com

March 8, 2018

RECEIVED
2018 MAR -8 PM 3: 12
JOINT ADMINISTRATIVE PROCEDURES COMMITTEE

Ms. Marjorie C. Holladay
Chief Attorney
Joint Administrative Procedures Committee
Room 680, Pepper Building
111 W. Madison Street
Tallahassee, Florida 32399-1400

Re: Department of Health, Board of Pharmacy
Rule 64B16-27.410, F.A.C.

Dear Ms. Holladay:

I am writing in response to your February 22, 2018, correspondence regarding the above referenced rule, wherein you make a number of comments, which the Board will address in turn below.

27.410(4), (5), (6)(a), and (6)(b). The Board agrees that section 465.014(1), F.S., authorizes the board to adopt guidelines for the supervision of more than one registered pharmacy technician by a licensed pharmacist ("technician ratio"). The Board believes this rule does just that. The Merriam-Webster Dictionary defines "guideline" as "an indication or outline of policy or conduct." Subsection (2) requires the establishment of, and training regarding, the policies and procedures of the pharmacy regarding registered pharmacy technicians, including training, supervision, minimum qualifications, and technician functions. These requirements clearly constitute "an outline of policy or conduct" in the establishment and use of a technician ratio in excess of 1:1.

More importantly, however, each of the cited provisions contain limiting language that the Prescription Department Manager (PDM) or Consultant Pharmacist of Record (CPR) may approve a ratio "of up to" the given number of technicians for the identified practice setting. Therefore, the Board has determined the actual ratio used must be within a range of between 1:1 and 1:{n}, {n} being the upper limit number for the practice setting. This range constitutes a guideline as to the ratio that may be used. When combined with the general provisions of subsection (2), the rule provisions clearly establish guidelines for the use of technician ratios in excess of 1:1, by indicating or outlining policy or conduct to be used by the PDM or CPR in establishing a technician ratio in excess of 1:1.

In subsection (6)(b), the Board will correct "a eight to one" to "an eight to one" as a technical change at the time the rule is filed for adoption.

27.410(7). The spelling of "permittee" and "judgment" will be corrected at the time the rule is filed for adoption.

You ask what the Board means by "appropriate pharmacist-technician supervision ratio." By way of background, in making the decision to include this new subsection, the Board extensively discussed the fact that every pharmacy situation is different, in in fact, can vary from day to day or even hour to hour. Given this variability, the Board decided the PDM/CPR, the person designated by statute and board rule as being responsible for ensuring the pharmacy permittee's compliance with the laws and rules governing the profession of pharmacy, had to be given the flexibility to determine the ratio to be used in any given situation or time. The establishment of the general guidelines in subsection (2), and the guideline of "up to" a fixed upper limit in subsections (4) – (6), provides guidance to the PDM/CPR in exercising his or her professional judgment in setting the right ratio for the situation and circumstances. At the same time, the Board is cognizant that there could be other pressures placed on the PDM/CPR to employ a ratio that the PDM/CPR may not believe, in the exercise of his or her professional judgment, is correct and fitting. Accordingly, the Board determined to include this provision to provide an additional guideline – that the PDM/CPR is responsible for setting the ratio, and that decision was not to be overridden or interfered with by any "person, permittee, or licensee."

As defined by the Merriam-Webster Dictionary, "appropriate" means "especially suitable or compatible; fitting." The Board intends for the "appropriate" ratio to be exactly that: the ratio that, in the PDM/CPR's professional judgment, is most suitable or fitting for the specific pharmacy situation.

As discussed above, this rule establishes guidelines to be used by the PDM/CPR in the establishment of technician ratios in excess of 1:1. Because the Board has established those guidelines, including establishment of a range that may be used in each specified practice setting, the Board has not improperly delegated its statutory authority. Further, although the Department and the Board are legal "persons," neither the Department nor the Board would or could direct or require a specific a technician ratio, or contravene the decision of the PDM/CPR. The Board is well aware that it may only exercise those powers and duties granted to it by the Legislature, and the Legislature has given the Department and the Board the ability to discipline licensees or permittees for violations of the Board's laws or rules. Accordingly, the PDM/CPR or pharmacy permittee could be disciplined for a violation of this rule, for example, exceeding the range established by the rule for a given practice setting, but in that case, the Board would not be interfering with the judgment of the PDM/CPR, it would be enforcing the guidelines established by the Rule. If the PDM/CPR establishes policies and procedures, and otherwise complies with the requirements of subsection (2), and then sets a technician ratio within the range allowed for that practice setting, neither the Department nor the Board would review the decision of the PDM/CPR.

The Board expects that the pharmacists and pharmacy technicians working in the pharmacy will be aware of the ratio set by the PDM/CPR, through either the Policies and Procedures manual; the training on the P&P required by paragraph (2)(c), or most directly, by the PDM/CPR setting the work schedule, including the number of pharmacists and technicians scheduled to work any particular shift.

Thank you for your comments, time, and assistance regarding this rule, and the Board's rulemaking endeavors in general. The Board anticipates that after review of this response, you will determine that the Board has fully, completely, and adequately resolved your comments and satisfied your concerns in their entirety. With the submission of this written response, the Board has met its statutory obligation under section 120.54(3)(e)4., F.S., and the Board intends to proceed with adoption of the rule without substantive change to the amendments as proposed. Please do not hesitate to contact me if you have any further questions or concerns.

Sincerely,

Lawrence D. Harris
Assistant Attorney General
Counsel to the Florida Board of Pharmacy

cc: Erica White, Executive Director
Angela Southwell, Paralegal Specialist

RECEIVED
2018 MAR -8 PM 3: 12
PROCEEDINGS COMMITTEE

Angela Southwell

From: greg@smartpharmacy.com
Sent: Monday, February 12, 2018 3:56 PM
To: carolyn@commer.net
Cc: Angela Southwell
Subject: User Comment From FLRules.com

FLRules.com comment:

Name: Gregory Balotin
Email: greg@smartpharmacy.com
Title: 64B16-27.410 Comment on RPhT Ratio
Comment: Hello, I am a pharmacy business owner of 3 pharmacies in Jacksonville Florida. I support this rule because we have clearly separate areas where pharmacy technicians work separate from any pharmaceuticals. Our pharmacists can very safely supervise 8 technicians doing clerical duties as there is no physical drug product to maintain. The record-keeping and drug inventory and dispensing aspects That don't exist in this "call center"
Environment allow for proper and competent supervision of more technicians.

I am available to discuss at 904-534-2130 or greg@smartpharmacy.com

Angela Southwell

From: karin@phcpharmacy.com
Sent: Monday, February 12, 2018 3:07 PM
To: carolyn@commer.net
Cc: Angela Southwell
Subject: One-time User Comment From FLRules.com

FLRules.com one-time comment:

Name: Karin Van Heerden
Email: karin@phcpharmacy.com
Title: RPh/Phcy tech ratio
Comment: I do not agree with this change. At present it is hard for pharmacists to keep up with the workload of checking prescriptions, if this rule is implemented, it will significantly increase the pressure on the pharmacist to accurately check prescriptions. It will result in a high risk of liability and the safety of the patients are at stake. I predict a sharp rise in quality incidents per minute. The cost of error is going to succeed the savings of hiring a tech vs a pharmacist. I suggest that a study must be conducted on the impact before implementing this rule. I cannot believe that this change is even considered - not a professional decision at all.

Angela Southwell

From: mceversc@comcast.net
Sent: Wednesday, February 14, 2018 2:19 PM
To: carolyn@commer.net
Cc: Angela Southwell
Subject: One-time User Comment From FLRules.com

FLRules.com one-time comment:

Name: Claudia McEvers
Email: mceversc@comcast.net
Title: 64B16-27.410 Registered Pharmacy Technician to Pharmacist Ratio
Comment: I do not agree with increasing the Technician to Pharmacist ratio in any setting. I believe that this would cause an increase in errors and would not be in the best interest of the patients.

TAB #4

Notice of Proposed Rule

DEPARTMENT OF HEALTH
Board of Pharmacy
RULE NO.: RULE TITLE:
64B16-27.450 Prescription Department Managers
PURPOSE AND EFFECT: The Board proposes the rule amendment to revise and clarify the requirements for designation as a prescription department manager for certain permit types; to update/correct the fingerprinting requirements; and to update the incorporated form.
SUMMARY: The requirements for designation as a prescription department manager for certain permit types will be revised and clarified. The fingerprinting requirements will be updated/corrected. The incorporated form will be updated.
SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION:
The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of $200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.
The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: During discussion of the economic impact of this rule at its Board meeting, the Board, based upon the expertise and experience of its members, determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. No person or interested party submitted additional information regarding the economic impact at that time.
Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.
RULEMAKING AUTHORITY: 465.005, 465.0155, 465.022(1), (10) FS.
LAW IMPLEMENTED: 456.0135, 465.018(2), 465.0197(1), (3)(b), 465.022(2), (3), (10), (11) FS.
IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: C. Erica White, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254.

THE FULL TEXT OF THE PROPOSED RULE IS:

64B16-27.450 Prescription Department Managers.
(1) Designation as Prescription Department Manager.
(a) Initial Designation. Pursuant to Sections 465.018, 465.0197, and 465.022, F.S., a permit for a community or internet pharmacy may not be issued unless a licensed pharmacist is designated as the prescription department manager. Pursuant to Rules 64B16-28.820, 64B16-28.830, and 64B16-28.901, applications for permits for a Special Parenteral and Enteral, Special Closed System, or Nuclear pharmacy require the supervising licensed pharmacist be designated as the prescription department manager. Finally, applications for a Special Sterile Compounding Permit require the supervising licensed pharmacist or consultant pharmacist be designated as either the prescription department manager or the consultant pharmacist of record, as applicable to the underlying permit type. Initial d~~D~~esignation is accomplished as part of the application process using the appropriate application form ~~for a Community Pharmacy Permit, utilizing Form DH MQA 1214, Community Pharmacy Permit Application and Information,~~ incorporated in Rule 64B16-28.100, F.A.C.
(b) Change of prescription department manager. No later than ten (10) days after a change of designated prescription department manager for a community pharmacy, a Special Parenteral and Enteral pharmacy, a Special Closed System pharmacy, ~~or~~ a Nuclear pharmacy, or a Special Sterile Compounding permitee, or thirty (30) days for an internet pharmacy, both the pharmacy permittee and the newly designated prescription department manager shall notify the Board of the change and the identity of the newly designated prescription department manager.

Notification shall be accomplished by completing Form DOH/MQA/PH10, 01/18 ~~12/16~~, Change of Prescription Department Manager, which is hereby incorporated by reference and which can be obtained from http://www.flrules.org/Gateway/reference.asp?No=Ref-___~~07929~~, the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or the Board's website at http://floridaspharmacy.gov/Applications/app-change-perscription-dept-manager.pdf. In addition, an outgoing prescription department manager may choose to notify the Board they will no longer serve as prescription department manager using this form.

(c) Submission of Fingerprints. In addition to submission of Form DOH/MQA/PH10, the newly designated prescription department manager shall comply with the fingerprinting requirements of Sections 456.0135 and 465.022, F.S. Electronic fingerprint information ("EFI") that has been submitted to the Florida Agency for Health Care Administration may be accessible by the Florida Department of Health for a period of sixty (60) months. If the Department is able to access EFI from AHCA, applicants will not be required to resubmit EFI for additional or new applications submitted during this time period. After sixty (60) months, new electronic fingerprint information must be submitted as part of all applications. ~~This paragraph does not apply to persons fingerprinted pursuant to these statutes on or after July 1, 2013.~~

(2) No change.

(3) All community, ~~and~~ internet, Special Parenteral and Enteral, Special Closed System, Nuclear and, if applicable, Special Sterile Compounding pharmacy permittees shall continuously maintain a designated prescription department manager at all times the pharmacy is open and in operation.

(4) No change.

Rulemaking Authority 465.005, 465.0155, 465.022(1), (10) FS. Law Implemented 456.0135, 465.018(2), 465.0197(1), (3)(b), 465.022(2), (3), (10), (11) FS. History–New 3-9-17,_____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy
NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Pharmacy
DATE PROPOSED RULE APPROVED BY AGENCY HEAD: February 6, 2018
DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: January 26, 2018

TAB #5

Notice of Proposed Rule

DEPARTMENT OF HEALTH
Board of Pharmacy
RULE NO.: RULE TITLE:
64B16-28.501 Institutional Permit - Consultant Pharmacist of Record
PURPOSE AND EFFECT: The Board proposes the rule amendment to revise and clarify the requirements for designation as a consultant pharmacist of record for certain permit types; to update the fingerprinting requirements, to update incorporated form, and require continuous designation of the Consultant Pharmacist of Record.
SUMMARY: The amendment will revise and clarify the requirements for designation as a consultant pharmacist of record for certain permit types, update the fingerprinting requirements, and require continuous designation of the Consultant Pharmacist of Record.
SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION:
The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of $200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.
The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: During discussion of the economic impact of this rule at its Board meeting, the Board, based upon the expertise and experience of its members, determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. No person or interested party submitted additional information regarding the economic impact at that time.
Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.
RULEMAKING AUTHORITY: 465.005, 465.0125, 465.022 FS.
LAW IMPLEMENTED: 465.0125, 465.019, 465.022, 465.0266 FS.
IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: C. Erica White, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254.

THE FULL TEXT OF THE PROPOSED RULE IS:

64B16-28.501 ~~Institutional Permit -~~ Consultant Pharmacist of Record; Initial Designation; Change.

(1) Designation as Consultant Pharmacist of Record.

(a) Initial Designation. Pursuant to Sections 465.019 and 465.022, F.S., a permit for an Institutional pharmacy may not be issued unless a licensed pharmacist is designated as the consultant pharmacist of record. In addition, pursuant to Rule 64B16-28.901, an application for a Special Assisted Living Facility pharmacy permit requires the supervising licensed pharmacist be designated as the consultant pharmacist of record. Finally, applications for Special Sterile Compounding Permits associated with an Institutional pharmacy require the pharmacist-in-charge be designated as the consultant pharmacist of record. Initial designation is accomplished as part of the application process using the appropriate application form incorporated in Rule 64B16-28.100, F.A.C.

(b) Change of Consultant Pharmacist of Record.

No later than ten (10) days after a change of designated consultant pharmacist for an Institutional, ~~or~~ Special Assisted Living Facility pharmacy, or a Special Sterile Compounding Permitee, both the pharmacy permittee and the newly designated consultant pharmacist of record shall notify the Board of the change and the identity of the newly designated consultant pharmacist. Notification shall be accomplished by completing Form DH-MQA 1184 (01/18), Change of Consultant Pharmacist of Record, which is hereby incorporated by reference and which can be obtained from http://www.flrules.org/Gateway/reference.asp?No=Ref- or the Board's website at http://floridaspharmacy.gov/Applications/app-change-consultant-pharmacist.pdf. In addition, an outgoing

consultant pharmacist of record may choose to notify the Board they will no longer serve as consultant pharmacist of record using this form.

(c) Submission of Fingerprints. In addition to submission of Form DH-MQA 1184, the newly designated consultant pharmacist shall comply with the fingerprinting requirements of Sections 456.0135 and 465.022, F.S. Electronic fingerprint information ("EFI") that has been submitted to the Florida Agency for Health Care Administration may be accessible by the Florida Department of Health for a period of sixty (60) months. If the Department is able to access EFI from AHCA, applicants will not be required to resubmit EFI for additional or new applications submitted during this time period. After sixty (60) months, new electronic fingerprint information must be submitted as part of all applications.

~~(1) Each facility holding a Class I, a Class II, or a Modified Class II Institutional permit shall designate a consultant pharmacist of record to ensure compliance with the laws and rules governing the permit. The Board office shall be notified in writing within ten (10) days of any change in the consultant pharmacist of record.~~

(2) Continuous Designation. All Institutional, Special Assisted Living Facility, and, if applicable, Special Sterile Compounding Pharmacy permittees shall continuously maintain a designated consultant pharmacist of record at all times the pharmacy is open and in operation.

(3)~~(2)~~ Drug Regimen Reviews. The consultant pharmacist of record for a Class I, Class II, or Modified Class II institutional permit shall conduct Drug Regimen Reviews as required by Federal or State law, inspect the facility and prepare a written report to be filed at the permitted facility at least monthly. In addition, the consultant pharmacist of record must monitor the facility system for providing medication administration records and physician order sheets to ensure that the most current record of medications is available for the monthly drug regimen review. The consultant pharmacist of record may utilize additional consultant pharmacists to assist in this review and in the monthly facility inspection.

(4)~~(3)~~ Remote Access. A consultant pharmacist licensed in Florida may remotely access a facility or pharmacy's electronic database from outside the facility or pharmacy to conduct any services additional or supplemental to regular drug regimen reviews, subject to the pharmacy or facility establishing policies and procedures to ensure the security and privacy of confidential patient records, including compliance with applicable Federal HIPAA regulations.

Rulemaking Authority 465.005, 465.0125, 465.022 FS. Law Implemented 465.0125, 465.019, 465.022, 465.0266 FS. History–New 7-18-94, Formerly 61F10-28.501, 59X-28.501, Amended 1-2-02, 12-30-07, 11-5-17,_____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy
NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Pharmacy
DATE PROPOSED RULE APPROVED BY AGENCY HEAD: February 6, 2018
DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: January 26, 2018

TAB #6

TAB #7

Notice of Proposed Rule

DEPARTMENT OF HEALTH
Board of Pharmacy
RULE NO.: RULE TITLE:
64B16-28.100 Pharmacy Permits - Applications and Permitting
PURPOSE AND EFFECT: The Board proposes the rule amendment to update and revise the rule and to update the application forms incorporated through the rule.
SUMMARY: Incorporated forms will be updated; the rule will be revised and updated.
SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION:
The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of $200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.
The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: During discussion of the economic impact of this rule at its Board meeting, the Board, based upon the expertise and experience of its members, determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. No person or interested party submitted additional information regarding the economic impact at that time.
Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.
RULEMAKING AUTHORITY: 465.005, 465.022 FS.
LAW IMPLEMENTED: 456.013, 456.025(3), 456.0635, 465.018, 465.019, 465.0193, 465.0196, 465.0197, 465.022 FS.
IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: C. Erica White, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254.

THE FULL TEXT OF THE PROPOSED RULE IS:

64B16-28.100 Pharmacy Permits – Applications and Permitting.
This rule section establishes ~~addresses~~ the application and permitting requirements for pharmacies ~~of business establishments~~ regulated under Chapter 465, F.S. Any pharmacy establishment ~~that is required to have a permit~~ shall apply to the board for the appropriate permit on forms indicated in this rule. Applications and forms referenced in this section may be accessed or downloaded from the web at http://floridaspharmacy.gov/resources/ ~~http://www.doh.state.fl.us/mqa/pharmacy~~ or may be obtained by contacting the Board of Pharmacy, at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850)488-0595. Inquiries regarding the status of the application or license verification may be obtained at http://www.FLHealthsource.gov. The application must be accompanied by the appropriate fee as specified by Rule 64B16-26.1022, F.A.C. ~~with a $250 initial permit fee, payable to the Board.~~

(1) All Permits:

(a) A permit is valid only for the name and, pursuant to Rule 64B16-28.113, F.A.C., physical location (address) to which it is issued. The name in which the permit is issued must be the name in which the company is doing business, i.e., the name that appears on purchase and sales invoices.

~~(a) A permit shall be issued only to a single entity at a single location. The service provided by the permit shall be consistent with the issued permit. A single location shall be defined as:~~

~~1. A contiguous area under the control of the permit holder. For purposes of this rule, a public thoroughfare will be considered to have not broken the area of contiguity; and,~~

~~2. An area not more than one half (1/2) mile from the central location of the permit.~~

1. (b) The name in which a permit is issued may be changed upon notification to the board. To change the name in which a permit is issued the person or establishment must file with the board an original Form DH-MQA 1227 "Pharmacy Permit Name Change Form" effective December 2010, which is incorporated by reference herein, and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02297 or on the web at http://floridaspharmacy.gov/resources/ http://www.doh.state.fl.us/mqa/pharmacy.

2. A pharmacy permit holder may request a change of practice location by completing the appropriate section(s) of the application form for the permit type.

3. Pharmacy permits are non-transferrable. However, pursuant to Rule 64B16-28.2021, transfers of ownership interests of business entities holding a permit may be allowed. A pharmacy permit holder shall notify the Board of changes of ownership interests of business entities by completing the appropriate section(s) of the application form for the permit type.

(b) (c) Each applicant must comply with the fingerprinting file with the board a legible set of fingerprint cards and a $48 fee for each person who submits an application meeting the requirements of section 465.022(3), F.S. Electronic fingerprint information ("EFI") that has been submitted to the Florida Agency for Health Care Administration may be accessible by the Florida Department of Health for a period of sixty (60) months. If the Department is able to access EFI from AHCA, applicants will not be required to resubmit EFI for additional or new applications submitted during this time period. After sixty (60) months, new electronic fingerprint information must be submitted as part of all applications. An applicant may register demographic information and purchase fingerprint cards (FD-258) at http://http://www.fldoh.sofn.net/. If an applicant chooses not to purchase a fingerprint card, the applicant must make sure the police or agency that rolls the fingerprints uses a FD-258 fingerprint card. A Non-Resident Pharmacy Registration applicant is not required to submit a legible set of fingerprints upon application.

(c)(d) No change.

(d)(e) Pursuant to section 465.022(4), F.S., eEach applicant must attach to the application the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships. The policy and procedure manual shall contain, at a minimum, the following:

1. Provisions to identify and guard against invalid practitioner-patient relationships.

2. Provisions to guard against filling fraudulent prescriptions for controlled substances.

3. Provisions to identify prescriptions that are communicated or transmitted legally.

4. Provisions to identify the characteristics of a forged or altered prescription.

(2) A Community Pharmacy Permit, as authorized by Section 465.018, F.S., is required for every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis. Applicants for a community pharmacy permit must complete an application for a permit using an original Form DH-MQA 1214, "Community Pharmacy Permit Application and Information," Rev 01/18, effective August 2012 which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref- 02298. (a) Applicants for a Community Pharmacy Permit must: 1. cComply with all permitting requirement found in subsection (1), of this rule; and, 2. dDesignate a prescription department manager as required by Section 465.018, F.S.

(b) The permittee and the newly designated prescription department manager shall notify the board within 10 days of any change in the prescription department manager using an original Form DH-MQA PH10, "Prescription Department Manager Change," effective December 2010, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02299.

(c) The policy and procedure manual for Community Pharmacies shall contain the procedures implemented to minimize the dispensing of controlled substances based on fraudulent representations. The policy and procedural manual shall provide the following:

1. Provisions to identify and guard against invalid practitioner-patient relationships.

2. Provisions to guard against filling fraudulent prescriptions for controlled substances.

3. Provisions to identify prescriptions that are communicated or transmitted legally.

4. Provisions to identify the characteristics of a forged or altered prescription.

(3) An Institutional Pharmacy Permits, as authorized by Section 465.019, F.S., is required for any location in any health care institution where medicinal drugs are compounded, dispensed, stored or sold. Applicants for an

Institutional Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1215, "Institutional Pharmacy Permit Application and Information," Rev 01/18 ~~effective August 2012~~, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02300. ~~(a)~~ Applicants for an Institutional Pharmacy Permit must~~: 1.~~ c~~C~~omply with all permitting requirements found in subsection (1) of this rule~~;~~ and~~,~~ d~~D~~esignate a consultant pharmacist of record as required by Section 465.019, F.S.

~~(b) The Board shall be notified in writing within 10 days of any change in the consultant pharmacist of record using an original Form DH-MQA 1184, "Change of Consultant Pharmacist of Record," effective December 2010, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02301.~~

(4) A Nuclear Pharmacy Permit, as authorized by Section 465.0193, F.S., is required for every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. Applicants for a Nuclear Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1218, "Nuclear Pharmacy Permit Application and Information," Rev 01/18 ~~effective August 2012~~, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02302. ~~(a)~~ Applicants for a Nuclear Pharmacy Permit must~~: 1.~~ c~~C~~omply with all permitting requirements found in subsection (1), of this rule~~;~~ and~~,~~ ~~2.~~ d~~D~~esignate a nuclear pharmacist as the prescription department manager as required by Rule 64B16-28.901(1), F.A.C. ~~nuclear pharmacist of record as required by Section 465.0193, F.S.~~

~~(b) The permittee and the newly designated prescription department manager shall notify the board within 10 days of any change in the prescription department manager using an original Form DH-MQA PH10, "Prescription Department Manager Change," effective December 2010.~~

(5) A Special Pharmacy Permit~~s~~ as authorized by ~~in~~ Section 465.0196, F.S., is required for any location where medicinal drugs are compounded, dispensed, stored, or sold and which is ~~are~~ not a community pharmacy, institutional pharmacy, nuclear pharmacy or internet pharmacy. Applicants for a Special-Limited Community, Special – Parenteral and Enteral, Special – Closed System Pharmacy, Special – End Stage Renal Disease (ESRD), Special – Parenteral/Enteral Extended Scope, and Special – Assisted Living Facility (ALF) permits must complete an application for a permit using an original Form DH-MQA 1220, "Special Pharmacy Permit Application and Information," Rev 01/18 ~~effective August 2012~~, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref- ~~02303~~.

(a) Applicants for a Special Pharmacy Permit must~~: 1.~~ c~~C~~omply with all permitting requirement found in subsection (1), of this rule; and~~,~~ ~~2.~~ d~~D~~esignate a prescription department manager or consultant pharmacist of record as required by Section 465.0196, F.S.

~~(b) The permittee and the newly designated prescription department manager shall notify the board within 10 days of any change in the prescription department manager using an original Form DH-MQA PH10, "Prescription Department Manager Change," effective December 2010.~~

~~(c) The Board shall be notified in writing within 10 days of any change in the consultant pharmacist of record using an original Form DH-MQA 1184, "Change of Consultant Pharmacist of Record," effective December 2010.~~

(b)~~(d)~~The Board recognized the following types of Special Pharmacy permits:

1. A Special Limited Community Permit is required for any ~~may be obtained by an~~ Institutional Class II Pharmacy that dispenses medicinal drugs to employees, medical staff, emergency room patients, and other patients on continuation of a course of therapy.

2. A Special Parenteral and Enteral Permit is required for any pharmacy which provides ~~to provide~~ parenteral (IV), enteral, and cytotoxic pharmacy services to outpatients. The applicant must be compliant with the Standard for Compounding Sterile Preparations found in Rule 64B16-27.797, F.A.C. Special – Parenteral and Enteral Pharmacy Permits may stand-alone or be used in conjunction with a Community Pharmacy or Special – Closed System Pharmacy Permit. The permittee must provide 24-hour telephone accessibility.

3. A Special Closed System Pharmacy Permit is required for any pharmacy not open to the public and where prescriptions are individually prepared for dispensing utilizing closed delivery systems, for ultimate consumers in health care institutions including nursing homes, jails, Assisted Living Facilities (ALFs), Intermediate Care Facilities for the Developmentally Delayed (ICF-IID) ~~Facility/Mentally Retarded (ICF-MR's)~~ or other custodial care

facilities when defined by AHCA rules which the Board may approve. This permit may not provide medications to in-patients in a hospital.

4. A Special Pharmacy – End Stage Renal Disease (ESRD) Permit is required for any ~~a type of special~~ pharmacy which is limited in scope of pharmacy practice to the provision of dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address.

5. A Special Pharmacy – Parenteral/Enteral Extended Scope Permit is required for any pharmacy which ~~pharmacies to~~ compounds patient specific parenteral/enteral preparations in conjunction with institutional pharmacy permits, as provided in Rule 64B16-28.560, F.A.C., ~~provided requirements set forth herein are satisfied.~~

6. No change.

(6) An Internet Pharmacy Permit, as authorized by Section 465.0197, F.S., is required for any location not otherwise licensed or issued a permit under this chapter, within or outside this state that uses the Internet to communicate with or obtain information from consumers and uses the information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Applicants for an Internet Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1220, "Special Pharmacy Permit Application and Information," Rev 01/18 ~~effective August 2012~~. ~~(a)~~ Applicants for an Internet Pharmacy Permit must~~:~~ ~~1.~~ c~~C~~omply with all permitting requirements found in subsection (1)~~,~~ of this rule~~;~~ and~~,~~ ~~2.~~ d~~D~~esignate a prescription department manager or consultant pharmacist of record as required by Section 465.0197, F.S.

~~(b) As set forth in Section 465.0197, F.S., the permittee shall notify the board within 30 days of any change of location, corporate officers, and the pharmacist serving as the prescription department manager using an original Form DH-MQA PH10, "Prescription Department Manager Change," effective December 2010.~~

(7) Special Sterile Compounding Permit: Except those pharmacies which already hold an active stand-alone Special Parenteral/Enteral or Special Parenteral/Enteral Extended Scope Compounding permit, or a Modified Class II-B pharmacy that meets the requirements of Rule 64B16-28.802(6), F.A.C. any pharmacy, including an outsourcing facility, engaged in sterile compounding must obtain a special sterile compounding permit by filing an application on form DH-MQA 1270, "Special Sterile Compounding Permit Application and Information," Rev 01/18 ~~effective May 2013~~, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-____ ~~03142~~.

~~(a) All applicants that hold an active pharmacy permit that are currently engaged in sterile compounding have 180 days from the effective date of this amendment (eff. 9/23/13) to obtain a Special Sterile Compounding Permit. All pharmacies, which obtain the permit within the 180 days, on or before March 21, 2014, are exempt from paying an additional application or license fee.~~

~~(b)~~ Applicants for a Special Sterile Compounding Permit must~~:~~ ~~1.~~ c~~C~~omply with all permitting requirements in subsection (1)~~,~~ of this rule~~,~~ and ~~2.~~ d~~D~~esignate a prescription department manager or consultant pharmacist of record.

~~(c) The permittee and the newly designated prescription department manager of record or consultant pharmacist of record shall notify the board within 10 days of any change in the prescription department manager or consultant pharmacists of record on FORM DH-MQA PH10, "Prescription Department Manager Change," effective December 2010 or FORM DH-MQA 1184, "Change of Consultant Pharmacist of Record."~~

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 456.013, 456.025(3), 456.0635, 465.018, 465.019, 465.0193, 465.0196, 465.0197, 465.022 FS. History–New 2-21-13, Amended 9-23-13, 5-31-17,_____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy
NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Pharmacy
DATE PROPOSED RULE APPROVED BY AGENCY HEAD: February 6, 2018
DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: December 12, 2017

TAB #8

DIVISION OF MEDICAL QUALITY ASSURANCE
BOARD OF PHARMACY
4052 BALD CYPRESS WAY, BIN #C-04
TALLAHASSEE, FLORIDA 32399-3254
(850) 245-4292

COMMUNITY PHARMACY PERMIT APPLICATION AND INFORMATION

January 2018

Dear Florida Pharmacy Permit Applicant,

Thank you for applying for a pharmacy permit in the State of Florida. The information in this packet has been designed to provide the essential information required to process your application in a timely manner. Your assistance in providing all required information will enable the Florida Board of Pharmacy (the Board) staff to process your application as soon as possible. You are encouraged to apply as early as possible to avoid processing delays caused by large volumes of applicants.

Florida Statutes require a completed application and fees before your application can be reviewed. Please read these instructions carefully and fully before submitting your application. You should keep a copy of the completed application and all other materials sent to the Board office for your records. When you mail the completed application and fees, use the address noted in the instructions and on the application form.

When your application arrives, your fees will be deposited and verified before the staff review can begin. You will receive a letter acknowledging receipt of your application. The staff will notify you within 30 days if any materials are incomplete.

If you need to communicate with the Board staff, you are encouraged to email the Board staff at info@floridaspharmacy.gov, or you may at call us at (850) 245-4292. Phone calls are returned within 24 hours and emails are responded to within 48 hours during normal business hours. Our staff is committed to providing prompt and reliable information to our customers. Many procedures have been streamlined to expedite the processing of applications; we certainly welcome your comments on how our services may be improved.

Sincerely,

The Board of Pharmacy

COMMUNITY PHARMACY PERMIT APPLICATION INFORMATION

Whether opening a new establishment, changing locations, or changing owners, a pharmacy permit is required prior to operating in the State of Florida. The permit application must be completed and returned to the Florida Board of Pharmacy with the required fee of $255.00. The application MUST have the original signatures of the owner or officer of the establishment and the Prescription Department Manager (PDM). If compounding sterile preparations, submit an additional application on Form DH-MQA 1270, "Special Sterile Compounding Permit" and pay the additional permitting fee.

A Community Pharmacy provides outpatient pharmacy services, and is open for a minimum of 20 hours per week unless reduced hours have been approved by the Board. Section 465.018, Florida Statutes, requires a permit holder to designate a pharmacist licensed in the State of Florida as the manager of the prescription department. The Prescription Department Manager (PDM) is responsible for ensuring the pharmacy permittee's compliance with all statutes and rules governing the practice of the profession of pharmacy, including maintenance of all drug records and ensuring the security of the prescription department, and shall competently and diligently exercise their responsibilities as a prescription department manager. Please see Rule 64B16-27.450, F.A.C., for more information.

Section 465.022(4), Florida Statutes, also provides that an application for a pharmacy permit must include the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships. Pursuant to Rule 64B16-28.100(1)(d), F.A.C., the policy and procedure manual for a Community Pharmacy shall contain the procedures implemented to minimize the dispensing of controlled substances based on fraudulent representations as follows:

1. Provisions to identify and guard against invalid practitioner-patient relationships.
2. Provisions to guard against filling fraudulent prescriptions for controlled substances.
3. Provisions to identify prescriptions that are communicated or transmitted legally.
4. Provisions to identify the characteristics of a forged or altered prescription.

Application Processing

Please read all application instructions before completing your application.

1) Please mail the application and the $255.00 application fee (cashier's check or money order made payable to the FLORIDA DEPARTMENT OF HEALTH) to the following address:

Application & Fees:
Department of Health
Board of Pharmacy
P.O. Box 6320
Tallahassee, Florida 32314-6320

Express Mail ONLY
Department of Health
Board of Pharmacy
4052 Bald Cypress Way, Bin C-04
Tallahassee, FL 32399-3254

Within 30 days of receipt of your application and fees, the Board office will notify you of the receipt of your application, any required documents, and your status. If the application is complete, you will be notified that an inspector will contact you to setup an inspection appointment. If your application is incomplete, you will be notified in writing of what is required to make your application complete.

2) Submit fingerprint results.

Failure to submit fingerprints will delay your application. All owners, officers, and PDMs are required to submit a set of fingerprints unless the corporation is exempt under Section 465.022, Florida Statutes, for corporations having more than $100 million of business taxable assets in this state. These corporations are only required to have the PDM to submit fingerprints.

Electronic fingerprint information ("EFI") that has been submitted to the Florida Agency for Health Care Administration may be accessible by the Florida Department of Health for a period of sixty (60) months. If the Department is able to access EFI from AHCA, applicants will not be required to resubmit EFI for additional or new applications submitted during this time period. After sixty (60) months, new electronic fingerprint information must be submitted as part of all applications. **Note: If your officer, owner, or PDM has already been fingerprinted at the time you are completing this Community Pharmacy permit application, please ensure to provide the Transaction Control Number (TCN), if known, with the requested information in the application.**

Applicants may use any Livescan vendor that has been approved by the Florida Department of Law Enforcement to submit their fingerprints to the department. Please ensure that the Originating Agency Identification (ORI) number is provided to the vendor when you submit your fingerprints. If you do not provide an ORI number or if you provide an incorrect ORI number to the vendor, the Board of Pharmacy will not receive your fingerprint results. The applicant is fully responsible for selecting the vendor and ensuring submission of the prints to the Department.

How do I find a Livescan vendor in order to submit my fingerprints to the Department?
The Department of Health accepts electronic fingerprinting service offered by Livescan device vendors that are approved by the Florida Department of Law Enforcement and listed at their site. You can view the vendor options and contact information at:

http://www.floridahealth.gov/licensing-and-regulation/background-screening/livescan-service-providers.html

What information must I provide to the Livescan vendor I choose?

- If you are an applicant seeking a license for any profession regulated by the Department of Health, which requires a criminal background search as a condition of licensure, you must provide accurate demographic information at the time your fingerprints are taken, ***including your Social Security number***. The Department will not be able to process a submission that does not include your Social Security number.
- You must provide the correct ORI number.

Where do I get the ORI number to submit to the vendor?

- The ORI number for the pharmacy profession is **EDOH4680Z.**

Attestation for Business Taxable Assets

- If the applicant has more than $100 million dollars of business taxable assets in this state, please submit a formal opinion letter from a Certified Public Accountant duly

licensed in the state of your principal place of business affirming the corporation has more than $100 million of business taxable assets in this state for the previous tax year. In lieu of submitting a formal opinion letter from a Certified Public Accountant, the applicant may submit a copy of its Florida Corporate Income/Franchise and Emergency Excise Tax Return (Form F-1120, Effective 01/09).

3) Privacy Statement and Attestation

In order for the Board of Pharmacy Office to receive your Livescan electronic fingerprinting results, you must affirm that you have been provided with and read the attached statement from the Florida Department of Law Enforcement regarding the sharing, retention, and right to challenge incorrect criminal history records, and the "Privacy Statement" document from the Federal Bureau of Investigation. The appropriate form(s) to provide this affirmation are included within Items #1 and #2 of the application.

Licensure Process

Once the application is deemed complete, the Board staff authorizes an inspection. Upon completion of the inspection, the inspector notifies the Board office as to whether the inspection was satisfactory or unsatisfactory. If the inspection is satisfactory, a permit number is issued within 7-10 days. You will receive the actual copy of your license within 7 days. **Please wait 7-14 days from your satisfactory inspection before checking on the status of your permit with the Board office**.

You may look up your license number on our website at http://www.flhealthsource.com/ under "Verify a License."

The Board recognizes that a delay may exist between the time a pharmacy receives a Florida pharmacy permit and commences to operate. Accordingly, upon receipt of Community Pharmacy permit, a pharmacy may delay commencement of operations in compliance with the requirements provided in Rule 64B16-28.1081, F.A.C.

Drug Enforcement Administration (DEA)

Please note that the DEA will not issue a registration until the Florida Board of Pharmacy has issued a pharmacy permit. More information is available by visiting the DEA website at http://www.DEAdiversion.usdoj.gov, or by contacting them at (800)667-9752.

IMPORTANT NOTICE: Pursuant to Section 465.022(5), F.S., the Department or Board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant:

(a) Has obtained a permit by misrepresentation or fraud.

(b) Has attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation.

(c) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy.

(d) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud.

(e) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009.

(f) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009.

(g) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period.

(h) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application.

(i) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

(j) Has 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.

For felonies in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the department shall deny the application if upon final resolution of the case the licensee has failed to successfully complete the program.

<u>If applicable to you, please provide the documentation to the Florida Board of Pharmacy.</u>

PHARMACY PERMIT APPLICATION CHECKLIST

Keep a copy of the completed application for your records.

It is recommended that you use the following checklist to help ensure that your application is complete. Failure to attach any required document, or to have required documentation sent to the Board, will result in an incomplete application. Final approval for inspection cannot be granted until the application is complete.

COMMUNITY PHARMACY PERMIT

_____All Application Questions Answered?

_____$255.00 Fee Attached (Permit fee includes $250 application fee and $5.00 unlicensed activity fee)

_____Articles of Incorporation paperwork from the Secretary of State provided?

_____PDM Designation and Privacy Statement Acknowledgement provided (Application Item #1)?

_____Affiliate/Owner Privacy Statement Acknowledgement provided for each affiliate/owner (Application Item #2)?

_____Applicant/Affiliate/Owner supplemental documents provided for explaining any previous ownership, disciplinary actions, voluntary relinquishments and/or criminal activity?

_____Applicant/Affiliate/Owner pharmacy permit questions answered and supplemental documents provided?

_____Policies and Procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships submitted?

FLORIDA BOARD OF PHARMACY
P.O. Box 6320
Tallahassee, FL 32314-6320
850-245-4292
http://www.floridaspharmacy.gov

COMMUNITY PHARMACY PERMIT

APPLICATION

Application Type – Please choose one of the following:

___New Establishment ($255.00 fee)
Complete: Section A only, along with Items #1 and 2.

___Change of Ownership ($255.00 fee)
Complete: Sections A and C only, along with Items #1 and 2.

___ Change of Location ($100.00 fee)
Complete: Sections A and B only.

___ Stock Transfer (no fee)
Complete: Section A, pages 2-3 and Section D only.

SECTION A. Please complete for all Application Types

Please list your Federal Employer Identification Number:

1. Corporate Name	**Telephone Number**

2. Doing Business As (d/b/a)	**E-Mail Address**** (see note below)

3. Mailing Address		
City	**State**	**Zip**

4. Physical Address		
City	**State**	**Zip**

5. Prescription Department Manager (PDM) Information

Name	**License Number**

Email Address ** (see note below)	**Telephone Number**

6. Contact Person	**Title**

Email Address ** (see note below)	**Telephone Number**

NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.

7. Operating Hours

Is the pharmacy open at least 20 hours per week? Yes_____ No_____

8. Ownership Information

a. Type of Ownership: _____Individual _____Corporation _____Partnership

NOTE: If the applicant is a corporation or limited partnership you must include with your application a copy of the Articles of Incorporation on file with the Florida Secretary of State's office.

b. Are the applicants, officers, directors, shareholders, members and partners over the age of 18?

Yes _____ No _____

c. Does the corporation have more than $100 million of business taxable assets in this state? *If yes, provide attestation from Certified Public Accountant for previous tax year or Florida Corporate Income /Franchise and Emergency Excise Tax Return (F-1120).*

Yes _____ No _____

d. List all the owners and officers of the corporation. Each person listed below having an ownership interest of 5% or greater and any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant including officers and members of the board of directors must submit a set of fingerprints and fees unless you answered yes to 8c. If 8c is "Yes", please list the owners below and only submit fingerprints for the Prescription Department Manager. If 8c is "Yes" and the prints are on file with DOH or AHCA and available to the Board of Pharmacy, the requirement to submit the prints for this person is met. Also, if the % of Ownership column does not add to 100%, please provide an explanation. *Attach a separate sheet if necessary.*

Owner/Officer-Title	Date of Birth	Mailing Address, City, State, Zip Code	% of Ownership
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%

9. Has anyone listed in 8.d had an ownership interest of 5% or more in a pharmacy or any other business permit which was disciplined, suspended, revoked, or closed involuntarily within the past 5 years? *If yes, please provide a signed statement disclosing the reason the entity was closed.*

Yes _____ No _____ .

9a. Has anyone listed in 8.d had an ownership interest of 5% or more in a pharmacy or any other business permit which was voluntarily relinquished or closed voluntarily within the past 5 years? *If yes, please provide a signed statement disclosing the reason the entity was closed.*

Yes _____ No _____ .

Pursuant to Section 465.022(5), Florida Statutes, questions 10 – 19 are being asked. If you answer "Yes" to any of the following questions, explain <u>on a separate sheet</u> providing accurate details and submit copies of supporting documentation.
10. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant obtained a permit by misrepresentation or fraud?
Yes _____ No_____
11. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation?
Yes _____ No _____
12. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy?
Yes _____ No_____
13. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud?
Yes_____ No_____
14. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009?
Yes _____ No_____
15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009?
Yes _____ No _____
16. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period?
Yes _____ No _____
17. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application?
Yes _____ No _____

18. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant currently listed on the United States Department of Health Human Services Office of Inspector General's List of Excluded Individuals and Entities? *(If yes, please submit proof.)*

Yes _____ No _____

19. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant 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?

Yes_____ No ___

20. Are you currently registered or permitted in any other states? *(If yes, provide the state, permit type and permit number for each permit. Attach a separate sheet if necessary.)*

Yes _____ No _____

State	Permit Type	Permit Number

21. Has the applicant, affiliated person, partner, officer, directors, or Prescription Department Manager ever owned a pharmacy? *(If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy. Attach a separate sheet if necessary.)*

Yes _____ No _____

Individual's Name	Pharmacy Name	State	Status

22. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, affiliated person, partner, officer, director, or Prescription Department Msanager?

Yes _____ No _____

23. Has the applicant, affiliated person, partner, officer, or director ever been convicted of a felony or misdemeanor, excluding minor traffic convictions? You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction.

Yes _____ No _____

24. Does the applicant, affiliated person, partner, officer, director have any outstanding fines, liens or overpayments assessed by a final order of the department? If yes please answer 24a.

Yes _____ No _____

24a. Does the applicant, affiliated person, partner, officer, director have a repayment plan approved by the department?
Yes _____ No _____
25. Will the Pharmacy Dispense Schedule II and/or III Controlled Substances?
Yes _____ No _____
26. Will the Pharmacy act as a Central Fill Pharmacy?
Yes _____ No_____
27. Is the applicant, affiliated persons, partners, officers, or directors, under investigation or prosecution for a crime in any jurisdiction?
Yes _____ No_____
27a. Is the applicant, affiliated persons, partners, officers, or directors, under investigation or pending administrative action by the licensing authority of any jurisdiction, including its agencies and subdivisions?
Yes _____ No_____

SECTION B. Please complete for Change of Location only.

1. Current Practice Location Address		
City	**State**	**Zip**
E-Mail Address** (see note below)	**Telephone Number**	
2. New Practice Location Address		
City	**State**	**Zip**
E-Mail Address** (see note below)	**Telephone Number**	

Please provide your existing Pharmacy Permit Number:

Please provide your existing federal DEA Number:

NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.

SECTION C. Please complete for Change of Ownership only.

1. Are you changing physical locations with this change of ownership?

Yes _____ No _____ *NOTE: If yes, please complete **Section B** above.*

2. Please provide date when business transaction for the change of ownership will be completed?

Date: _____

3. Do you have a signed letter from both the buyer and seller which indicates dates that pharmacy permit license should be transferred? *NOTE: A copy of the signed letter should be provided with your application.*

Yes _____ No _____

SECTION D. Please complete for Stock Transfer of Ownership Interests only.

1. Please provide the date when the transfer of ownership interest took place?

Date: _____

2. Did your company's FEIN change as a result of the transfer of ownership interest referenced in Section D, Question 1 above?

Yes _____ No _____ *NOTE: If yes, please complete **Section C** above and include necessary fee.*

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

****

Section 456.013(1), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application, which takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department.

I swear or affirm that the statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations that they deem appropriate and to secure any additional information concerning me, and I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, Board, or any municipal, county, state, or federal governmental agencies or units, and I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other item, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

Under penalty of perjury I have read the foregoing document and that the facts stated in it are true. I recognize that providing false information may result in disciplinary action against my license or criminal penalties.

SIGNATURE _____ DATE_____
(Owner or officer of establishment)

FLORIDA DEPARTMENT OF LAW ENFORCEMENT

NOTICE FOR APPLICANTS SUBMITTING FINGERPRINTS WHERE CRIMINAL RECORD RESULTS WILL BECOME PART OF THE CARE PROVIDER BACKGROUND SCREENING CLEARINGHOUSE

NOTICE OF:

- **SHARING OF CRIMINAL HISTORY RECORD INFORMATION WITH SPECIFIED AGENCIES,**
- **RETENTION OF FINGERPRINTS,**
- **PRIVACY POLICY, AND**
- **RIGHT TO CHALLENGE AN INCORRECT CRIMINAL HISTORY RECORD**

This notice is to inform you that when you submit a set of fingerprints to the Florida Department of Law Enforcement (FDLE) for the purpose of conducting a search for any Florida and national criminal history records that may pertain to you, the results of that search will be returned to the Care Provider Background Screening Clearinghouse. By submitting fingerprints, you are authorizing the dissemination of any state and national criminal history record that may pertain to you to the Specified Agency or Agencies from which you are seeking approval to be employed, licensed, work under contract, or to serve as a volunteer, pursuant to the National Child Protection Act of 1993, as amended, and Section 943.0542, Florida Statutes. "Specified agency" means the Department of Health, the Department of Children and Family Services, the Division of Vocational Rehabilitation within the Department of Education, the Agency for Health Care Administration, the Department of Elder Affairs, the Department of Juvenile Justice, and the Agency for Persons with Disabilities when these agencies are conducting state and national criminal history background screening on persons who provide care for children or persons who are elderly or disabled. The fingerprints submitted will be retained by FDLE and the Clearinghouse will be notified if FDLE receives Florida arrest information on you.

Your Social Security Number (SSN) is needed to keep records accurate because other people may have the same name and birth date. Disclosure of your SSN is imperative for the performance of the Clearinghouse agencies' duties in distinguishing your identity from that of other persons whose identification information may be the same as or similar to yours.
Licensing and employing agencies are allowed to release a copy of the state and national criminal record information to a person who requests a copy of his or her own record if the identification of the record was based on submission of the person's fingerprints. Therefore, if you wish to review your record, you may request that the agency that is screening the record provide you with a copy. After you have reviewed the criminal history record, if you believe it is incomplete or inaccurate, you may conduct a personal review as provided in s. 943.056, F.S., and Rule 11C8.001, F.A.C. If national information is believed to be in error, the FBI should be contacted at 304-625-2000. You can receive any national criminal history record that may pertain to you directly from the FBI, pursuant to 28 CFR Sections 16.30-16.34. You have the right to obtain a prompt determination as to the validity of your challenge before a final decision is made about your status as an employee, volunteer, contractor, or subcontractor.

Until the criminal history background check is completed, you may be denied unsupervised access to children, the elderly, or persons with disabilities.

The FBI's Privacy Statement follows on a separate page and contains additional information.

US Department of Justice, Federal Bureau of Investigation,
Criminal Justice Information Services Division

Privacy Statement

Authority: The FBI's acquisition, preservation and exchange of information requested by this form is generally authorized under 28 U.S.C. 534. Depending on the nature of your application, supplemental authorities include numerous Federal statutes, hundreds of State statutes pursuant to Pub.L.92-544, Presidential executive orders, regulations and/or orders of the Attorney General of the United States, or other authorized authorities. Examples include, but are not limited to: 5 U.S.C. 9101; Pub.L.94-29; Pub.L.101-604; and Executive Orders 10450 and 12968. Providing the requested information is voluntary; however, failure to furnish the information may affect timely completion of approval of your application.

Social Security Account Number (SSAN): Your SSAN is needed to keep records accurate because other people may have the same name and birth date. Pursuant to the Federal Privacy Act of 1974 (5 USC 552a), the requesting agency is responsible for informing you whether disclosure is mandatory or voluntary, by what statutory or other authority your SSAN is solicited, and what uses will be made of it. Executive Order 9397 also asks Federal Agencies to use this number to help identify individuals in agency records.

Principal Purpose: Certain determinations, such as employment, security, licensing and adoption, may be predicated on fingerprint based checks. Your fingerprints and other information contained on (and along with) this form may be submitted to the requesting agency, the agency conducting the application investigation, and/or FBI for the purpose of comparing the submitted information to available records in order to identify other information that may be pertinent to the application. During the processing of this application, and for as long hereafter as my be relevant to the activity for which this application is being submitted, the FBI(may disclose any potentially pertinent information to the requesting agency and/or to the agency conducting the investigation. The FBI may also retain the submitted information in the FBI's permanent collection of fingerprints and related information, where it will be subject to comparisons against other submissions received by the FBI. Depending on the nature of your application, the requesting agency and/or the agency conducting the application investigation may also retain the fingerprints and other submitted information for other authorized purposes of such agency(ies).

Routine Uses: The fingerprints and information reported on this form may be disclosed pursuant to your consent, and may also be disclosed by the FBI without your consent as permitted by the Federal Privacy Act of 1974 (5 USC 552a(b)) and all applicable routine uses as many be published at any time in the Federal Register, including the routine uses for the FBI Fingerprint Identification Records System (Justice, FBI-009) and the FBI's Blanket Routine Uses (Justice/FBI-BRU). Routine uses include, but are not limited to, disclosures to: appropriate governmental authorities responsible for civil or criminal law enforcement counterintelligence, national security or public safety matters to which the information may be relevant; to State and local governmental agencies and nongovernmental entities for application processing as authorized by Federal and State legislation, executive order, or regulation, including employment, security, licensing, and adoption checks; and as otherwise authorized by law , treaty, executive order, regulation, or other lawful authority. If other agencies are involved in processing the application, they may have additional routine uses.

Additional Information: The requesting agency and/or the agency conducting the application investigation will provide you additional information pertinent to the specific circumstances of this application, which may include identification of other authorities, purposes, uses, and consequences of not providing requested information. In addition, any such agency in the Federal Executive Branch has also published notice.

Electronic Fingerprinting

Take this form with you to the Live Scan service provider. Please check the service provider's requirements to see if you need to bring any additional items.

- Background screening results are obtained from the Florida Department of Law Enforcement and the Federal Bureau of Investigation by submitting to a fingerprint scan using the Livescan method;
- You can find a Livescan service provider at: http://www.floridahealth.gov/licensing-and-regulation/background-screening/livescan-service-providers.html
- Failure to submit background screening will delay your application;
- Applicants may use any Livescan service provider approved by the Florida Department of Law Enforcement to submit their background screening to the department;
- If you do not provide the correct Originating Agency Identification (ORI) number to the livescan service provider the Board office will not receive your background screening results;
- You must provide accurate demographic information to the livescan service provider at the time your fingerprints are taken, ***including your Social Security number (SSN)***;
- The ORI number for the Board of Pharmacy is **EDOH4680Z.**
- Typically background screening results submitted through a Livescan service provider are received by the Board within 24-72 hours of being processed.
- If you obtain your livescan from a service provider who does not capture your photo you may be required to be reprinted by another agency in the future.

Name:_____ SSN#: _____ - ____ - _____

Aliases:_____

Address:_____Apt. Number:_____

City:_____ State: _____Zip Code: _____

Date of Birth: _____/_____/_____ Place of Birth: _____
(MM/DD/YYYY)

Weight: _____ Height: _____ Eye Color:_____ Hair Color: _____

Race: _____
(W-White/Latino(a); B-Black; A-Asian; NA-Native American; U-Unknown)

Sex: _____
(M=Male; F=Female)

Citizenship: _____

Transaction Control Number (TCN#):_____
(*This will be provided to you by the Live Scan Service provider*.)

Keep this form for your records.

Item #1- PDM Designation and Privacy Statement Acknowledgement

File #: (if known):
License #: (if applicable):

To: **Florida Board of Pharmacy**
Post Office Box 6320
Tallahassee, FL 32314-6320
(850) 245-4292- phone
(850) 413-6982 - fax
MQAPharmPDMAffiliate@flhealth.gov

Section A. Prescription Department Manager (PDM) Designation

Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailing Address:		
City	**State**	**Zip**
Incoming PDM Name:		**License#:**
		PS
Date Beginning as PDM:	**Incoming PDM Signature**	
PDM Transaction Control Number (TCN) – related to Livescan Fingerprints *(optional, if known)*: ** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs**		
****OPTIONAL: Only provide following information if there is an Outgoing PDM at current pharmacy****		
Outgoing PDM Name:		**License#:**
		PS
Date Ending as PDM:	**Outgoing PDM Signature** *(optional)*	

Section B. Incoming PDM Privacy Statement Acknowledgement

Note: Acknowledgment should be completed by same person listed in Section A above as Incoming PDM.

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

Date:	**Incoming PDM Signature**

Item #2- Affiliate/Owner Privacy Statement Acknowledgement

To be completed by EACH Affiliate/Owner listed in the application.

To: **Florida Board of Pharmacy, Post Office Box 6320, Tallahassee, FL 32314-6320**
(850) 245-4292- phone * (850) 413-6982 – fax * MQAPharmPDMAffiliate@flhealth.gov

From:

Affiliate / Owner Name:		**File # (required):**
Applicant Name:		
Affiliate/Owner Mailing Address:		
City	**State**	**Zip**
Affiliate/Owner E-Mail ** (see note below)	**Affiliate/Owner Telephone Number**	
Affiliate/Owner Transaction Control Number (TCN) *(optional, if known)*: ** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs**		
NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.		

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

_____ _____

Affiliate/Owner Signature (Required) **Date (of signature)**

DIVISION OF MEDICAL QUALITY ASSURANCE
BOARD OF PHARMACY
4052 BALD CYPRESS WAY, BIN #C-04
TALLAHASSEE, FLORIDA 32399-3254
(850) 245-4292

INSTITUTIONAL PHARMACY PERMIT APPLICATION AND INFORMATION

January 2018

Dear Florida Pharmacy Permit Applicant,

Thank you for applying for a pharmacy permit in the State of Florida. The information in this packet has been designed to provide the essential information required to process your application in a timely manner. Your assistance in providing all required information will enable the Florida Board of Pharmacy (the board) staff to process your application as soon as possible. You are encouraged to apply as early as possible, to avoid delays due to a large volume of applicants.

Florida Statutes require a completed application and fees before your application can be reviewed. Please read these instructions carefully and fully before submitting the application. You should keep a copy of the completed application and all other materials sent to the board office for your records. When you mail the completed application and fees, use the address noted in the instructions and on the application form.

When your application arrives, your fees will be deposited and verified before the staff review can begin. You will receive a letter acknowledging receipt of your application. The staff will notify you within 30 days if any materials are incomplete.

If you need to communicate with the board staff, you are encouraged to email the board staff at info@floridaspharmacy.gov or you may at call us at (850) 245-4292. Phone calls are returned within 24 hours and emails are responded to within 48 hours during normal business hours. Our staff is committed to providing prompt and reliable information to our customers. Many procedures have been streamlined to expedite the processing of applications; we certainly welcome your comments on how our services may be improved.

Sincerely,

The Board of Pharmacy

INSTITUTIONAL PHARMACY PERMIT APPLICATION INFORMATION

Whether opening a new establishment, changing locations, or changing owners, a pharmacy permit is required prior to operating in the State of Florida. The permit application must be completed and returned to the Florida Board of Pharmacy with the required fee of $255.00. The application MUST have the original signatures of the owner or officer of the establishment and the Consultant Pharmacist of Record (COR). If compounding sterile preparations, submit an additional application on Form DH-MQA 1270, "Special Sterile Compounding Permit" and pay the additional permitting fee.

There are three types of Institutional Pharmacy Permit applicants. Please read the description below. Check which permit type you are applying for on the application.

1. **Institutional Class I Pharmacy** – An Institutional Class I pharmacy is an institutional pharmacy in which all medicinal drugs are administered from individual prescription containers to the individual patient and in which medicinal drugs are not dispensed on the premises. No medicinal drugs may be dispensed in a Class I Institutional pharmacy. A Special- Closed System Pharmacy Permit, Special Parenteral and Enteral Pharmacy Permit, or Community Pharmacy Permit allow dispensing of individual patient prescriptions.

2. **Institutional Class II Pharmacy Permit** – An Institutional Class II pharmacy is an institutional pharmacy that employs the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution. An Institutional Class II pharmacy is required be open sufficient hours to meet the needs of the hospital facility.

3. **Modified Institutional Class II Pharmacy Permits -** Modified Institutional Class II pharmacies are those institutional pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements. Modified Class II Institutional pharmacies are designated as Type "A", Type "B" and Type "C" according to the type of specialized pharmaceutical delivery system utilized. Please review Rule 64B16-28.702, Florida Administrative Code for specific requirements.

Section 465.022(4), Florida Statutes, also provides that an application for a pharmacy permit must include the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships. The policy and procedure manual shall contain the procedures implemented to minimize the dispensing of controlled substances based on fraudulent representations as follows:

1. Provisions to identify and guard against invalid practitioner-patient relationships.
2. Provisions to guard against filling fraudulent prescriptions for controlled substances.
3. Provisions to identify prescriptions that are communicated or transmitted legally.
4. Provisions to identify the characteristics of a forged or altered prescription.

Application Processing

Please read all application instructions before completing your application.

1) Mail Application.

Please mail the application and the $255.00 application fee (cashier's check or money order made payable to the FLORIDA DEPARTMENT OF HEALTH) to the following address:

Application & Fees:	**Express Mail ONLY**
Department of Health	Department of Health
Board of Pharmacy	Board of Pharmacy
P.O. Box 6320	4052 Bald Cypress Way, Bin C-04
Tallahassee, Florida 32314-6320	Tallahassee, FL 32399-3254

Within 30 days of receipt of your application and fees, the Board office will notify you of the receipt of your application, any required documents, and your status. If the application is complete, you will be notified that an inspector will contact you to setup an inspection appointment. If your application is incomplete, you will be notified in writing of what is required to make your application complete.

2) Submit fingerprint results.

Failure to submit fingerprints will delay your application. All owners, officers, and Consultant Pharmacists of Record (CORs) are required to submit a set of fingerprints unless the corporation is exempt under Section 465.022, Florida Statutes, for corporations having more than $100 million of business taxable assets in this state. These corporations are only required to have the COR to submit fingerprints.

Electronic fingerprint information ("EFI") that has been submitted to the Florida Agency for Health Care Administration may be accessible by the Florida Department of Health for a period of sixty (60) months. If the Department is able to access EFI from AHCA, applicants will not be required to resubmit EFI for additional or new applications submitted during this time period. After sixty (60) months, new electronic fingerprint information must be submitted as part of all applications. **Note: If your officer, owner, or Consultant Pharmacist of Record has already been fingerprinted at the time you are completing this Institutional Pharmacy permit application, please ensure to provide the Transaction Control Number (TCN), if known, with the requested information in the application.**

Applicants may use any Livescan vendor that has been approved by the Florida Department of Law Enforcement to submit their fingerprints to the department. Please ensure that the Originating Agency Identification (ORI) number is provided to the vendor when you submit your fingerprints. If you do not provide an ORI number or if you provide an incorrect ORI number to the vendor, the Board of Pharmacy will not receive your fingerprint results. The applicant is fully responsible for selecting the vendor and ensuring submission of the prints to the Department.

How do I find a Livescan vendor in order to submit my fingerprints to the Department?
The Department of Health accepts electronic fingerprinting service offered by Livescan device vendors that are approved by the Florida Department of Law Enforcement and listed at their site. You can view the vendor options and contact information at:

http://www.floridahealth.gov/licensing-and-regulation/background-screening/livescan-service-providers.html

What information must I provide to the Livescan vendor I choose?

- If you are an applicant seeking a license for any profession regulated by the Department of Health, which requires a criminal background search as a condition of licensure, you must provide accurate demographic information at the time your fingerprints are taken, ***including your Social Security number***. The Department will not be able to process a submission that does not include your Social Security number.
- You must provide the correct ORI number.

Where do I get the ORI number to submit to the vendor?
The ORI number for the pharmacy profession is **EDOH4680Z**.

Attestation for Business Taxable Assets
If the applicant has more than $100 million dollars of business taxable assets in this state, please submit a formal opinion letter from a Certified Public Accountant duly licensed in the state of your principal place of business affirming the corporation has more than $100 million of business taxable assets in this state for the previous tax year. In lieu of submitting a formal opinion letter from a Certified Public Accountant, the applicant may submit its Florida Corporate Income/Franchise and Emergency Excise Tax Return (Form F-1120, Effective 01/09).

3) Privacy Statement and Attestation

In order for the Board of Pharmacy Office to receive your Livescan electronic fingerprinting results, you must affirm that you have been provided with and read the attached statement from the Florida Department of Law Enforcement regarding the sharing, retention, and right to challenge incorrect criminal history records, and the "Privacy Statement" document from the Federal Bureau of Investigation. The appropriate form(s) to provide this affirmation are included within Items #1 and #2 of the application.

Licensure Process

Once the application is deemed complete, the board staff authorizes an inspection. Upon completion of the inspection, the inspector notifies the board office as to whether the inspection was satisfactory or unsatisfactory. If the inspection is satisfactory, a permit number is issued within 10 days. **Please wait 7 - 14 days from your satisfactory inspection before checking on the status of your permit**.

You may look up your license number on our website at http://www.flhealthsource.com/ under "Verify a License."

Drug Enforcement Administration (DEA)

Please note that the DEA will not issue a registration until the Florida Board of Pharmacy has issued a pharmacy permit. More information is available by visiting the DEA website at http://www.DEAdiversion.usdoj.gov, or by contacting them at (800)667-9752.

IMPORTANT NOTICE: Pursuant to Section 465.022(5), F.S., the Department or Board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant:

(a) Has obtained a permit by misrepresentation or fraud.

(b) Has attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation.

(c) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy.

(d) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud.

(e) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009.

(f) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009.

(g) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period.

(h) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application.

(i) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

(j) Has 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.

For felonies in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the department shall deny the application if upon final resolution of the case the licensee has failed to successfully complete the program.

<u>If applicable to you, please provide the documentation to the Florida Board of Pharmacy.</u>

PHARMACY PERMIT APPLICATION CHECKLIST

Keep a copy of the completed application for your records.

It is recommended that you use the following checklist to help ensure that your application is complete. Failure to attach any required document, or to have required documentation sent to the Board, will result in an incomplete application. Final approval for inspection cannot be granted until the application is complete.

INSTITUTIONAL PHARMACY PERMIT

_____All Application Questions Answered?

_____$255.00 Fee Attached (Permit fee includes $250 application fee and $5.00 unlicensed activity fee)

_____Articles of Incorporation paperwork from the Secretary of State provided?

_____COR Designation and Privacy Statement Acknowledgement provided (Application Item #1)?

_____Affiliate/Owner Privacy Statement Acknowledgement provided for each affiliate/owner (Application Item #2)?

_____Answers to Policy and Procedure Questions provided for **Institutional Pharmacy** applicants (Application Item #3)?

_____Answers to Policy and Procedure Questions provided for **Modified Class II Institutional Pharmacy** applicants (Application Item #4)?

_____Applicant/Affiliate/Owner supplemental documents provided for explaining any previous ownership, disciplinary actions, voluntary relinquishments and/or criminal activity?

_____Applicant/Affiliate/Owner pharmacy permit questions answered and supplemental documents provided?

_____Policies and Procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships submitted?

FLORIDA BOARD OF PHARMACY
P.O. Box 6320
Tallahassee, FL 32314-6320
850-245-4292
http://www.floridaspharmacy.gov

INSTITUTIONAL PHARMACY PERMIT

APPLICATION

Application Type – Please choose one of the following:

___New Establishment ($255.00 fee)
Complete: Section A only, along with Items #1 and 2.

___Change of Ownership ($255.00 fee)
Complete: Sections A and C only, along with Items #1 and 2.

___ Change of Location ($100.00 fee)
Complete: Sections A and B only.

___ Stock Transfer (no fee)
Complete: Section A, pages 2-3 and Section D only.

Pharmacy Permit Type – Please choose only one of the following:

____Institutional Class I

____Institutional Class II
Complete: Item #3 only,

Modified Institutional Class II A ___Class II B____ Class II C___
Complete: Item #4 only,

SECTION A. Please complete for all Application Types

Please list your Federal Employer Identification Number:

1. Corporate Name	**Telephone Number**

2. Doing Business As (d/b/a)	**E-Mail Address**** (see note below)

3. Mailing Address		
City	**State**	**Zip**

4. Physical Address		
City	**State**	**Zip**

5. Consultant Pharmacist of Record (COR) Information

Name	**License Number**

Email Address ** (see note below)	**Telephone Number**

6. Contact Person	**Title**

Email Address ** (see note below)	**Telephone Number**

NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.

7. Ownership Information

a Type of Ownership: _____Individual _____Corporation _____Partnership

NOTE: If the applicant is a corporation or limited partnership you must include with your application a copy of the Articles of Incorporation on file with the Florida Secretary of State's office.

b. Are the applicants, officers, directors, shareholders, members and partners over the age of 18?

Yes _____ No_____

c. Does the corporation have more than $100 million of business taxable assets in this state? *If yes, provide attestation from Certified Public Accountant for previous tax year or Florida Corporate Income /Franchise and Emergency Excise Tax Return (F-1120).*

Yes _____ No_____

d. List all the owners and officers of the corporation. Each person listed below having an ownership interest of 5% or greater and any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant including officers and members of the board of directors must submit a set of fingerprints and fees unless you answered yes to 7c. If 7c. is "Yes", please list the owners below and only submit fingerprints for the Consultant Pharmacist of Record. If 7c. is "Yes" and the prints are on file with DOH or AHCA and available to the Board of Pharmacy, the requirement to submit the prints for this person is met. Also, if the % of Ownership column does not add to 100%, please provide an explanation. *Attach a separate sheet if necessary.*

Owner/Officer-Title	Date of Birth	Mailing Address, City, State, Zip Code	% of Ownership
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%

8. Has anyone listed in 7d. has an ownership interest of 5% or more in a pharmacy or any other business permit which was disciplined, suspended, revoked, or closed involuntarily within the past 5 years? *If yes, please provide a signed statement disclosing the reason the entity was closed.*

Yes_____ No_____

8a. Has anyone listed in 7d. had an ownership interest of 5% or more in a pharmacy or any other business permit which was voluntarily relinquished or closed voluntarily within the past 5 years? *If yes, please provide a signed statement disclosing the reason the entity was closed.*

Yes _____ No _____

Pursuant to Section 465.022(5), the questions 9 – 17 are being asked. If you answer "Yes" to any of the following questions, explain on a separate sheet providing accurate details and submit copies of supporting documentation.
9. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant obtained a permit by misrepresentation or fraud?
Yes _____ No_____
10. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation?
Yes _____ No _____
11. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy?
Yes _____ No_____
12. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud?
Yes_____ No_____
13. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009?
Yes _____ No_____
14. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period?
Yes _____ No _____
15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application?
Yes _____ No _____
16. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant currently listed on the United States Department of Health Human Services Office of Inspector General's List of Excluded Individuals and Entities? *(If yes, please submit proof.)*
Yes _____ No _____

17. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant 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?

Yes _____ No _____

18. Are you currently registered or permitted in any other states? *(If yes, provide the state, permit type and permit number for each permit. Attach a separate sheet if necessary.)*

Yes_____ No _____

State	Permit Type	Permit Number

19. Has the applicant, affiliated persons, partners, officer, directors, or Consultant Pharmacist of Record ever owned a pharmacy? *(If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy. Attach a separate sheet if necessary.*

Yes _____ No _____

Individual's Name	Pharmacy Name	State	Status

20. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, affiliated persons, partners, officers, directors or consultant pharmacist of record?

Yes _____ No _____

21. Has the applicant, affiliated person, partner, officer, or director ever been convicted of a felony or misdemeanor, excluding minor traffic convictions? You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction.

Yes _____ No _____

22. Does the applicant, affiliated person, partner, officer, director have any outstanding fines, liens or overpayments assessed by a final order of the department? *(If yes, please answer question #22a,)*

Yes _____ No _____

22a. Does the applicant, affiliated person, partner, officer, director have a repayment plan approved by the department?
Yes _____ No _____
23. Is the applicant, affiliated persons, partners, officers, or directors, under investigation or prosecution for a crime in any jurisdiction?
Yes _____ No_____
24. Is the applicant, affiliated persons, partners, officers, or directors, under investigation or pending administrative action by the licensing authority of any jurisdiction, including its agencies and subdivisions?
Yes _____ No_____

SECTION B. Please complete for Change of Location only.

1. Current Practice Location Address		
City	**State**	**Zip**
E-Mail Address** (see note below)	**Telephone Number**	
2. New Practice Location Address		
City	**State**	**Zip**
E-Mail Address** (see note below)	**Telephone Number**	

Please provide your existing Pharmacy Permit Number:
Please provide your existing federal DEA Number:
NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.

SECTION C. Please complete for Change of Ownership only.

1. Are you changing physical locations with this change of ownership?
Yes _____ No _____ *NOTE: If yes, please complete **Section B** above.*
2. Please provide date when business transaction for the change of ownership will be completed?
Date:
3. Do you have a signed letter from both the buyer and seller which indicates dates that pharmacy permit license should be transferred? *NOTE: A copy of the signed letter should be provided with your application.*
Yes _____ No _____

SECTION D. Please complete for Stock Transfer of Ownership Interests only.
1. Please provide the date when the transfer of ownership interest took place?
Date:
2. Did your company's FEIN change as a result of the transfer of ownership interest referenced in Section D, Question 1 above?
Yes_____ No _____ *NOTE: If yes, please complete **Section C** above and include necessary fee.*

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

****

Section 456.013(1), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application, which takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department.

I swear and affirm that the statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations that they deem appropriate and to secure any additional information concerning me, and I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, Board, or any municipal, county, state, or federal governmental agencies or units, and I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other item, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

Under penalty of perjury I have read the foregoing document and that the facts stated in it are true. I recognize that providing false information may result in disciplinary action against my license or criminal penalties.

SIGNATURE _____ DATE_____
(Owner or officer of establishment)

FLORIDA DEPARTMENT OF LAW ENFORCEMENT

NOTICE FOR APPLICANTS SUBMITTING FINGERPRINTS WHERE CRIMINAL RECORD RESULTS WILL BECOME PART OF THE CARE PROVIDER BACKGROUND SCREENING CLEARINGHOUSE

NOTICE OF:

- **SHARING OF CRIMINAL HISTORY RECORD INFORMATION WITH SPECIFIED AGENCIES,**
- **RETENTION OF FINGERPRINTS,**
- **PRIVACY POLICY, AND**
- **RIGHT TO CHALLENGE AN INCORRECT CRIMINAL HISTORY RECORD**

This notice is to inform you that when you submit a set of fingerprints to the Florida Department of Law Enforcement (FDLE) for the purpose of conducting a search for any Florida and national criminal history records that may pertain to you, the results of that search will be returned to the Care Provider Background Screening Clearinghouse. By submitting fingerprints, you are authorizing the dissemination of any state and national criminal history record that may pertain to you to the Specified Agency or Agencies from which you are seeking approval to be employed, licensed, work under contract, or to serve as a volunteer, pursuant to the National Child Protection Act of 1993, as amended, and Section 943.0542, Florida Statutes. "Specified agency" means the Department of Health, the Department of Children and Family Services, the Division of Vocational Rehabilitation within the Department of Education, the Agency for Health Care Administration, the Department of Elder Affairs, the Department of Juvenile Justice, and the Agency for Persons with Disabilities when these agencies are conducting state and national criminal history background screening on persons who provide care for children or persons who are elderly or disabled. The fingerprints submitted will be retained by FDLE and the Clearinghouse will be notified if FDLE receives Florida arrest information on you.

Your Social Security Number (SSN) is needed to keep records accurate because other people may have the same name and birth date. Disclosure of your SSN is imperative for the performance of the Clearinghouse agencies' duties in distinguishing your identity from that of other persons whose identification information may be the same as or similar to yours.
Licensing and employing agencies are allowed to release a copy of the state and national criminal record information to a person who requests a copy of his or her own record if the identification of the record was based on submission of the person's fingerprints. Therefore, if you wish to review your record, you may request that the agency that is screening the record provide you with a copy. After you have reviewed the criminal history record, if you believe it is incomplete or inaccurate, you may conduct a personal review as provided in s. 943.056, F.S., and Rule 11C8.001, F.A.C. If national information is believed to be in error, the FBI should be contacted at 304-625-2000. You can receive any national criminal history record that may pertain to you directly from the FBI, pursuant to 28 CFR Sections 16.30-16.34. You have the right to obtain a prompt determination as to the validity of your challenge before a final decision is made about your status as an employee, volunteer, contractor, or subcontractor.

Until the criminal history background check is completed, you may be denied unsupervised access to children, the elderly, or persons with disabilities.

The FBI's Privacy Statement follows on a separate page and contains additional information.

US Department of Justice, Federal Bureau of Investigation,
Criminal Justice Information Services Division

Privacy Statement

Authority: The FBI's acquisition, preservation and exchange of information requested by this form is generally authorized under 28 U.S.C. 534. Depending on the nature of your application, supplemental authorities include numerous Federal statutes, hundreds of State statutes pursuant to Pub.L.92-544, Presidential executive orders, regulations and/or orders of the Attorney General of the United States, or other authorized authorities. Examples include, but are not limited to: 5 U.S.C. 9101; Pub.L.94-29; Pub.L.101-604; and Executive Orders 10450 and 12968. Providing the requested information is voluntary; however, failure to furnish the information may affect timely completion of approval of your application.

Social Security Account Number (SSAN): Your SSAN is needed to keep records accurate because other people may have the same name and birth date. Pursuant to the Federal Privacy Act of 1974 (5 USC 552a), the requesting agency is responsible for informing you whether disclosure is mandatory or voluntary, by what statutory or other authority your SSAN is solicited, and what uses will be made of it. Executive Order 9397 also asks Federal Agencies to use this number to help identify individuals in agency records.

Principal Purpose: Certain determinations, such as employment, security, licensing and adoption, may be predicated on fingerprint based checks. Your fingerprints and other information contained on (and along with) this form may be submitted to the requesting agency, the agency conducting the application investigation, and/or FBI for the purpose of comparing the submitted information to available records in order to identify other information that may be pertinent to the application. During the processing of this application, and for as long hereafter as my be relevant to the activity for which this application is being submitted, the FBI(may disclose any potentially pertinent information to the requesting agency and/or to the agency conducting the investigation. The FBI may also retain the submitted information in the FBI's permanent collection of fingerprints and related information, where it will be subject to comparisons against other submissions received by the FBI. Depending on the nature of your application, the requesting agency and/or the agency conducting the application investigation may also retain the fingerprints and other submitted information for other authorized purposes of such agency(ies).

Routine Uses: The fingerprints and information reported on this form may be disclosed pursuant to your consent, and may also be disclosed by the FBI without your consent as permitted by the Federal Privacy Act of 1974 (5 USC 552a(b)) and all applicable routine uses as many be published at any time in the Federal Register, including the routine uses for the FBI Fingerprint Identification Records System (Justice, FBI-009) and the FBI's Blanket Routine Uses (Justice/FBI-BRU). Routine uses include, but are not limited to, disclosures to: appropriate governmental authorities responsible for civil or criminal law enforcement counterintelligence, national security or public safety matters to which the information may be relevant; to State and local governmental agencies and nongovernmental entities for application processing as authorized by Federal and State legislation, executive order, or regulation, including employment, security, licensing, and adoption checks; and as otherwise authorized by law , treaty, executive order, regulation, or other lawful authority. If other agencies are involved in processing the application, they may have additional routine uses.

Additional Information: The requesting agency and/or the agency conducting the application investigation will provide you additional information pertinent to the specific circumstances of this application, which may include identification of other authorities, purposes, uses, and consequences of not providing requested information. In addition, any such agency in the Federal Executive Branch has also published notice.

Electronic Fingerprinting

Take this form with you to the Live Scan service provider. Please check the service provider's requirements to see if you need to bring any additional items.

- Background screening results are obtained from the Florida Department of Law Enforcement and the Federal Bureau of Investigation by submitting to a fingerprint scan using the Livescan method;
- You can find a Livescan service provider at: http://www.floridahealth.gov/licensing-and-regulation/background-screening/livescan-service-providers.html
- Failure to submit background screening will delay your application;
- Applicants may use any Livescan service provider approved by the Florida Department of Law Enforcement to submit their background screening to the department;
- If you do not provide the correct Originating Agency Identification (ORI) number to the livescan service provider the Board office will not receive your background screening results;
- You must provide accurate demographic information to the livescan service provider at the time your fingerprints are taken, ***including your Social Security number (SSN)***;
- The ORI number for the Board of Pharmacy is **EDOH4680Z**.
- Typically background screening results submitted through a Livescan service provider are received by the Board within 24-72 hours of being processed.
- If you obtain your livescan from a service provider who does not capture your photo you may be required to be reprinted by another agency in the future.

Name:_____ SSN#: _____ - ____ - _____

Aliases:_____

Address: _____ Apt. Number: _____

City:_____ State: _____Zip Code: _____

Date of Birth: _____/_____/_____ Place of Birth: _____
(MM/DD/YYYY)

Weight: _____ Height: _____ Eye Color:_____ Hair Color: _____

Race: _____
(W-White/Latino(a); B-Black; A-Asian; NA-Native American; U-Unknown)

Sex: _____
(M=Male; F=Female)

Citizenship: _____

Transaction Control Number (TCN#):_____
(*This will be provided to you by the Live Scan Service provider*.)

Keep this form for your records.

Item #1- Consultant Pharmacist of Record Designation and Privacy Statement Acknowledgement

To: **Florida Board of Pharmacy**
Post Office Box 6320
Tallahassee, FL 32314-6320
(850) 245-4292- phone
(850) 413-6982 - fax
MQAPharmPDMAffiliate@flhealth.gov

File #: (if known):
License #: (if applicable):

Section A. Consultant Pharmacist of Record (COR) Designation

Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailing Address:		
City	**State**	**Zip**
Incoming COR Name:		**License#:**
		PU
Date Beginning as COR:	**Incoming COR Signature**	
Transaction Control Number (TCN) – related to Livescan Fingerprints *(optional, if known)*: ** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs**		
****OPTIONAL: Only provide following information if there is an Outgoing COR at current pharmacy****		
Outgoing COR Name:		**License#:**
		PU
Date Ending as COR:	**Outgoing COR Signature** *(optional)*	

Section B. Incoming COR Privacy Statement Acknowledgement

Note: Acknowledgment should be completed by same person listed in Section A above as Incoming COR.

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

Date:	**Incoming COR Signature**

Item #2- Affiliate/Owner Privacy Statement Acknowledgement

To be completed by EACH Affiliate/Owner listed in the application.

To: **Florida Board of Pharmacy, Post Office Box 6320, Tallahassee, FL 32314-6320**
(850) 245-4292- phone * (850) 413-6982 – fax * MQAPharmPDMAffiliate@flhealth.gov

From:

Affiliate / Owner Name:		**File # (required):**
Applicant Name:		
Affiliate/Owner Mailing Address:		
City	**State**	**Zip**
Affiliate/Owner E-Mail ** (see note below)	**Affiliate/Owner Telephone Number**	
Affiliate/Owner Transaction Control Number (TCN) *(optional, if known)*: ** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs**		
NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.		

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

_____ _____

Affiliate/Owner Signature (Required) **Date (of signature)**

Item #3 - Policy and Procedure Questions

To be completed by Institutional Class II Pharmacy Permit Applicants

The Consultant Pharmacist of Record is responsible for developing and maintaining a current policy and procedure manual. A copy of the permittee's policy and procedure manual as provided herein shall accompany the permit application. The original policy and procedure manual shall be kept within the Class II Institutional Pharmacy and shall be available for inspection by the Department of Health. The board office will approve the policy and procedure manual based upon answers submitted for the following questions, where applicable, by using excerpts or summaries from the policy and procedure manual.

1) List the following:
   Firm Name:
   Doing business as (d/b/a):
   Telephone number: Address:
   Permit number (if already licensed as an institutional pharmacy):

2) Explain the practice setting of the proposed facility.

3) What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice.

4) What are the experience, qualifications, special education, and/or training of the compounding pharmacist? Please provide a resume.

5) Address the ratio of supportive personnel to each pharmacist. How will the supportive personnel be utilized? Include a job description for any such supportive personnel.

6) Describe the drug delivery system. Begin with the ordering of medications and track your procedures up to delivery to the patient. If utilizing remote medication order processing and the pharmacist is not an employee of the institution, describe the pharmacist and institution's responsibility.

7) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.

8) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how products are protected from extreme temperature conditions.

9) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.

10) Address the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed, please state so accordingly.

11) Address the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.

12) What is the procedure for the annual review and updating of the policy and procedure manual?

13) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.

14) Include a sample copy of a patient profile.

15) Address the use of aseptic techniques.

16) Describe the Quality Assurance Program.

17) Describe with detail the policy and procedure for patient education, including the personnel involved.

18) Address the policy and procedure for handling waste and returns.

19) Describe the type of certified laminar flow hood(s) used and the frequency of certification.

20) Describe the refrigerator/freezer to be used.

21) Describe appropriate waste containers for:

    a. Used needles and syringes.

    b. Cytotoxic waste including disposable apparel used in preparation.

22) Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.

23) Address the following references to be used:

    a. Chapters 465 and 893, F.S., and Rule Title 64B16,F.A.C.
    b. Authoritative Therapeutic Reference.
    c. Handbook of injectable drugs by American Society of Health-System Pharmacists.

24) Occupational Safety and Health Administration guidelines for safe handling of cytotoxic drugs.

Item #4 - Policy and Procedure Questions

To be completed by Modified Institutional Class II Pharmacy Permit Applicants

Modified Institutional Class II pharmacies are those institutional pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements. Modified Class II Institutional pharmacies are designated as Type "A", Type "B" and Type "C" according to the type of specialized pharmaceutical delivery system utilized. Please review Rule 64B16-28.702, Florida Administrative Code for specific requirements.

The Consultant Pharmacist of Record is responsible for developing and maintaining a current policy and procedure manual. A copy of the permittee's policy and procedure manual as provided herein shall accompany the permit application. The original policy and procedure manual shall be kept within the Modified Class II Institutional Pharmacy and shall be available for inspection by the Department of Health. The board office will approve the policy and procedure manual based upon answers submitted for the following questions, where applicable, by using excerpts or summaries from the policy and procedure manual

1) List the following:
   Firm Name:
   Doing business as (d/b/a):
   Telephone number:
   Address:
   Consultant pharmacist of record:

2) Describe the purpose of the establishment. What sector of the community are you serving?

3) Is this is an inpatient facility? If so, how many beds are housed in the facility?
   What is the average length of stay?

4) List the drug formulary to be used.

5) Include a diagram of pharmacy storage space and a description of drug security measures.

6) Describe the consultant pharmacist of record's responsibilities.

7) Under whose DEA registration will controlled substances be ordered?

8) Describe the drug delivery system. Begin with the ordering of medications and track your procedures up to delivery to the patient.

9) Include a statement that perpetual inventory records will be maintained for controlled substances and injectable inventory.

10) Include a statement to the effect that no drugs will be dispensed from the facility.

If compounding sterile preparations, please answer the additional questions below.

11) If compounding sterile preparations, describe compliance with Rule 64B16- 27.797, F.A.C.

12) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.

13) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how this product is protected from extreme temperature conditions.

14) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.

15) Address the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed, please state so accordingly.

16) Address the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.

17) What is the procedure for the annual review and updating of the policy and procedure manual?

18) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.

19) Include a sample copy of a patient profile.

20) Address the use of aseptic techniques.

21) Describe the Quality Assurance Program.

22) Describe with detail the policy and procedure for patient education, including the personnel involved.

23) Address the policy and procedure for handling waste and returns.

24) Describe the type of certified laminar flow hood(s) to be used and the frequency of certification.

25) Describe the refrigerator/freezer to be used.

26) Describe appropriate waste containers for:
    a. Used needles and syringes.
    b. Cytotoxic waste including disposable apparel used in preparation.

27) Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.

28) Address the following references to be used:
    a. Chapters 465 and 893, F.S., and Title 64B16, F.A.C.
    b. Authoritative Therapeutic Reference.
    c. Handbook of Injectable Drugs by American Society of Health-System Pharmacists.
    d. Occupational Safety and Health Administration guidelines for safe handling of cytotoxic drugs.

DIVISION OF MEDICAL QUALITY ASSURANCE
BOARD OF PHARMACY
4052 BALD CYPRESS WAY, BIN #C-04
TALLAHASSEE, FLORIDA 32399-3254
(850) 245-4292

INTERNET PHARMACY PERMIT APPLICATION AND INFORMATION

January 2018

Dear Florida Pharmacy Permit Applicant,

Thank you for applying for a pharmacy permit in the State of Florida. The information in this packet has been designed to provide the essential information required to process your application in a timely manner. Your assistance in providing all required information will enable the Florida Board of Pharmacy (the Board) staff to process your application as soon as possible. You are encouraged to apply as early as possible to avoid processing delays caused by large volumes of applicants.

Florida Statutes require a completed application and fees before your application can be reviewed. Please read these instructions carefully and fully before submitting your application. You should keep a copy of the completed application and all other materials sent to the Board office for your records. When you mail the completed application and fees, use the address noted in the instructions and on the application form.

When your application arrives, your fees will be deposited and verified before the staff review can begin. You will receive a letter acknowledging receipt of your application. The staff will notify you within 30 days if any materials are incomplete.

If you need to communicate with the Board staff, you are encouraged to email the Board staff at info@floridaspharmacy.gov, or you may at call us at (850) 245-4292. Phone calls are returned within 24 hours and emails are responded to within 48 hours during normal business hours. Our staff is committed to providing prompt and reliable information to our customers. Many procedures have been streamlined to expedite the processing of applications; we certainly welcome your comments on how our services may be improved.

Sincerely,

The Board of Pharmacy

INTERNET PHARMACY PERMIT APPLICATION INFORMATION

Whether opening a new establishment, changing locations, or changing owners, a pharmacy permit is required prior to operating in the State of Florida. The permit application must be completed and returned to the Florida Board of Pharmacy with the required fee of $255.00. The application MUST have the original signatures of the owner or officer of the establishment and the Prescription Department Manager (PDM). If compounding sterile preparations, submit an additional application on Form DH-MQA 1270, "Special Sterile Compounding Permit" and pay the additional permitting fee.

An Internet Pharmacy as authorized by Section 465.0197, F.S., is required for any location not otherwise licensed or issued a permit under this chapter, within or outside this state that uses the Internet to communicate with or obtain information from consumers and uses the information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state.

The Internet Pharmacy Permit is open at least 6 days per week for a minimum of 40 hours per week. A toll-free telephone number shall be provided to facilitate communication between patients in this state and a pharmacist in the pharmacy who has access to the patient's records.

Section 465.022(4), Florida Statutes, also provides that an application for a pharmacy permit must include the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships. The policy and procedure manual shall contain the procedures implemented to minimize the dispensing of controlled substances based on fraudulent representations as follows:

1. Provisions to identify and guard against invalid practitioner-patient relationships.
2. Provisions to guard against filling fraudulent prescriptions for controlled substances.
3. Provisions to identify prescriptions that are communicated or transmitted legally.
4. Provisions to identify the characteristics of a forged or altered prescription.

Application Processing

Please read all application instructions before completing your application.

1) Please mail the application and the $255.00 application fee (check or money order made payable to the FLORIDA DEPARTMENT OF HEALTH) to the following address:

Application & Fees:
Department of Health
Board of Pharmacy
P.O. Box 6320
Tallahassee, Florida 32314-6320

Express Mail ONLY
Department of Health
Board of Pharmacy
4052 Bald Cypress Way, Bin C-04
Tallahassee, FL 32399-3254

Within 30 days of receipt of your application and fees, the board office will notify you of the receipt of your application, any required documents, and your status. If the application is complete, you will be notified that an inspector will contact you to setup an inspection appointment. Please do not contact the board office concerning your inspection date, and allow 30 days for the inspector to contact you. If you have not been contacted by the inspector within 30 days, then notify the board. If your application is incomplete, you will be notified in writing of what is required to make your application complete.

2) Submit fingerprint results.

Failure to submit fingerprints will delay your application. All owners, officers, and PDMs are required to submit a set of fingerprints unless the corporation is exempt under Section 465.022, Florida Statutes, for corporations having more than $100 million of business taxable assets in this state. These corporations are only required to have the PDM to submit fingerprints.

Electronic fingerprint information ("EFI") that has been submitted to the Florida Agency for Health Care Administration may be accessible by the Florida Department of Health for a period of sixty (60) months. If the Department is able to access EFI from AHCA, applicants will not be required to resubmit EFI for additional or new applications submitted during this time period. After sixty (60) months, new electronic fingerprint information must be submitted as part of all applications. **Note: If your officer, owner, or PDM has already been fingerprinted at the time you are completing this Internet Pharmacy permit application, please ensure to provide the Transaction Control Number (TCN), if known, with the requested information in the application.**

Applicants may use any Livescan vendor that has been approved by the Florida Department of Law Enforcement to submit their fingerprints to the department. Please ensure that the Originating Agency Identification (ORI) number is provided to the vendor when you submit your fingerprints. If you do not provide an ORI number or if you provide an incorrect ORI number to the vendor, the Board of Pharmacy will not receive your fingerprint results. The applicant is fully responsible for selecting the vendor and ensuring submission of the prints to the Department.

How do I find a Livescan vendor in order to submit my fingerprints to the Department?
The Department of Health accepts electronic fingerprinting service offered by Livescan device vendors that are approved by the Florida Department of Law Enforcement and listed at their site. You can view the vendor options and contact information at:

http://www.floridahealth.gov/licensing-and-regulation/background-screening/livescan-service-providers.html

What information must I provide to the Livescan vendor I choose?

- If you are an applicant seeking a license for any profession regulated by the Department of Health, which requires a criminal background search as a condition of licensure, you must provide accurate demographic information at the time your fingerprints are taken, ***including your Social Security number***. The Department will not be able to process a submission that does not include your Social Security number.
- You must provide the correct ORI number.

Where do I get the ORI number to submit to the vendor?

- The ORI number for the pharmacy profession is **EDOH4680Z.**

Attestation for Business Taxable Assets

- If the applicant has more than $100 million dollars of business taxable assets in this state, please submit a formal opinion letter from a Certified Public Accountant duly licensed in the state of your principal place of business affirming the corporation has more than $100 million of business taxable assets in this state for the previous tax year. In lieu of submitting a formal opinion letter from a Certified Public Accountant, the applicant may submit a copy of its Florida Corporate Income/Franchise and Emergency Excise Tax Return (Form F-1120, Effective 01/09).

3) Privacy Statement and Attestation

In order for the Board of Pharmacy Office to receive your Livescan electronic fingerprinting results, you must affirm that you have been provided with and read the attached statement from the Florida Department of Law Enforcement regarding the sharing, retention, and right to challenge incorrect criminal history records, and the "Privacy Statement" document from the Federal Bureau of Investigation. The appropriate form(s) to provide this affirmation are included within Items #1 and #2 of the application.

Licensure Process

Once the application is deemed complete, the Board staff authorizes an inspection. Upon completion of the inspection, the inspector notifies the Board office as to whether the inspection was satisfactory or unsatisfactory. If the inspection is satisfactory, a permit number is issued within 7-10 days. You will receive the actual copy of your license within 7 days. **Please wait 7-14 days from your satisfactory inspection before checking on the status of your permit with the Board office**.

You may look up your license number on our website at http://www.flhealthsource.com/ under "Verify a License."

Drug Enforcement Administration (DEA)

Please note that the DEA will not issue a registration until the Florida Board of Pharmacy has issued a pharmacy permit. More information is available by visiting the DEA website at http://www.DEAdiversion.usdoj.gov, or by contacting them at (800)667-9752.

IMPORTANT NOTICE: Pursuant to Section 465.022(5), F.S., the Department or Board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant:

(a) Has obtained a permit by misrepresentation or fraud.

(b) Has attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation.

(c) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy.

(d) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud.

(e) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009.

(f) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009.

(g) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period.

(h) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application.

(i) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

(j) Has 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.

For felonies in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the department shall deny the application if upon final resolution of the case the licensee has failed to successfully complete the program.

<u>If applicable to you, please provide the documentation to the Florida Board of Pharmacy.</u>

INTERNET PHARMACY PERMIT APPLICATION CHECKLIST

Keep a copy of the completed application for your records.

It is recommended that you use the following checklist to help ensure that your application is complete. Failure to attach any required document, or to have required documentation sent to the Board, will result in an incomplete application. Final approval for inspection cannot be granted until the application is complete.

INTERNET PHARMACY PERMIT

_____All Application Questions Answered?

_____$255.00 Fee Attached (Permit fee includes $250 application fee and $5.00 unlicensed activity fee)

_____Articles of Incorporation paperwork from the Secretary of State provided?

_____PDM Designation and Privacy Statement Acknowledgement provided (Application Item #1)?

_____Affiliate/Owner Privacy Statement Acknowledgement provided for each affiliate/owner (Application Item #2)?

_____Applicant/Affiliate/Owner supplemental documents provided for explaining any previous ownership, disciplinary actions, voluntary relinquishments and/or criminal activity?

_____Applicant/Affiliate/Owner pharmacy permit questions answered and supplemental documents provided?

_____Policies and Procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships submitted?

FLORIDA BOARD OF PHARMACY
P.O. Box 6320
Tallahassee, FL 32314-6320
Telephone (850) 488-0595
http://www.floridaspharmacy.gov

INTERNET PHARMACY PERMIT

APPLICATION

Application Type – Please choose one of the following:

___New Establishment ($255.00 fee)
Complete: Section A only, along with Items #1 and 2.

___Change of Ownership ($255.00 fee)
Complete: Sections A and C only, along with Items #1 and 2

___ Change of Location ($100.00 fee)
Complete: Sections A and B only.

___ Stock Transfer (no fee)
Complete: Section A, pages 2-3 and Section D only.

SECTION A. Please complete for all Application Types

Please list your Federal Employer Identification Number:

1. Corporate Name		**Telephone Number**
2. Doing Business As (d/b/a)		**E-Mail Address**** (see note below)
3. Mailing Address		
City	**State**	**Zip**
4. Physical Address		
City	**State**	**Zip**
5. Prescription Department Manager (PDM) Information		
Name		**License Number**
E-Mail Address** (see note below)		**Telephone Number**
6. Contact Person		**Title**
E-Mail Address** (see note below)		**Telephone Number**

NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.

7. Operating Hours

Is the pharmacy least 6 days per week for a minimum of 40 hours per week? Yes_____ No_____

Please provide Toll-Free Telephone Number? _____

8. Ownership Information

a. Type of Ownership: _____Individual _____Corporation _____Partnership

NOTE: If the applicant is a corporation or limited partnership you must include with your application a copy of the Articles of Incorporation on file with the Florida Secretary of State's office.

b. Are the applicants, officers, directors, shareholders, members and partners over the age of 18?

Yes _____ No _____

c. Does the corporation have more than $100 million of business taxable assets in this state?

Yes _____ No _____ If yes, provide attestation from Certified Public Accountant for previous tax year or Florida Corporate Income/Franchise and Emergency Excise Tax Return (F-1120). If no, continue to 12d.

d. List all the owners and officers of the corporation. Each person listed below having an ownership interest of 5% or greater and any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant including officers and members of the board of directors must submit a set of fingerprints and fees unless you answered yes to 8c. If 8c is "Yes", please list the owners below and only submit fingerprints for the Prescription Department Manager. If 8c is "Yes" and the prints are on file with DOH or AHCA and available to the Board of Pharmacy, the requirement to submit the prints for this person is met. Also, if the % of Ownership column does not add to 100%, please provide an explanation. *Attach a separate sheet if necessary.*

Owner/Officer-Title	Date of Birth	Mailing Address, City, State, Zip Code	% of Ownership
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%

9. Has anyone listed in 8.d had an ownership interest of 5% or more in a pharmacy or any other business permit which was disciplined, suspended, revoked, or closed involuntarily within the past 5 years? *If yes, please provide a signed statement disclosing the reason the entity was closed.*

Yes _____ No _____ .

9a. Has anyone listed in 8.d had an ownership interest of 5% or more in a pharmacy or any other business permit which was voluntarily relinquished or closed voluntarily within the past 5 years?
If yes, please provide a signed statement disclosing the reason the entity was closed.

Yes _____ No _____

Pursuant to Section 465.022(5), questions 10 – 19 are being asked. If you answer "Yes" to any of the following questions, explain on a separate sheet providing accurate details and submit copies of supporting documentation.
10. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant obtained a permit by misrepresentation or fraud?
Yes_____ No_____
11. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation?
Yes _____ No _____
12. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy?
Yes _____ No_____
13. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud?
Yes_____ No_____
14. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009?
Yes _____ No_____
15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009?
Yes _____ No _____
16. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period?
Yes _____ No _____
17. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application?
Yes _____ No _____
18. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant currently listed on the United States Department of Health Human Services Office of Inspector General's List of Excluded Individuals and Entities? *(If yes, please submit proof.)*
Yes _____ No _____

19. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant 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?

Yes_____ No_____

20. Are you currently registered or permitted in any other states? *(If yes, provide the state, permit type and permit number for each permit. Attach a separate sheet if necessary.)*

Yes _____ No ____

State	Permit Type	Permit Number

21. Has the applicant, affiliated person, partner, officer, directors, or Prescription Department Manager ever owned a pharmacy? *(If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy. Attach a separate sheet if necessary.)*

Yes _____ No_____

Individual's Name	Pharmacy Name	State	Status

22. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, affiliated person, partner, officer, director, or Prescription Department Manager?

Yes _____ No_____

23. Has the applicant, affiliated person, partner, officer, or director ever been convicted of a felony or misdemeanor, excluding minor traffic convictions? You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction.

Yes_____ No_____

24. Does the applicant, affiliated person, partner, officer, or director have any outstanding fines, liens or overpayments assessed by a final order of the department? If yes please answer 24a.

Yes_____ No

24a. Does the applicant, affiliated person, partner, officer, or director have a repayment plan approved by the department?

Yes_____ No_____

25. Will the Pharmacy Dispense Schedule II and/or III Controlled Substances?
Yes_____ No_____
26. Is the applicant, affiliated persons, partners, officers, or directors, under investigation or prosecution for a crime in any jurisdiction?
Yes _____ No_____
27. Is the applicant, affiliated persons, partners, officers, or directors, under investigation or pending administrative action by the licensing authority of any jurisdiction, including its agencies and subdivisions?
Yes _____ No_____

SECTION B. Please complete for Change of Location only.

1. Current Practice Location Address		
City	**State**	**Zip**

E-Mail Address** (see note below)	Telephone Number

2. New Practice Location Address		
City	**State**	**Zip**

E-Mail Address** (see note below)	Telephone Number

Please provide your existing Pharmacy Permit Number:

Please provide your existing federal DEA Number:

NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.

SECTION C. Please complete for Change of Ownership only.

1. Are you changing physical locations with this change of ownership?

Yes _____ No _____ *NOTE: If yes, please complete **Section B** above.*

2. Please provide date when business transaction for the change of ownership will be completed?

Date: _____

3. Do you have a signed letter from both the buyer and seller which indicates dates that pharmacy permit license should be transferred? *NOTE: A copy of the signed letter should be provided with your application.*

Yes _____ No _____

SECTION D. Please complete for Stock Transfer of Ownership Interest only.
1. Please provide the date when the transfer of ownership interest took place?
Date: _____
2. Did your company's FEIN change as a result of the transfer of ownership interest referenced in Section D, Question 1 above?
Yes _____ No _____ *NOTE: If yes, please complete **Section C** above and include necessary fee.*

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

****

Section 456.013(1), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application, which takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department.

I swear or affirm that the statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations that they deem appropriate and to secure any additional information concerning me, and I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, Board, or any municipal, county, state, or federal governmental agencies or units, and I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other item, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

Under penalty of perjury I have read the foregoing document and that the facts stated in it are true. I recognize that providing false information may result in disciplinary action against my license or criminal penalties.

SIGNATURE _____ DATE_____
(Owner or officer of establishment)

FLORIDA DEPARTMENT OF LAW ENFORCEMENT

NOTICE FOR APPLICANTS SUBMITTING FINGERPRINTS WHERE CRIMINAL RECORD RESULTS WILL BECOME PART OF THE CARE PROVIDER BACKGROUND SCREENING CLEARINGHOUSE

NOTICE OF:

- **SHARING OF CRIMINAL HISTORY RECORD INFORMATION WITH SPECIFIED AGENCIES,**
- **RETENTION OF FINGERPRINTS,**
- **PRIVACY POLICY, AND**
- **RIGHT TO CHALLENGE AN INCORRECT CRIMINAL HISTORY RECORD**

This notice is to inform you that when you submit a set of fingerprints to the Florida Department of Law Enforcement (FDLE) for the purpose of conducting a search for any Florida and national criminal history records that may pertain to you, the results of that search will be returned to the Care Provider Background Screening Clearinghouse. By submitting fingerprints, you are authorizing the dissemination of any state and national criminal history record that may pertain to you to the Specified Agency or Agencies from which you are seeking approval to be employed, licensed, work under contract, or to serve as a volunteer, pursuant to the National Child Protection Act of 1993, as amended, and Section 943.0542, Florida Statutes. "Specified agency" means the Department of Health, the Department of Children and Family Services, the Division of Vocational Rehabilitation within the Department of Education, the Agency for Health Care Administration, the Department of Elder Affairs, the Department of Juvenile Justice, and the Agency for Persons with Disabilities when these agencies are conducting state and national criminal history background screening on persons who provide care for children or persons who are elderly or disabled. The fingerprints submitted will be retained by FDLE and the Clearinghouse will be notified if FDLE receives Florida arrest information on you.

Your Social Security Number (SSN) is needed to keep records accurate because other people may have the same name and birth date. Disclosure of your SSN is imperative for the performance of the Clearinghouse agencies' duties in distinguishing your identity from that of other persons whose identification information may be the same as or similar to yours.

Licensing and employing agencies are allowed to release a copy of the state and national criminal record information to a person who requests a copy of his or her own record if the identification of the record was based on submission of the person's fingerprints. Therefore, if you wish to review your record, you may request that the agency that is screening the record provide you with a copy. After you have reviewed the criminal history record, if you believe it is incomplete or inaccurate, you may conduct a personal review as provided in s. 943.056, F.S., and Rule 11C8.001, F.A.C. If national information is believed to be in error, the FBI should be contacted at 304-625-2000. You can receive any national criminal history record that may pertain to you directly from the FBI, pursuant to 28 CFR Sections 16.30-16.34. You have the right to obtain a prompt determination as to the validity of your challenge before a final decision is made about your status as an employee, volunteer, contractor, or subcontractor.

Until the criminal history background check is completed, you may be denied unsupervised access to children, the elderly, or persons with disabilities.

The FBI's Privacy Statement follows on a separate page and contains additional information.

US Department of Justice, Federal Bureau of Investigation,
Criminal Justice Information Services Division

Privacy Statement

Authority: The FBI's acquisition, preservation and exchange of information requested by this form is generally authorized under 28 U.S.C. 534. Depending on the nature of your application, supplemental authorities include numerous Federal statutes, hundreds of State statutes pursuant to Pub.L.92-544, Presidential executive orders, regulations and/or orders of the Attorney General of the United States, or other authorized authorities. Examples include, but are not limited to: 5 U.S.C. 9101; Pub.L.94-29; Pub.L.101-604; and Executive Orders 10450 and 12968. Providing the requested information is voluntary; however, failure to furnish the information may affect timely completion of approval of your application.

Social Security Account Number (SSAN): Your SSAN is needed to keep records accurate because other people may have the same name and birth date. Pursuant to the Federal Privacy Act of 1974 (5 USC 552a), the requesting agency is responsible for informing you whether disclosure is mandatory or voluntary, by what statutory or other authority your SSAN is solicited, and what uses will be made of it. Executive Order 9397 also asks Federal Agencies to use this number to help identify individuals in agency records.

Principal Purpose: Certain determinations, such as employment, security, licensing and adoption, may be predicated on fingerprint based checks. Your fingerprints and other information contained on (and along with) this form may be submitted to the requesting agency, the agency conducting the application investigation, and/or FBI for the purpose of comparing the submitted information to available records in order to identify other information that may be pertinent to the application. During the processing of this application, and for as long hereafter as my be relevant to the activity for which this application is being submitted, the FBI(may disclose any potentially pertinent information to the requesting agency and/or to the agency conducting the investigation. The FBI may also retain the submitted information in the FBI's permanent collection of fingerprints and related information, where it will be subject to comparisons against other submissions received by the FBI. Depending on the nature of your application, the requesting agency and/or the agency conducting the application investigation may also retain the fingerprints and other submitted information for other authorized purposes of such agency(ies).

Routine Uses: The fingerprints and information reported on this form may be disclosed pursuant to your consent, and may also be disclosed by the FBI without your consent as permitted by the Federal Privacy Act of 1974 (5 USC 552a(b)) and all applicable routine uses as many be published at any time in the Federal Register, including the routine uses for the FBI Fingerprint Identification Records System (Justice, FBI-009) and the FBI's Blanket Routine Uses (Justice/FBI-BRU). Routine uses include, but are not limited to, disclosures to: appropriate governmental authorities responsible for civil or criminal law enforcement counterintelligence, national security or public safety matters to which the information may be relevant; to State and local governmental agencies and nongovernmental entities for application processing as authorized by Federal and State legislation, executive order, or regulation, including employment, security, licensing, and adoption checks; and as otherwise authorized by law , treaty, executive order, regulation, or other lawful authority. If other agencies are involved in processing the application, they may have additional routine uses.

Additional Information: The requesting agency and/or the agency conducting the application investigation will provide you additional information pertinent to the specific circumstances of this application, which may include identification of other authorities, purposes, uses, and consequences of not providing requested information. In addition, any such agency in the Federal Executive Branch has also published notice.

Electronic Fingerprinting

Take this form with you to the Livescan service provider. Please check the service provider's requirements to see if you need to bring any additional items.

- Background screening results are obtained from the Florida Department of Law Enforcement and the Federal Bureau of Investigation by submitting to a fingerprint scan using the Livescan method;
- You can find a Livescan service provider at: http://www.floridahealth.gov/licensing-and-regulation/background-screening/livescan-service-providers.html
- Failure to submit background screening will delay your application;
- Applicants may use any Livescan service provider approved by the Florida Department of Law Enforcement to submit their background screening to the department;
- If you do not provide the correct Originating Agency Identification (ORI) number to the Livescan service provider the Board office will not receive your background screening results;
- You must provide accurate demographic information to the livescan service provider at the time your fingerprints are taken, ***including your Social Security number (SSN)***;
- The ORI number for the Board of Pharmacy is **EDOH4680Z.**
- Typically background screening results submitted through a Livescan service provider are received by the Board within 24-72 hours of being processed.
- If you obtain your livescan from a service provider who does not capture your photo you may be required to be reprinted by another agency in the future.

Name:_____ SSN#: _____ - ____ - _____

Aliases:_____

Address: _____ Apt. Number: _____

City:_____ State: _____Zip Code: _____

Date of Birth: _____/_____/_____ Place of Birth: _____
(MM/DD/YYYY)

Weight: _____ Height: _____ Eye Color:_____ Hair Color: _____

Race: _____ Sex: _____

Citizenship: _____
(W-White/Latino(a); B-Black; A-Asian; NA-Native American; U-Unknown) (M=Male; F=Female)

Transaction Control Number (TCN#):_____
(*This will be provided to you by the Live Scan Service provider*.)

Keep this form for your records.

Item #1- PDM Designation and Privacy Statement Acknowledgement

File #: (if known):
License #: (if applicable):

To: Florida Board of Pharmacy
Post Office Box 6320
Tallahassee, FL 32314-6320
(850) 245-4292- phone
(850) 413-6982 - fax
MQAPharmPDMAffiliate@flhealth.gov

Section A. Prescription Department Manager (PDM) Designation

Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailing Address:		
City	**State**	**Zip**
Incoming PDM Name:		**License#:**
Date Beginning as PDM:	**Incoming PDM Signature**	
PDM Transaction Control Number (TCN) – related to Livescan Fingerprints *(optional, if known)*: ** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs**		
*****Only provide following information if there is an Outgoing PDM at current pharmacy location.*****		
Outgoing PDM Name:		**License#:**
Date Ending as PDM:	**Outgoing PDM Signature** *(optional)*	

Section B. Incoming PDM Privacy Statement Acknowledgement

Note: Acknowledgment should be completed by same person listed in Section A above as Incoming PDM.

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

Date:	**Incoming PDM Signature**

Item #2- Affiliate/Owner Privacy Statement Acknowledgement

To be completed by EACH Affiliate/Owner listed in the application.

To: **Florida Board of Pharmacy, Post Office Box 6320, Tallahassee, FL 32314-6320**
(850) 245-4292- phone * (850) 413-6982 – fax * MQAPharmPDMAffiliate@flhealth.gov

From:

Affiliate / Owner Name:		**File # (required):**
Applicant Name:		
Affiliate/Owner Mailing Address:		
City	**State**	**Zip**
Affiliate/Owner E-Mail ** (see note below)	**Affiliate/Owner Telephone Number**	
Affiliate/Owner Transaction Control Number (TCN) *(optional, if known)***:** ** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs**		
NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.		

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

_____ _____

Affiliate/Owner Signature (Required) **Date (of signature)**

DIVISION OF MEDICAL QUALITY ASSURANCE
BOARD OF PHARMACY
4052 BALD CYPRESS WAY, BIN #C-04
TALLAHASSEE, FLORIDA 32399-3254
(850) 245-4292

NUCLEAR PHARMACY PERMIT APPLICATION AND INFORMATION

January 2018

Dear Florida Pharmacy Permit Applicant,

Thank you for applying for a pharmacy permit in the State of Florida. The information in this packet has been designed to provide the essential information required to process your application in a timely manner. Your assistance in providing all required information will enable the Florida Board of Pharmacy (the Board) staff to process your application as soon as possible. You are encouraged to apply as early as possible to avoid processing delays caused by large volumes of applicants.

Florida Statutes require a completed application and fees before your application can be reviewed. Please read these instructions carefully and fully before submitting your application. You should keep a copy of the completed application and all other materials sent to the Board office for your records. When you mail the completed application and fees, use the address noted in the instructions and on the application form.

When your application arrives, your fees will be deposited and verified before the staff review can begin. You will receive a letter acknowledging receipt of your application. The staff will notify you within 30 days if any materials are incomplete.

If you need to communicate with the Board staff, you are encouraged to email the Board staff at info@floridaspharmacy.gov, or you may at call us at (850) 245-4292. Phone calls are returned within 24 hours and emails are responded to within 48 hours during normal business hours. Our staff is committed to providing prompt and reliable information to our customers. Many procedures have been streamlined to expedite the processing of applications; we certainly welcome your comments on how our services may be improved.

Sincerely,

The Board of Pharmacy

NUCLEAR PHARMACY PERMIT APPLICATION INFORMATION

Whether opening a new establishment, changing locations, or changing owners, a pharmacy permit is required prior to operating in the State of Florida. The permit application must be completed and returned to the Florida Board of Pharmacy with the required fee of $255.00. The application MUST have the original signatures of the owner or officer of the establishment and the Nuclear pharmacist designated as Prescription Department Manager (PDM). If compounding sterile preparations, submit an additional application on Form DH-MQA 1270, "Special Sterile Compounding Permit" and pay the additional permitting fee.

Nuclear pharmacy permits as authorized by Section 465.0193, F.S., are required for every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. Chapter 465, F.S., requires Nuclear Pharmacies to be under the professional supervision of a State of Florida licensed Nuclear Pharmacist who serves as the PDM. The PDM is responsible for ensuring the pharmacy permittee's compliance with all statutes and rules governing the practice of the profession of pharmacy, including maintenance of all drug records and ensuring the security of the prescription department, and shall competently and diligently exercise their responsibilities as a prescription department manager. Please see Rule 64B16-27.450, F.A.C., for more information.

Section 465.022(4), Florida Statutes, also provides that an application for a pharmacy permit must include the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships. The policy and procedure manual shall contain the procedures implemented to minimize the dispensing of controlled substances based on fraudulent representations as follows:

1. Provisions to identify and guard against invalid practitioner-patient relationships.
2. Provisions to guard against filling fraudulent prescriptions for controlled substances.
3. Provisions to identify prescriptions that are communicated or transmitted legally.
4. Provisions to identify the characteristics of a forged or altered prescription.

Application Processing

Please read all application instructions before completing your application.

1) Please mail the application and the $255.00 application fee (cashiers check or money order made payable to the FLORIDA DEPARTMENT OF HEALTH) to the following address:

Application & Fees:	**Express Mail ONLY:**
Department of Health	Department of Health
Board of Pharmacy	Board of Pharmacy
P.O. Box 6320	4052 Bald Cypress Way, Bin C-04
Tallahassee, Florida 32314-6320	Tallahassee, FL 32399-3254

2) Submit fingerprint results.

   Failure to submit fingerprints will delay your application. All owners, officers, and PDMs are required to submit a set of fingerprints unless the corporation is exempt under Section 465.022, Florida Statutes, for corporations having more than $100 million of business taxable assets in this state. These corporations are only required to have the Nuclear PDM to submit fingerprints.

Electronic fingerprint information ("EFI") that has been submitted to the Florida Agency for Health Care Administration may be accessible by the Florida Department of Health for a period of sixty (60) months. If the Department is able to access EFI from AHCA, applicants will not be required to resubmit EFI for additional or new applications submitted during this time period. After sixty (60) months, new electronic fingerprint information must be submitted as part of all applications. **Note: If your officer, owner, or Nuclear PDM has already been fingerprinted at the time you are completing this Nuclear Pharmacy permit application, please ensure to provide the Transaction Control Number (TCN), if known, with the requested information in the application.**

Applicants may use any Livescan vendor that has been approved by the Florida Department of Law Enforcement to submit their fingerprints to the department. Please ensure that the Originating Agency Identification (ORI) number is provided to the vendor when you submit your fingerprints. If you do not provide an ORI number or if you provide an incorrect ORI number to the vendor, the Board of Pharmacy will not receive your fingerprint results. The applicant is fully responsible for selecting the vendor and ensuring submission of the prints to the Department.

How do I find a Livescan vendor in order to submit my fingerprints to the Department?
Department of Health accepts electronic fingerprinting service offered by Livescan device vendors that are approved by the Florida Department of Law Enforcement and listed at their site. You can view the vendor options and contact information at:

http://www.floridahealth.gov/licensing-and-regulation/background-screening/livescan-service-providers.html

What information must I provide to the Livescan vendor I choose?

- If you are an applicant seeking a license for any profession regulated by the Department of Health, which requires a criminal background search as a condition of licensure, you must provide accurate demographic information at the time your fingerprints are taken, ***including your Social Security number***. The Department will not be able to process a submission that does not include your Social Security number.
- You must provide the correct ORI number.

Where do I get the ORI number to submit to the vendor?

- The ORI number for the pharmacy profession is **EDOH4680Z.**

Attestation for Business Taxable Assets

- If the applicant has more than $100 million dollars of business taxable assets in this state, please submit a formal opinion letter from a Certified Public Accountant duly licensed in the state of your principal place of business affirming the corporation has more than $100 million of business taxable assets in this state for the previous tax year. In lieu of submitting a formal opinion letter from a Certified Public Accountant, the applicant may submit a copy of its Florida Corporate Income/Franchise and Emergency Excise Tax Return (Form F-1120, Effective 01/09).

3) Privacy Statement and Attestation

In order for the Board of Pharmacy Office to receive your Livescan electronic fingerprinting results, you must affirm that you have been provided with and read the attached statement from the Florida Department of Law Enforcement regarding the sharing, retention, and right to challenge incorrect criminal history records, and the

"Privacy Statement" document from the Federal Bureau of Investigation. The appropriate form(s) to provide this affirmation are included within Items #1 and #2 of the application.

Licensure Process

Once the application is deemed complete, the Board staff authorizes an inspection. Upon completion of the inspection, the inspector notifies the Board office as to whether the inspection was satisfactory or unsatisfactory. If the inspection is satisfactory, a permit number is issued within 7-10 days. You will receive the actual copy of your license within 7 days. **Please wait 7-14 days from your satisfactory inspection before checking on the status of your permit with the Board office**.

You may look up your license number on our website at http://www.flhealthsource.com/ under "Verify a License."

Drug Enforcement Administration (DEA)

Please note that the DEA will not issue a registration until the Florida Board of Pharmacy has issued a pharmacy permit. More information is available by visiting the DEA website at http://www.DEAdiversion.usdoj.gov, or by contacting them at (800)667-9752.

IMPORTANT NOTICE: Pursuant to Section 465.022(5), F.S., the Department or Board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant:

(a) Has obtained a permit by misrepresentation or fraud.

(b) Has attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation.

(c) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy.

(d) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud.

(e) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009.

(f) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009.

(g) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period.

(h) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application.

(i) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

(j) Has 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.

For felonies in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the department shall deny the application if upon final resolution of the case the licensee has failed to successfully complete the program.

<u>If applicable to you, please provide the documentation to the Florida Board of Pharmacy.</u>

NUCLEAR PHARMACY PERMIT APPLICATION CHECKLIST

Keep a copy of the completed application for your records.

It is recommended that you use the following checklist to help ensure that your application is complete. Failure to attach any required document, or to have required documentation sent to the Board, will result in an incomplete application. Final approval for inspection cannot be granted until the application is complete.

NUCLEAR PHARMACY PERMIT

_____All Application Questions Answered?

_____$255.00 Fee Attached (Permit fee includes $250 application fee and $5.00 unlicensed activity fee)

_____Articles of Incorporation paperwork from the Secretary of State provided?

_____PDM Designation and Privacy Statement Acknowledgement provided (Application Item #1)?

_____Affiliate/Owner Privacy Statement Acknowledgement provided for each affiliate/owner (Application Item #2)?

_____Applicant/Affiliate/Owner supplemental documents provided for explaining any previous ownership, disciplinary actions, voluntary relinquishments and/or criminal activity?

_____Applicant/Affiliate/Owner pharmacy permit questions answered and supplemental documents provided?

_____Policies and Procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships submitted?

FLORIDA BOARD OF PHARMACY
P.O. Box 6320
Tallahassee, FL 32314-6320
Telephone (850) 488-0595
http://www.floridaspharmacy.gov

NUCLEAR PHARMACY PERMIT

APPLICATION

Application Type – Please choose one of the following:

___New Establishment ($255.00 fee)
Complete: Section A only, along with Items #1, #2, and #3.

___Change of Ownership ($255.00 fee)
Complete: Sections A and C only, along with Items #1 and 2.

___ Change of Location ($100.00 fee)
Complete: Sections A and B only.

___ Stock Transfer (no fee)
Complete: Section A, pages 2-3 and Section D only.

SECTION A. Please complete for all Application Types

Please list your Federal Employer Identification Number: _____

1. Corporate Name	**Telephone Number**
2. Doing Business As (d/b/a)	**E-Mail Address**** (see note below)

3. Mailing Address		
City	**State**	**Zip**

4. Physical Address		
City	**State**	**Zip**

5. List the Nuclear Pharmacist of Record Information:

Name	**License#:**	
	PS	**NP**
E-Mail Address** (see note below)	**Telephone Number**	

6. Contact Person	**Title**
E-Mail Address** (see note below)	**Phone Number**

NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.

7. Ownership Information

a. Type of Ownership: _____Individual _____Corporation _____Partnership

_____Other: _____

NOTE: IF CORPORATION OR LIMITED PARTNERSHIP YOU MUST INCLUDE WITH YOUR APPLICATION A COPY OF THE ARTICLES OF INCORPORATION ON FILE WITH THE FLORIDA SECRETARY OF STATE'S OFFICE.

b. Are the applicants, officers, directors, shareholders, members and partners over the age of 18?

Yes _____ No _____

c. Does the corporation have more than $100 million of business taxable assets in this state? *If yes, provide attestation from Certified Public Accountant for previous tax year or Florida Corporate Income /Franchise and Emergency Excise Tax Return (F-1120).*

Yes _____ No _____

d. List all the owners and officers of the corporation. Each person listed below having an ownership interest of 5% or greater and any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant including officers and members of the board of directors must submit a set of fingerprints and fees unless you answered yes to 7c. If 7c is "Yes", please list the owners below and only submit fingerprints for the Prescription Department Manager. If 7c is "Yes" and the prints are on file with DOH or AHCA and available to the Board of Pharmacy, the requirement to submit the prints for this person is met. Also, if the % of Ownership column does not add to 100%, please provide an explanation. *Attach a separate sheet if necessary.*

Owner/Officer-Title	Date of Birth	Mailing Address, City, State, Zip Code	% of Ownership
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%

8. Has anyone listed in 7.d had an ownership interest of 5% or more in a pharmacy or any other business permit which was disciplined, suspended, revoked, or closed involuntarily within the past 5 years? *If yes, please provide a signed statement disclosing the reason the entity was closed.*

Yes _____ No _____

8a. Has anyone listed in 7.d had an ownership interest of 5% or more in a pharmacy or any other business permit which was voluntarily relinquished or closed voluntarily within the past 5 years? *If yes, please provide a signed statement disclosing the reason the entity was closed.*

Yes _____ No _____

Pursuant to Section 465.022(5), the questions 9 – 18 are being asked. If you answer "Yes" to any of the following questions, explain <u>on a separate sheet</u> providing accurate details and submit copies of supporting documentation.
9. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant obtained a permit by misrepresentation or fraud?
Yes _____ No_____
10. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation?
Yes _____ No_____
11. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy?
Yes _____ No_____
12. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud?
Yes _____ No_____
13. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009?
Yes _____ No_____
14. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009?
Yes _____ No_____
15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period?
Yes _____ No_____
16. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application?
Yes _____ No_____

17. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant currently listed on the United States Department of Health Human Services Office of Inspector General's List of Excluded Individuals and Entities? *(If yes, please submit proof.)*

Yes _____ No _____

18. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant 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?

Yes_____ No ____

19. Are you currently registered or permitted in any other states? *(If yes, provide the state, permit type and permit number for each permit. Attach a separate sheet if necessary.)*

Yes _____No _____

State	Permit Type	Permit Number

20. Has the applicant, affiliated person, partner, officer, directors, or Prescription Department Manager ever owned a pharmacy? *(If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy. Attach a separate sheet if necessary.)*

Yes _____ No_____

Individual's Name	Pharmacy Name	State	Status

21. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, affiliated person, partner, officer, director, or Prescription Department Manager?

Yes _____ No_____

22. Has the applicant, affiliated person, partner, officer, or director ever been convicted of a felony or misdemeanor, excluding minor traffic convictions? You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction.

Yes _____ No_____

23. Does the applicant, affiliated person, partner, officer, director have any outstanding fines, liens or overpayments assessed by a final order of the department? *(If yes, please answer question #23a.)*

Yes _____ No _____

23a. Does the applicant, affiliated person, partner, officer, director have a repayment plan approved by the department? *(If yes, explain on a separate sheet providing accurate details.)*

Yes _____ No _____

24. Is the applicant, affiliated persons, partners, officers, or directors, under investigation or prosecution for a crime in any jurisdiction?

Yes _____ No_____

25. Is the applicant, affiliated persons, partners, officers, or directors, under investigation or pending administrative action by the licensing authority of any jurisdiction, including its agencies and subdivisions?

Yes _____ No_____

SECTION B. Please complete for a Change of Location only.

1. Current Practice Location Address

City	**State**	**Zip**

E-Mail Address** (see note below)	**Telephone Number**

2. New Practice Location Address

City	**State**	**Zip**

E-Mail Address** (see note below)	**Telephone Number**

Please provide your existing Pharmacy Permit Number(s):

Please provide your existing Federal DEA Number:

NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.

SECTION C. Please complete for Change of Ownership only.

1. Are you changing physical locations with this change of ownership?

Yes _____ No _____ *Note: If yes, please complete Section B above*

2. Please provide date when business transaction for the change of ownership will be completed?

Date: _____

3. **Do you have a signed letter from both the buyer and seller which indicates dates the pharmacy permit license should be transferred?**

Yes _____ No _____

SECTION D. Please complete for Stock Transfer of Ownership Interests only.
1. Please provide the date when the transfer of ownership interest took place?
Date:
2. Did your company's FEIN change as a result of the transfer of ownership interest referenced in Section D, question 1 above?
Yes _____ No _____ *Note: If yes, please complete Section C above and include the necessary fee*

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

****

*Section 456.013(1), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application, which takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department.

I certify that the statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations that they deem appropriate and to secure any additional information concerning me, and I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, Board, or any municipal, county, state, or federal governmental agencies or units, and I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other item, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

Under penalty of perjury I have read the foregoing document and that the facts stated in it are true. I recognize that providing false information may result in disciplinary action against my license or criminal penalties.

SIGNATURE _____ DATE_____
(Owner or officer of establishment)

FLORIDA DEPARTMENT OF LAW ENFORCEMENT

NOTICE FOR APPLICANTS SUBMITTING FINGERPRINTS WHERE CRIMINAL RECORD RESULTS WILL BECOME PART OF THE CARE PROVIDER BACKGROUND SCREENING CLEARINGHOUSE

NOTICE OF:

- **SHARING OF CRIMINAL HISTORY RECORD INFORMATION WITH SPECIFIED AGENCIES,**
- **RETENTION OF FINGERPRINTS,**
- **PRIVACY POLICY, AND**
- **RIGHT TO CHALLENGE AN INCORRECT CRIMINAL HISTORY RECORD**

This notice is to inform you that when you submit a set of fingerprints to the Florida Department of Law Enforcement (FDLE) for the purpose of conducting a search for any Florida and national criminal history records that may pertain to you, the results of that search will be returned to the Care Provider Background Screening Clearinghouse. By submitting fingerprints, you are authorizing the dissemination of any state and national criminal history record that may pertain to you to the Specified Agency or Agencies from which you are seeking approval to be employed, licensed, work under contract, or to serve as a volunteer, pursuant to the National Child Protection Act of 1993, as amended, and Section 943.0542, Florida Statutes. "Specified agency" means the Department of Health, the Department of Children and Family Services, the Division of Vocational Rehabilitation within the Department of Education, the Agency for Health Care Administration, the Department of Elder Affairs, the Department of Juvenile Justice, and the Agency for Persons with Disabilities when these agencies are conducting state and national criminal history background screening on persons who provide care for children or persons who are elderly or disabled. The fingerprints submitted will be retained by FDLE and the Clearinghouse will be notified if FDLE receives Florida arrest information on you.

Your Social Security Number (SSN) is needed to keep records accurate because other people may have the same name and birth date. Disclosure of your SSN is imperative for the performance of the Clearinghouse agencies' duties in distinguishing your identity from that of other persons whose identification information may be the same as or similar to yours.
Licensing and employing agencies are allowed to release a copy of the state and national criminal record information to a person who requests a copy of his or her own record if the identification of the record was based on submission of the person's fingerprints. Therefore, if you wish to review your record, you may request that the agency that is screening the record provide you with a copy. After you have reviewed the criminal history record, if you believe it is incomplete or inaccurate, you may conduct a personal review as provided in s. 943.056, F.S., and Rule 11C8.001, F.A.C. If national information is believed to be in error, the FBI should be contacted at 304-625-2000. You can receive any national criminal history record that may pertain to you directly from the FBI, pursuant to 28 CFR Sections 16.30-16.34. You have the right to obtain a prompt determination as to the validity of your challenge before a final decision is made about your status as an employee, volunteer, contractor, or subcontractor.

Until the criminal history background check is completed, you may be denied unsupervised access to children, the elderly, or persons with disabilities.

The FBI's Privacy Statement follows on a separate page and contains additional information.

US Department of Justice, Federal Bureau of Investigation,
Criminal Justice Information Services Division

Privacy Statement

Authority: The FBI's acquisition, preservation and exchange of information requested by this form is generally authorized under 28 U.S.C. 534. Depending on the nature of your application, supplemental authorities include numerous Federal statutes, hundreds of State statutes pursuant to Pub.L.92-544, Presidential executive orders, regulations and/or orders of the Attorney General of the United States, or other authorized authorities. Examples include, but are not limited to: 5 U.S.C. 9101; Pub.L.94-29; Pub.L.101-604; and Executive Orders 10450 and 12968. Providing the requested information is voluntary; however, failure to furnish the information may affect timely completion of approval of your application.

Social Security Account Number (SSAN): Your SSAN is needed to keep records accurate because other people may have the same name and birth date. Pursuant to the Federal Privacy Act of 1974 (5 USC 552a), the requesting agency is responsible for informing you whether disclosure is mandatory or voluntary, by what statutory or other authority your SSAN is solicited, and what uses will be made of it. Executive Order 9397 also asks Federal Agencies to use this number to help identify individuals in agency records.

Principal Purpose: Certain determinations, such as employment, security, licensing and adoption, may be predicated on fingerprint based checks. Your fingerprints and other information contained on (and along with) this form may be submitted to the requesting agency, the agency conducting the application investigation, and/or FBI for the purpose of comparing the submitted information to available records in order to identify other information that may be pertinent to the application. During the processing of this application, and for as long hereafter as my be relevant to the activity for which this application is being submitted, the FBI(may disclose any potentially pertinent information to the requesting agency and/or to the agency conducting the investigation. The FBI may also retain the submitted information in the FBI's permanent collection of fingerprints and related information, where it will be subject to comparisons against other submissions received by the FBI. Depending on the nature of your application, the requesting agency and/or the agency conducting the application investigation may also retain the fingerprints and other submitted information for other authorized purposes of such agency(ies).

Routine Uses: The fingerprints and information reported on this form may be disclosed pursuant to your consent, and may also be disclosed by the FBI without your consent as permitted by the Federal Privacy Act of 1974 (5 USC 552a(b)) and all applicable routine uses as many be published at any time in the Federal Register, including the routine uses for the FBI Fingerprint Identification Records System (Justice, FBI-009) and the FBI's Blanket Routine Uses (Justice/FBI-BRU). Routine uses include, but are not limited to, disclosures to: appropriate governmental authorities responsible for civil or criminal law enforcement counterintelligence, national security or public safety matters to which the information may be relevant; to State and local governmental agencies and nongovernmental entities for application processing as authorized by Federal and State legislation, executive order, or regulation, including employment, security, licensing, and adoption checks; and as otherwise authorized by law , treaty, executive order, regulation, or other lawful authority. If other agencies are involved in processing the application, they may have additional routine uses.

Additional Information: The requesting agency and/or the agency conducting the application investigation will provide you additional information pertinent to the specific circumstances of this application, which may include identification of other authorities, purposes, uses, and consequences of not providing requested information. In addition, any such agency in the Federal Executive Branch has also published notice.

Electronic Fingerprinting

Take this form with you to the Livescan service provider. Please check the service provider's requirements to see if you need to bring any additional items.

- Background screening results are obtained from the Florida Department of Law Enforcement and the Federal Bureau of Investigation by submitting to a fingerprint scan using the Livescan method;
- You can find a Livescan service provider at:
- http://www.floridahealth.gov/licensing-and-regulation/background-screening/livescan-service-providers.html
- Failure to submit background screening will delay your application;
- Applicants may use any Livescan service provider approved by the Florida Department of Law Enforcement to submit their background screening to the department;
- If you do not provide the correct Originating Agency Identification (ORI) number to the Livescan service provider the Board office will not receive your background screening results;
- You must provide accurate demographic information to the livescan service provider at the time your fingerprints are taken, ***including your Social Security number (SSN)***;
- The ORI number for the Board of Pharmacy is EDOH4680Z
- Typically background screening results submitted through a Livescan service provider are received by the Board within 24-72 hours of being processed.
- If you obtain your livescan from a service provider who does not capture your photo you may be required to be reprinted by another agency in the future.

Name:_____ SSN#: _____ - ____ - _____

Aliases:_____

Address: _____ Apt. Number: _____

City:_____ State:_____Zip Code: _____

Date of Birth: _____/_____/_____ Place of Birth: _____
(MM/DD/YYYY)

Weight: _____ Height: _____Eye Color:_____ Hair Color: _____

Race: _____ Sex: _____
(W-White/Latino(a); B-Black; A-Asian; (M=Male; F=Female)
NA-Native American; U-Unknown)

Citizenship: _____

Transaction Control Number (TCN#):_____
(*This will be provided to you by the Livescan Service provider*.)

Keep this form for your records.

Item #1- Nuclear Prescription Department Manager Designation and Privacy Statement Acknowledgement

File # (if known)**:**	**License #** (if applicable)**:**

To: Florida Board of Pharmacy, Post Office Box 6320, Tallahassee, FL 32314-6320
(850) 245-4292- phone * (850) 413-6982 – fax * MQAPharmPDMAffiliate@flhealth.gov

Section A. Nuclear Prescription Department Manager (PDM)

Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailing Address:		
City	**State**	**Zip**
Incoming Nuclear PDM Name:		**License#:**
		NP
Date Beginning:	**Incoming Nuclear Pharmacist Signature**	
PDM Transaction Control Number (TCN) – related to Livescan Fingerprints *(optional, if known)***:** ** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs		
*****Only provide following information if there is an Outgoing PDM at current pharmacy location.*****		
Outgoing Nuclear PDM Name:		**License#:**
		NP
Date Ending as PDM:	**Outgoing Nuclear PDM Signature** *(optional)*	

Section B. Incoming PDM Privacy Statement Acknowledgement

Note: Acknowledgment should be completed by same person listed in Section A above as Incoming PDM.	
I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."	
Date:	**Incoming Nuclear PDM Signature**

Item #2- Affiliate/Owner Privacy Statement Acknowledgement

To be completed by EACH Affiliate/Owner listed in the application.

To: **Florida Board of Pharmacy, Post Office Box 6320, Tallahassee, FL 32314-6320**
(850) 245-4292- phone * (850) 413-6982 – fax * MQAPharmPDMAffiliate@flhealth.gov

From:

Affiliate / Owner Name:		**File # (required):**
Applicant Name:		
Affiliate/Owner Mailing Address:		
City	**State**	**Zip**
Affiliate/Owner Email ** (see note below)	**Affiliate/Owner Telephone Number**	
Affiliate/Owner Transaction Control Number (TCN) *(optional, if known)***:** ** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs**		
NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.		

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

_____ _____

Affiliate/Owner Signature (Required) **Date (of signature)**

Item #3 - Policy and Procedure Questions

To be completed by Nuclear Pharmacy Applicants

Each Nuclear Pharmacy shall designate a Nuclear Pharmacist as the Prescription Department Manager who shall be responsible for compliance with all laws and regulations, both state and federal pertaining to radiopharmaceuticals and radiopharmaceutical services. A Nuclear Pharmacist must personally supervise the operation of only one Nuclear Pharmacy during all times when radiopharmaceutical services are being performed.

1) List the following:
   Firm Name:
   Doing business as (d/b/a):
   Telephone number:
   Address:
   Permit number (if already licensed as an institutional pharmacy):

2) Explain the practice setting of the proposed facility.

3) What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice.
4) What are the experience, qualifications, special education, and/or training of the compounding pharmacist? Please provide a resume.
5) Address the ratio of supportive personnel to each pharmacist. How will the supportive personnel be utilized? Include a job description for any such supportive personnel.
6) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.
7) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how products are protected from extreme temperature conditions.
8) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.
9) Address the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed, please state so accordingly.
10) Address the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.

11) What is the procedure for the annual review and updating of the policy and procedure manual?

12) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink, and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.

13) Include a sample copy of a patient profile.

14) Address the use of aseptic techniques.

15) Describe the Quality Assurance Program.

16) Describe with detail the policy and procedure for patient education, including the personnel involved.

17) Address the policy and procedure for handling waste and returns.

18) Describe the type of certified laminar flow hood(s) to be used and the frequency of certification.

19) Describe the refrigerator/freezer to be used.

20) Describe appropriate waste containers for:
    a. Used needles and syringes.
    b. Cytotoxic waste including disposable apparel used in preparation.

21) Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.

22) Address the following references to be used:
    a. Chapters 465 and 893, F.S., and Rule 64B16, F.A.C.
    b. Authoritative Therapeutic Reference.
    c. Handbook of injectable drugs by American Society of Health-System Pharmacists.

23) Occupational Safety and Health Administration guidelines for safe handling of cytotoxic drugs.

DIVISION OF MEDICAL QUALITY ASSURANCE
BOARD OF PHARMACY
4052 BALD CYPRESS WAY, BIN #C-04
TALLAHASSEE, FLORIDA 32399-3254
(850) 245-4292

SPECIAL PHARMACY PERMIT APPLICATION AND INFORMATION

January 2018

Dear Florida Pharmacy Permit Applicant,

Thank you for applying for a pharmacy permit in the State of Florida. The information in this packet has been designed to provide the essential information required to process your application in a timely manner. Your assistance in providing all required information will enable the Florida Board of Pharmacy (the Board) staff to process your application as soon as possible. You are encouraged to apply as early as possible to avoid processing delays caused by large volumes of applicants.

Florida Statutes require a completed application and fees before your application can be reviewed. Please read these instructions carefully and fully before submitting your application. You should keep a copy of the completed application and all other materials sent to the Board office for your records. When you mail the completed application and fees, use the address noted in the instructions and on the application form.

When your application arrives, your fees will be deposited and verified before the staff review can begin. You will receive a letter acknowledging receipt of your application. The staff will notify you within 30 days if any materials are incomplete.

If you need to communicate with the Board staff, you are encouraged to email the Board staff at info@floridaspharmacy.gov, or you may at call us at (850) 245-4292. Phone calls are returned within 24 hours and emails are responded to within 48 hours during normal business hours. Our staff is committed to providing prompt and reliable information to our customers. Many procedures have been streamlined to expedite the processing of applications; we certainly welcome your comments on how our services may be improved.

Sincerely,

The Board of Pharmacy

SPECIAL PHARMACY PERMIT APPLICATION INFORMATION

Whether opening a new establishment, changing locations, or changing owners, a pharmacy permit is required prior to operating in the State of Florida. The permit application must be completed and returned to the Florida Board of Pharmacy with the required fee of $255.00. The application MUST have the original signatures of the owner or officer of the establishment and the Prescription Department Manager (PDM) or Consultant Pharmacist of Record (COR). If compounding sterile preparations, the applicant must submit an additional application on Form DH-MQA 1270, "Special Sterile Compounding Permit" and pay the additional permitting fee.

Special pharmacies are pharmacies providing miscellaneous specialized pharmacy service functions. There are six (6) types of Special Pharmacy Permit applicants**. Please read the descriptions below. Check which permit type you are applying on the application.**

1. **Special Limited Community Pharmacy Permits** may be obtained by an Institutional Class II Pharmacy that dispenses medicinal drugs to employees, medical staff, emergency room patients, and other patients on continuation of a course of therapy.

2. **Special Parenteral and Enteral Pharmacy Permits** provide parenteral (IV), enteral, and cytotoxic pharmacy services to outpatients. The applicant must be compliant with the Standard for Compounding Sterile Preparations found in Rule 64B16-27.797, F.A.C. Special- Parenteral and Enteral Pharmacy Permits may stand-alone or be used in conjunction with a Community Pharmacy or Special-Closed System Pharmacy Permit. The permittee must provide 24-hour telephone accessibility.

3. **Special Closed System Pharmacy Permits** are not open to the public and prescriptions are individually prepared for dispensing utilizing closed delivery systems for ultimate consumers in health care institutions including nursing homes, jails, Assisted Living Facilities (ALF's), Intermediate Care Facility/Developmentally Delayed (ICF-IID's) or other custodial care facilities when defined by Agency for Health Care Administration (AHCA) rules. This permit may not provide medications to in-patients in a hospital.

4. **Special End Stage Renal Dialysis (ESRD) Pharmacy Permits** provides dialysis products and supplies to persons with chronic kidney disease. This permit may not provide medications to in-patients in a hospital.

5. **Special Parenteral/Enteral Extended Scope Pharmacy Permits** is required to compound patient specific enteral/parenteral preparations in conjunction with Institutional Pharmacy permits. The applicant must be compliant with the Standard for Compounding Sterile Preparations found in Rule 64B16-27.797, F.A.C.

6. **Special Assisted Living Facility (ALF) Pharmacy Permits** is an optional permit for those ALF's providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging.

Pursuant to Rule 64B16-28.800, applicants for any special pharmacy permit shall provide the Board of Pharmacy with a Policy and Procedure Manual which sets for a detailed description of the type of pharmacy services to be provided within the special pharmacy practice. Section 465.022(4), Florida Statutes, also provides that an application for a pharmacy permit must include the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships.

Pursuant to Rule 64B16-28.100(1)(e), F.A.C., the policy and procedure manual shall contain the procedures implemented to minimize the dispensing of controlled substances based on fraudulent representations as follows:

1. Provisions to identify and guard against invalid practitioner-patient relationships.
2. Provisions to guard against filling fraudulent prescriptions for controlled substances.
3. Provisions to identify prescriptions that are communicated or transmitted legally.
4. Provisions to identify the characteristics of a forged or altered prescription.

APPLICATION PROCESSING

Please read all application instructions before completing your application.

1) Please mail the application and the $255.00 application fee and fingerprint fees (check or money order made payable to the FLORIDA DEPARTMENT OF HEALTH) to the following address:

Application & Fees:	**Express Mail ONLY**
Department of Health	Department of Health
Board of Pharmacy	Board of Pharmacy
P.O. Box 6320	4052 Bald Cypress Way, Bin C-04
Tallahassee, Florida 32314-6320	Tallahassee, FL 32399-3254

Within 30 days of receipt of your application and fees, the board office will notify you of the receipt of your application, any required documents, and your status. If the application is complete, you will be notified that an inspector will contact you to setup an inspection appointment. Please do not contact the board office concerning your inspection date, and allow 30 days for the inspector to contact you. If the inspector has not contacted you within 30 days, then notify the board. If your application is incomplete, you will be notified in writing of what is required to make your application complete.

2) Submit fingerprint results.

Failure to submit fingerprints will delay your application. All owners, officers, and PDMs or CORs are required to submit a set of fingerprints unless the corporation is exempt under Section 465.022, Florida Statutes, for corporations having more than $100 million of business taxable assets in this state. These corporations are only required to have the PDM or COR to submit fingerprints.

Electronic fingerprint information ("EFI") that has been submitted to the Florida Agency for Health Care Administration may be accessible by the Florida Department of Health for a period of sixty (60) months. If the Department is able to access EFI from AHCA, applicants will not be required to resubmit EFI for additional or new applications submitted during this time period. After sixty (60) months, new electronic fingerprint information must be submitted as part of all applications. **Note: If your officer, owner, or PDM/COR has already been fingerprinted at the time you are completing this Special Pharmacy permit application, please ensure to provide the Transaction Control Number (TCN), if known, with the requested information in the application.**

Applicants may use any Livescan vendor that has been approved by the Florida Department of Law Enforcement to submit their fingerprints to the department. Please ensure that the Originating Agency Identification (ORI) number is provided to the vendor when you submit your fingerprints. If you do not provide an ORI number or if you provide an incorrect ORI number to the vendor, the Board of Pharmacy will not receive your fingerprint results. The applicant is fully responsible for selecting the vendor and ensuring submission of the prints to the Department.

How do I find a Livescan vendor in order to submit my fingerprints to the Department?
The Department of Health accepts electronic fingerprinting service offered by Livescan device vendors that are approved by the Florida Department of Law Enforcement and listed at their site. You may view the vendor options and contact information at:

http://www.floridahealth.gov/licensing-and-regulation/background-screening/livescan-service-providers.html

What information must I provide to the Livescan vendor I choose?

- If you are an applicant seeking a license for any profession regulated by the Department of Health, which requires a criminal background search as a condition of licensure, you must provide accurate demographic information at the time your fingerprints are taken, ***including your Social Security number***. The Department will not be able to process a submission that does not include your Social Security number.
- You must provide the correct ORI number.

Where do I get the ORI number to submit to the vendor?

- The ORI number for the pharmacy profession is **EDOH4680Z.**

Attestation for Business Taxable Assets

- If the applicant has more than $100 million dollars of business taxable assets in this state, please submit a formal opinion letter from a Certified Public Accountant duly licensed in the state of your principal place of business affirming the corporation has more than $100 million of business taxable assets in this state for the previous tax year. In lieu of submitting a formal opinion letter from a Certified Public Accountant, the applicant may submit a copy of its Florida Corporate Income/Franchise and Emergency Excise Tax Return (Form F-1120, Effective 01/09).

(3) Privacy Statement and Attestation

In order for the Board of Pharmacy Office to receive your Livescan electronic fingerprinting results, you must affirm that you have been provided with and read the attached statement from the Florida Department of Law Enforcement regarding the sharing, retention, and right to challenge incorrect criminal history records, and the "Privacy Statement" document from the Federal Bureau of Investigation. The appropriate form(s) to provide this affirmation are included within Items #1 and #2 of the application.

Licensure Process

Once the application is deemed complete, the Board staff authorizes an inspection. Upon completion of the inspection, the inspector notifies the Board office as to whether the inspection was satisfactory or unsatisfactory. If the inspection is satisfactory, a permit number is issued within 7-10 days. You will receive the actual copy of your license within 7 days. **Please wait 7-14 days from your satisfactory inspection before checking on the status of your permit with the Board office**.

You may look up your license number on our website at http://www.flhealthsource.com/ under "Verify a License."

Drug Enforcement Administration (DEA)
Please note that the DEA will not issue a registration until the Florida Board of Pharmacy has issued a pharmacy permit. More information is available by visiting the DEA website at http://www.DEAdiversion.usdoj.gov, or by contacting them at (800)667-9752.

IMPORTANT NOTICE: Pursuant to Section 465.022(5), F.S., the Department or Board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant:

(a) Has obtained a permit by misrepresentation or fraud.

(b) Has attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation.

(c) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy.

(d) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud.

(e) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009.

(f) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009.

(g) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period.

(h) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application.

(i) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

(j) Has 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.

For felonies in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the department shall deny the application if upon final resolution of the case the licensee has failed to successfully complete the program.

<u>If applicable to you, please provide the documentation to the Florida Board of Pharmacy.</u>

SPECIAL PHARMACY PERMIT APPLICATION CHECKLIST

Keep a copy of the completed application for your records.

It is recommended that you use the following checklist to help ensure that your application is complete. Failure to attach any required document, or to have required documentation sent to the Board, will result in an incomplete application. Final approval for inspection cannot be granted until the application is complete.

SPECIAL PHARMACY PERMIT

_____All Application Questions Answered, including Policy and Procedure questions located within Item #3?

_____$255.00 Fee Attached (Permit fee includes $250 application fee and $5.00 unlicensed activity fee)

_____Articles of Incorporation paperwork from the Secretary of State provided?

_____PDM or COR Designation and Privacy Statement Acknowledgement provided (Application Item #1)?

_____Affiliate/Owner Privacy Statement Acknowledgement provided for each affiliate/owner (Application Item #2)?

_____Applicant/Affiliate/Owner supplemental documents provided for explaining any previous ownership, disciplinary actions, voluntary relinquishments and/or criminal activity?

_____Applicant/Affiliate/Owner pharmacy permit questions answered and supplemental documents provided?

_____Policies and Procedures which sets forth a detailed description of the type of pharmacy services to be provided within the special pharmacy submitted?

_____Policies and Procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships submitted?

FLORIDA BOARD OF PHARMACY
P.O. Box 6320
Tallahassee, FL 32314-6320
Telephone (850) 488-0595
http://www.floridaspharmacy.gov

SPECIAL PHARMACY PERMIT

APPLICATION

Application Type – Please choose one of the following:

___New Establishment ($255.00 fee)
Complete: Section A only, along with Items #1, #2, and #3.

___Change of Ownership ($255.00 fee)
Complete: Sections A and C only, along with Items #1 and 2.

___ Change of Location ($100.00 fee)
Complete: Sections A and B only.

___ Stock Transfer (no fee)
Complete: Section A, pages 2-3 and Section D only.

Pharmacy Permit Type – Please choose permit type(s) (fee is $255 for each permit type)

____ Special- ALF
____ Special- ESRD
_____Special- Limited Community
_____ Special- Parenteral and Enteral
____ Special- Closed System Pharmacy
____ Special- Parenteral/Enteral Extended Scope

SECTION A. Please Complete for all Application Types

Please list your Federal Employer Identification Number:

1. Corporate Name		**Telephone Number**
2. Doing Business As (d/b/a)		**E-Mail Address**** (see note below)
3. Mailing Address		
City	**State**	**Zip**
4. Physical Address		
City	**State**	**Zip**
5. List Prescription Department Manager (PDM) or Consultant Pharmacist of Record (COR)		
Name		**License Number (PS or PU)**
E-Mail Address** (see note below)		**Telephone Number**
6. Contact Person		**Title**
E-Mail Address** (see note below)		**Telephone Number**

NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.

7. Special- Parenteral & Enteral Permits - ONLY
Provide 24-Hour Accessible Telephone Number Below:

(_____) _____- _____

8. Ownership Information

a. Type of Ownership: _____Individual _____Corporation _____Partnership

_____Other: _____

NOTE: IF CORPORATION OR LIMITED PARTNERSHIP YOU MUST INCLUDE WITH YOUR APPLICATION A COPY OF THE ARTICLES OF INCORPORATION ON FILE WITH THE FLORIDA SECRETARY OF STATE'S OFFICE

b. Are the applicants, officers, directors, shareholders, members and partners over the age of 18?

Yes _____ No _____

c. Does the corporation have more than $100 million of business taxable assets in this state? *If yes, provide attestation from Certified Public Accountant for previous tax year or Florida Corporate Income /Franchise and Emergency Excise Tax Return (F-1120).*

Yes _____ No _____

d. List all the owners and officers of the corporation. Each person listed below having an ownership interest of 5% or greater and any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant including officers and members of the board of directors must submit a set of fingerprints and fees unless you answered yes to 8c. If 8c is "Yes", please list the owners below and only submit fingerprints for the Prescription Department Manager or Consultant Pharmacist of Record. If 8c is "Yes" and the prints are on file with DOH or AHCA and available to the Board of Pharmacy, the requirement to submit the prints for this person is met. Also, if the % of Ownership column does not add to 100%, please provide an explanation. *Attach a separate sheet if necessary.*

Owner/Officer-Title	Date of Birth	Mailing Address, City State, Zip Code	% of Ownership
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%

9. Has anyone listed in 8d. had an ownership interest of 5% or more in a pharmacy or any other business permit which was disciplined, suspended, revoked, or closed involuntarily within the past 5 years? *If yes, please provide a signed statement disclosing the reason the entity was closed.*

Yes _____ No _____

9a. Has anyone listed in 8d. had an ownership interest of 5% or more in a pharmacy or any other business permit which was voluntarily relinquished or closed voluntarily within the past 5 years? *If yes, please provide a signed statement disclosing the reason the entity was closed.*

Yes _____ No _____

Pursuant to Section 465.022(5), Florida Statutes, questions 10 – 19 are being asked. If you answer "Yes" to any of the following questions, explain <u>on a separate sheet</u> providing accurate details and submit copies of supporting documentation.
10. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant obtained a permit by misrepresentation or fraud?
Yes _____ No_____
11. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation?
Yes _____ No _____
12. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy?
Yes _____ No_____
13. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud?
Yes_____ No_____
14. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009?
Yes _____ No_____
15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009?
Yes _____ No _____
16. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period?
Yes _____ No _____
17. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application?
Yes _____ No _____

18. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant currently listed on the United States Department of Health Human Services Office of Inspector General's List of Excluded Individuals and Entities? *(If yes, please submit proof.)*

Yes _____ No _____

19. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant 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?

Yes _____ No _____

20. Are you currently registered or permitted in any other states? *(If yes, provide the state, permit type, and permit number for each permit. Attach a separate sheet if necessary.)*

Yes _____ No _____

State	Permit Type	Permit Number

21. Has the applicant, affiliated person, partner, officer, directors, Prescription Department Manager or Consultant Pharmacist of Record ever owned a pharmacy? *(If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy. Attach a separate sheet if necessary.)*

Yes _____ No _____

Individual's Name	Pharmacy Name	State	Status

22. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, affiliated persons, partners, officers, directors, Prescription Department Manager, or Consultant Pharmacist of Record in this state or any other?

Yes _____ No _____

23. Has the applicant, affiliated person, partner, officer, or director ever been convicted of a felony or misdemeanor, excluding minor traffic convictions? You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction.

Yes _____ No _____

24. Does the applicant, affiliated person, partner, officer, director have any outstanding fines, liens or overpayments assessed by a final order of the department? If yes please answer 24a.

Yes _____ No _____

24a. Does the applicant, affiliated person, partner, officer, director have a repayment plan approved by the department?
Yes _____ No_____
25. Is the applicant, affiliated persons, partners, officers, or directors, under investigation or prosecution for a crime in any jurisdiction?
Yes _____ No_____
26. Is the applicant, affiliated persons, partners, officers, or directors, under investigation or pending administrative action by the licensing authority of any jurisdiction, including its agencies and subdivisions?
Yes _____ No_____

SECTION B. Please complete for Change of Location only.

1. Current Practice Location Address		
City	**State**	**Zip**

E-Mail Address** (see note below)	**Telephone Number**

2. New Practice Location Address		
City	**State**	**Zip**

E-Mail Address** (see note below)	**Telephone Number**

Please provide your existing Pharmacy Permit Number(s):
Please provide your existing Federal DEA Number:
NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.

SECTION C. Please complete for a Change of Ownership only.

1. Are you changing physical locations with this change of ownership?
Yes _____ No _____ *NOTE: If yes, please complete Section B above.*
2. Please provide date when business transaction for the change of ownership will be completed?
Date: _____
3. Do you have a signed letter from both the buyer and seller which indicates dates that pharmacy permit license should be transferred? *Note: A copy of the signed letter should be provided with your application.*
Yes _____ No _____

SECTION D. Please complete for a Stock Transfer of Ownership Interests only.
1. Please provide the date the transfer of ownership interest took place?
Date: _____
2. Did your company's FEIN change as a result of the transfer of ownership interest referenced in Section D, question 1 above?
Yes _____ No _____ *NOTE: If yes, please complete Section C above and include the necessary fee.*

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

****

Section 456.013(1), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application, which takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department.

I swear or affirm that the statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations that they deem appropriate and to secure any additional information concerning me, and I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, Board, or any municipal, county, state, or federal governmental agencies or units, and I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other item, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

Under penalty of perjury I have read the foregoing document and that the facts stated in it are true. I recognize that providing false information may result in disciplinary action against my license or criminal penalties.

SIGNATURE _____ DATE_____
(Owner or officer of establishment)

FLORIDA DEPARTMENT OF LAW ENFORCEMENT

NOTICE FOR APPLICANTS SUBMITTING FINGERPRINTS WHERE CRIMINAL RECORD RESULTS WILL BECOME PART OF THE CARE PROVIDER BACKGROUND SCREENING CLEARINGHOUSE

NOTICE OF:

- **SHARING OF CRIMINAL HISTORY RECORD INFORMATION WITH SPECIFIED AGENCIES,**
- **RETENTION OF FINGERPRINTS,**
- **PRIVACY POLICY, AND**
- **RIGHT TO CHALLENGE AN INCORRECT CRIMINAL HISTORY RECORD**

This notice is to inform you that when you submit a set of fingerprints to the Florida Department of Law Enforcement (FDLE) for the purpose of conducting a search for any Florida and national criminal history records that may pertain to you, the results of that search will be returned to the Care Provider Background Screening Clearinghouse. By submitting fingerprints, you are authorizing the dissemination of any state and national criminal history record that may pertain to you to the Specified Agency or Agencies from which you are seeking approval to be employed, licensed, work under contract, or to serve as a volunteer, pursuant to the National Child Protection Act of 1993, as amended, and Section 943.0542, Florida Statutes. "Specified agency" means the Department of Health, the Department of Children and Family Services, the Division of Vocational Rehabilitation within the Department of Education, the Agency for Health Care Administration, the Department of Elder Affairs, the Department of Juvenile Justice, and the Agency for Persons with Disabilities when these agencies are conducting state and national criminal history background screening on persons who provide care for children or persons who are elderly or disabled. The fingerprints submitted will be retained by FDLE and the Clearinghouse will be notified if FDLE receives Florida arrest information on you.

Your Social Security Number (SSN) is needed to keep records accurate because other people may have the same name and birth date. Disclosure of your SSN is imperative for the performance of the Clearinghouse agencies' duties in distinguishing your identity from that of other persons whose identification information may be the same as or similar to yours.
Licensing and employing agencies are allowed to release a copy of the state and national criminal record information to a person who requests a copy of his or her own record if the identification of the record was based on submission of the person's fingerprints. Therefore, if you wish to review your record, you may request that the agency that is screening the record provide you with a copy. After you have reviewed the criminal history record, if you believe it is incomplete or inaccurate, you may conduct a personal review as provided in s. 943.056, F.S., and Rule 11C8.001, F.A.C. If national information is believed to be in error, the FBI should be contacted at 304-625-2000. You can receive any national criminal history record that may pertain to you directly from the FBI, pursuant to 28 CFR Sections 16.30-16.34. You have the right to obtain a prompt determination as to the validity of your challenge before a final decision is made about your status as an employee, volunteer, contractor, or subcontractor.

Until the criminal history background check is completed, you may be denied unsupervised access to children, the elderly, or persons with disabilities.

The FBI's Privacy Statement follows on a separate page and contains additional information.

US Department of Justice, Federal Bureau of Investigation,
Criminal Justice Information Services Division

Privacy Statement

Authority: The FBI's acquisition, preservation and exchange of information requested by this form is generally authorized under 28 U.S.C. 534. Depending on the nature of your application, supplemental authorities include numerous Federal statutes, hundreds of State statutes pursuant to Pub.L.92-544, Presidential executive orders, regulations and/or orders of the Attorney General of the United States, or other authorized authorities. Examples include, but are not limited to: 5 U.S.C. 9101; Pub.L.94-29; Pub.L.101-604; and Executive Orders 10450 and 12968. Providing the requested information is voluntary; however, failure to furnish the information may affect timely completion of approval of your application.

Social Security Account Number (SSAN): Your SSAN is needed to keep records accurate because other people may have the same name and birth date. Pursuant to the Federal Privacy Act of 1974 (5 USC 552a), the requesting agency is responsible for informing you whether disclosure is mandatory or voluntary, by what statutory or other authority your SSAN is solicited, and what uses will be made of it. Executive Order 9397 also asks Federal Agencies to use this number to help identify individuals in agency records.

Principal Purpose: Certain determinations, such as employment, security, licensing and adoption, may be predicated on fingerprint based checks. Your fingerprints and other information contained on (and along with) this form may be submitted to the requesting agency, the agency conducting the application investigation, and/or FBI for the purpose of comparing the submitted information to available records in order to identify other information that may be pertinent to the application. During the processing of this application, and for as long hereafter as my be relevant to the activity for which this application is being submitted, the FBI(may disclose any potentially pertinent information to the requesting agency and/or to the agency conducting the investigation. The FBI may also retain the submitted information in the FBI's permanent collection of fingerprints and related information, where it will be subject to comparisons against other submissions received by the FBI. Depending on the nature of your application, the requesting agency and/or the agency conducting the application investigation may also retain the fingerprints and other submitted information for other authorized purposes of such agency(ies).

Routine Uses: The fingerprints and information reported on this form may be disclosed pursuant to your consent, and may also be disclosed by the FBI without your consent as permitted by the Federal Privacy Act of 1974 (5 USC 552a(b)) and all applicable routine uses as many be published at any time in the Federal Register, including the routine uses for the FBI Fingerprint Identification Records System (Justice, FBI-009) and the FBI's Blanket Routine Uses (Justice/FBI-BRU). Routine uses include, but are not limited to, disclosures to: appropriate governmental authorities responsible for civil or criminal law enforcement counterintelligence, national security or public safety matters to which the information may be relevant; to State and local governmental agencies and nongovernmental entities for application processing as authorized by Federal and State legislation, executive order, or regulation, including employment, security, licensing, and adoption checks; and as otherwise authorized by law , treaty, executive order, regulation, or other lawful authority. If other agencies are involved in processing the application, they may have additional routine uses.

Additional Information: The requesting agency and/or the agency conducting the application investigation will provide you additional information pertinent to the specific circumstances of this application, which may include identification of other authorities, purposes, uses, and consequences of not providing requested information. In addition, any such agency in the Federal Executive Branch has also published notice.

Electronic Fingerprinting

Take this form with you to the Live Scan service provider. Please check the service provider's requirements to see if you need to bring any additional items.

- Background screening results are obtained from the Florida Department of Law Enforcement and the Federal Bureau of Investigation by submitting to a fingerprint scan using the Livescan method;
- You can find a Livescan service provider at: http://www.floridahealth.gov/licensing-and-regulation/background-screening/livescan-service-providers.html
- Failure to submit background screening will delay your application;
- Applicants may use any Livescan service provider approved by the Florida Department of Law Enforcement to submit their background screening to the department;
- If you do not provide the correct Originating Agency Identification (ORI) number to the livescan service provider the Board office will not receive your background screening results;
- You must provide accurate demographic information to the livescan service provider at the time your fingerprints are taken, ***including your Social Security number (SSN)***;
- The ORI number for the Board of Pharmacy is **EDOH4680Z**.
- Typically background screening results submitted through a Livescan service provider are received by the Board within 24-72 hours of being processed.
- If you obtain your livescan from a service provider who does not capture your photo you may be required to be reprinted by another agency in the future.

Name:_____ SSN#: _____ - ____ - _____

Aliases: _____

Address: _____Apt. Number: _____

City:_____ State_____Zip Code: _____

Date of Birth: _____/_____/_____ Place of Birth: _____
(MM/DD/YYYY)

Weight: _____ Height: _____ Eye Color:_____ Hair Color: _____

Race: _____
(W-White/Latino(a); B-Black; A-Asian; NA-Native American; U-Unknown)

Sex: _____
(M=Male; F=Female)

Citizenship: _____

Transaction Control Number (TCN#):_____
(*This will be provided to you by the Livescan Service provider*.)

Keep this form for your records.

Item #1- Prescription Department Manager (PDM) or Consultant Pharmacist of Record (COR) Privacy Statement Acknowledgement

File # (if known)**:**	**License #** (if applicable)**:**

To: Florida Board of Pharmacy, Post Office Box 6320, Tallahassee, FL 32314-6320
(850) 245-4292- phone * (850) 413-6982 – fax * MQAPharmPDMAffiliate@flhealth.gov

Section A. Prescription Department Manager (PDM) or Consultant Pharmacist of Record (COR) Designation

Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailing Address:		
City	**State**	**Zip**
Incoming PDM / COR Name:		**License#:**
Date Beginning as PDM / COR:	**Incoming PDM / COR Signature**	
PDM / COR Transaction Control Number (TCN) – related to Livescan Fingerprints *(optional, if known)***:** ** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs**		
*****Only provide following information if there is an Outgoing PDM or COR at current pharmacy location.*****		
Outgoing PDM / COR Name:		**License#:**
Date Ending as PDM / COR:	**Outgoing PDM/COR Signature** *(optional)*	

Section B. Incoming PDM / COR Privacy Statement Acknowledgement

Note: Acknowledgment should be completed by same person listed in Section A above as Incoming PDM or COR.

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

Date:	**Incoming PDM / COR Signature**

Item #2- Affiliate/Owner Privacy Statement Acknowledgement

To be completed by EACH Affiliate/Owner listed in the application.

To: **Florida Board of Pharmacy, Post Office Box 6320, Tallahassee, FL 32314-6320**
(850) 245-4292- phone * (850) 413-6982 – fax * MQAPharmPDMAffiliate@flhealth.gov

From:

Affiliate / Owner Name:		**File # (required):**
Applicant Name:		
Affiliate/Owner Mailing Address:		
City	**State**	**Zip**
Affiliate/Owner Email ** (see note below)	**Affiliate/Owner Telephone Number**	
Affiliate/Owner Transaction Control Number (TCN) *(optional, if known)***:** ** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs**		
NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.		

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

_____ _____

Affiliate/Owner Signature (Required) **Date (of signature)**

Item #3 - Policy and Procedure Questions

Special-Parenteral and Enteral and Special-Parenteral/Enteral Extended Scope Applicants Complete the Following Questions.

The Consultant Pharmacist of Record is responsible for developing and maintaining a current policy and procedure manual. A copy of the permittee's policy and procedure manual as provided herein shall accompany the permit application. The original policy and procedure manual shall be kept within the pharmacy and shall be available for inspection by the Department of Health. The Board office will approve the policy and procedure manual based upon answers submitted for the following questions, where applicable, by using excerpts or summaries from the policy and procedure manual.

1) List the following:
   Firm Name:
   Doing business as (d/b/a):
   Telephone number:
   Address:
   Permit number (if already licensed as an institutional pharmacy):

2) Explain the practice setting of the proposed facility.

3) What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice.

4) What are the experience, qualifications, special education, and/or training of the compounding pharmacist? Please provide a resume.

5) Address the ratio of supportive personnel to each pharmacist. How will the supportive personnel be utilized? Include a job description for any such supportive personnel.

6) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.

7) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how products are protected from extreme temperature conditions.

8) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.

9) Address the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed, please state so accordingly.

10) Address the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.

11) What is the procedure for the annual review and updating of the policy and procedure manual?

12) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink, and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.

13) Include a sample copy of a patient profile.

14) Address the use of aseptic techniques.

15) Describe the Quality Assurance Program.

16) Describe with detail the policy and procedure for patient education, including the personnel involved.

17) Address the policy and procedure for handling waste and returns.

18) Describe the type of certified laminar flow hood(s) to be used and the frequency of certification.

19) Describe the refrigerator/freezer to be used.

20) Describe appropriate waste containers for:

    a. Used needles and syringes.

    b. Cytotoxic waste including disposable apparel used in preparation.

21) Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.

22) Address the following references to be used:

    a. Chapters 465 and 893, F.S., and Rule Title 64B16, F.A.C.

    b. Authoritative Therapeutic Reference.

    c. Handbook of Injectable Drugs by American Society of Health-System Pharmacists.

23) Occupational Safety and Health Administration guidelines for safe handling of cytotoxic drugs.

If applying for a Special- Parenteral/Enteral Extended Scope Permit, answer the additional questions below:

24) Describe the individual responsibilities of the Special- Parenteral/Enteral Extended Scope Permit and the supplied institutional pharmacy permits, if applicable.

25) Address the maintenance of patient profiles and the offer to counsel if dispensing to outpatients.

26) Describe the system for the maintenance of compounding records.

DIVISION OF MEDICAL QUALITY ASSURANCE
BOARD OF PHARMACY
4052 BALD CYPRESS WAY, BIN #C-04
TALLAHASSEE, FLORIDA 32399-3254
(850) 245-4292

SPECIAL STERILE COMPOUNDING PERMIT APPLICATION AND INFORMATION

January 2018

Dear Florida Pharmacy Permit Applicant,

Thank you for applying for a pharmacy permit in the State of Florida. The information in this packet has been designed to provide the essential information required to process your application in a timely manner. Your assistance in providing all required information will enable the Florida Board of Pharmacy (the Board) staff to process your application as soon as possible. You are encouraged to apply as early as possible to avoid processing delays caused by large volumes of applicants.

Florida Statutes require a completed application and fees before your application can be reviewed. Please read these instructions carefully and fully before submitting your application. You should keep a copy of the completed application and all other materials sent to the Board office for your records. When you mail the completed application and fees, use the address noted in the instructions and on the application form.

When your application arrives, your fees will be deposited and verified before the staff review can begin. You will receive a letter acknowledging receipt of your application. The staff will notify you within 30 days if any materials are incomplete.

If you need to communicate with the Board staff, you are encouraged to email the Board staff at info@floridaspharmacy.gov, or you may at call us at (850) 245-4292. Phone calls are returned within 24 hours and emails are responded to within 48 hours during normal business hours. Our staff is committed to providing prompt and reliable information to our customers. Many procedures have been streamlined to expedite the processing of applications; we certainly welcome your comments on how our services may be improved.

Sincerely,

The Board of Pharmacy

SPECIAL STERILE COMPOUNDING PHARMACY PERMIT APPLICATION INFORMATION

A Special Sterile Compounding Pharmacy (SSCP) Permit is a type of special permit, which is required before any permitted pharmacy may engage in the preparation of compounded sterile products. An Outsourcing Facility is considered a pharmacy. An SSCP is not a stand-alone pharmacy permit, and can only be issued to an Outsourcing Facility or a pharmacy in this state that holds an active pharmacy permit. However, the SSCP permit is not required for the following permittees:

- A Special Parenteral/Enteral or Special Parenteral / Enteral Extended Scope pharmacy if the pharmacy holds no other pharmacy permit and is not registered as an Outsourcing Facility; or
- A Type B Modified Class II Institutional Pharmacy that compounds low risk level sterile products for immediate-use in full compliance with Rule 64B16 - 28.802, F.A.C.

The compounding of sterile products must be in strict compliance with the standards set forth in Rules 64B16-27.797 and 64B16-27.700, F.A.C. Passing an on-site inspection is a prerequisite for obtaining a SSCP.

Section 465.022(4), Florida Statutes, also provides that an application for a pharmacy permit must include the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships. Pursuant to Rule 64B16-28.100(1)(e), F.A.C., the policy and procedure manual shall contain the procedures implemented to minimize the dispensing of controlled substances based on fraudulent representations as follows:

1. Provisions to identify and guard against invalid practitioner-patient relationships.
2. Provisions to guard against filling fraudulent prescriptions for controlled substances.
3. Provisions to identify prescriptions that are communicated or transmitted legally.
4. Provisions to identify the characteristics of a forged or altered prescription.

In addition to the written policies and procedures for preventing controlled substance dispensing based on fraudulent prescriptions, the applicant for an SSCP must have and submit written policies and procedures that demonstrate the applicant is in full compliance with the compounding standards set forth by statue and rule.

Application Processing

Please read all application instructions before completing your application.

1) Please mail the application and the $255.00 application fee (cashier's check or money order made payable to the FLORIDA DEPARTMENT OF HEALTH) to the following address:

Application & Fees:
Department of Health
Board of Pharmacy
P.O. Box 6320
Tallahassee, Florida 32314-6320

Express Mail ONLY
Department of Health
Board of Pharmacy
4052 Bald Cypress Way, Bin C-04
Tallahassee, FL 32399-3254

Within 30 days of receipt of your application and fees, the Board office will notify you of the receipt of your application, any required documents, and your status. If the application is complete, you will be notified that an inspector will contact you to setup an inspection

appointment. If your application is incomplete, you will be notified in writing of what is required to make your application complete.

2) Submit fingerprint results.

Failure to submit fingerprints will delay your application. All owners, officers, and Prescription Department Managers (PDMs) or Consultant Pharmacists of Record (CORs) are required to submit a set of fingerprints unless the corporation is exempt under Section 465.022, Florida Statutes, for corporations having more than $100 million of business taxable assets in this state. These corporations are only required to have the PDM or COR to submit fingerprints.

Electronic fingerprint information ("EFI") that has been submitted to the Florida Agency for Health Care Administration may be accessible by the Florida Department of Health for a period of sixty (60) months. If the Department is able to access EFI from AHCA, applicants will not be required to resubmit EFI for additional or new applications submitted during this time period. After sixty (60) months, new electronic fingerprint information must be submitted as part of all applications. **Note: If your officer, owner, PDM or COR has already been fingerprinted at the time you are completing this SSCP permit application, please ensure to provide the Transaction Control Number (TCN), if known, with the requested information in the application.**

Applicants may use any Livescan vendor that has been approved by the Florida Department of Law Enforcement to submit their fingerprints to the department. Please ensure that the Originating Agency Identification (ORI) number is provided to the vendor when you submit your fingerprints. If you do not provide an ORI number or if you provide an incorrect ORI number to the vendor, the Board of Pharmacy will not receive your fingerprint results. The applicant is fully responsible for selecting the vendor and ensuring submission of the prints to the Department.

How do I find a Livescan vendor in order to submit my fingerprints to the Department?
The Department of Health accepts electronic fingerprinting service offered by Livescan device vendors that are approved by the Florida Department of Law Enforcement and listed at their site. You can view the vendor options and contact information at:

http://www.floridahealth.gov/licensing-and-regulation/background-screening/livescan-service-providers.html

What information must I provide to the Livescan vendor I choose?

- If you are an applicant seeking a license for any profession regulated by the Department of Health, which requires a criminal background search as a condition of licensure, you must provide accurate demographic information at the time your fingerprints are taken, ***including your Social Security number***. The Department will not be able to process a submission that does not include your Social Security number.
- You must provide the correct ORI number.

Where do I get the ORI number to submit to the vendor?

- The ORI number for the pharmacy profession is **EDOH4680Z.**

Attestation for Business Taxable Assets

- If the applicant has more than $100 million dollars of business taxable assets in this state, please submit a formal opinion letter from a Certified Public Accountant duly licensed in the state of your principal place of business affirming the corporation has more than $100 million of business taxable assets in this state for the previous tax year. In lieu of submitting a formal opinion letter from a Certified Public Accountant, the applicant may submit a copy of its Florida Corporate Income/Franchise and Emergency Excise Tax Return (Form F-1120, Effective 01/09).

3) Privacy Statement and Attestation

In order for the Board of Pharmacy Office to receive your Livescan electronic fingerprinting results, you must affirm that you have been provided with and read the attached statement from the Florida Department of Law Enforcement regarding the sharing, retention, and right to challenge incorrect criminal history records, and the "Privacy Statement" document from the Federal Bureau of Investigation. The appropriate form(s) to provide this affirmation are included within Items #1 and #2 of the application.

Licensure Process

Once the application is deemed complete, the Board staff authorizes an inspection. Upon completion of the inspection, the inspector notifies the Board office as to whether the inspection was satisfactory or unsatisfactory. If the inspection is satisfactory, a permit number is issued within 7-10 days. You will receive the actual copy of your permit within 7 days. **Please wait 7-14 days from your satisfactory inspection before checking on the status of your permit with the Board office**.

You may look up your permit number on our website at http://www.flhealthsource.com/ under "Verify a License."

Drug Enforcement Administration (DEA)

Please note that the DEA will not issue a registration until the Florida Board of Pharmacy has issued a pharmacy permit. More information is available by visiting the DEA website at http://www.DEAdiversion.usdoj.gov, or by contacting them at (800)667-9752.

IMPORTANT NOTICE: Pursuant to Section 465.022(5), F.S., the Department or Board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant:

(a) Has obtained a permit by misrepresentation or fraud.

(b) Has attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation.

(c) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy.

(d) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud.

(e) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009.

(f) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009.

(g) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period.

(h) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application.

(i) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

(j) Has 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.

For felonies in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the department shall deny the application if upon final resolution of the case the licensee has failed to successfully complete the program.

<u>If applicable to you, please provide the documentation to the Florida Board of Pharmacy.</u>

PHARMACY PERMIT APPLICATION CHECKLIST

Keep a copy of the completed application for your records.

It is recommended that you use the following checklist to help ensure that your application is complete. Failure to attach any required document, or to have required documentation sent to the Board, will result in an incomplete application. Final approval for inspection cannot be granted until the application is complete.

SPECIAL STERILE COMPOUNDING PHARMACY PERMIT

_____All Application Questions Answered?

_____$255.00 Fee Attached (Permit fee includes $250 application fee and $5.00 unlicensed activity fee)

_____Articles of Incorporation paperwork from the Secretary of State provided?

_____PDM or COR Designation and Privacy Statement Acknowledgement provided (Application Item #1)?

_____Affiliate/Owner Privacy Statement Acknowledgement provided for each affiliate/owner (Application Item #2)?

_____Applicant/Affiliate/Owner supplemental documents provided for explaining any previous ownership, disciplinary actions, voluntary relinquishments and/or criminal activity?

_____Applicant/Affiliate/Owner pharmacy permit questions answered and supplemental documents provided?

_____Policies and Procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships submitted?

_____Policies and Procedures for the compounding of sterile products?

FLORIDA BOARD OF PHARMACY
P.O. Box 6320
Tallahassee, FL 32314-6320
Telephone (850) 488-0595
http://www.floridaspharmacy.gov

SPECIAL STERILE COMPOUNDING PERMIT

APPLICATION

Application Type – Please choose one of the following:	
___New Establishment ($255.00 fee) **Complete: Section A only, along with Items #1, #2, and #3.**	___ Change of Location ($100.00 fee) **Complete: Sections A and B only.**
___Change of Ownership ($255.00 fee) **Complete: Sections A and C only, along with Items #1 and 2.**	___ Stock Transfer (no fee) **Complete: Section A, pages 2-3 and Section D only.**

SECTION A. Please Complete for all Application Types

Please list your Federal Employer Identification Number:

Please provide your current pharmacy permit number(s):

Is the applicant an outsourcing facility? Yes _____ No_____

1. Corporate Name		**Telephone Number**
2. Doing Business As (d/b/a)		**E-Mail Address**** (see note below)
3. Mailing Address		
City	**State**	**Zip**
4. Physical Address		
City	**State**	**Zip**
5. List Prescription Department Manager (PDM) or Consultant Pharmacist of Record (COR)		
Name		**License Number (PS or PU)**
E-Mail Address** (see note below)		**Telephone Number**
6. Contact Person		**Title**
E-Mail Address** (see note below)		**Telephone Number**

NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.

7. Ownership Information

a. Type of Ownership: _____Individual _____Corporation _____Partnership

_____Other: _____

NOTE: IF CORPORATION OR LIMITED PARTNERSHIP YOU MUST INCLUDE WITH YOUR APPLICATION A COPY OF THE ARTICLES OF INCORPORATION ON FILE WITH THE FLORIDA SECRETARY OF STATE'S OFFICE

b. Are the applicants, officers, directors, shareholders, members and partners over the age of 18?

Yes _____ No _____

c. Does the corporation have more than $100 million of business taxable assets in this state? *If yes, provide attestation from Certified Public Accountant for previous tax year or Florida Corporate Income /Franchise and Emergency Excise Tax Return (F-1120).*

Yes _____ No _____

d. List all the owners and officers of the corporation. Each person listed below having an ownership interest of 5% or greater and any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant including officers and members of the board of directors must submit a set of fingerprints and fees unless you answered yes to 7c. If 7c is "Yes", please list the owners below and only submit fingerprints for the Prescription Department Manager or Consultant Pharmacist of Record. If 7c is "Yes" and the prints are on file with DOH or AHCA and available to the Board of Pharmacy, the requirement to submit the prints for this person is met. Also, if the % of Ownership column does not add to 100%, please provide an explanation. *Attach a separate sheet if necessary.*

Owner/Officer-Title	Date of Birth	Mailing Address, City State, Zip Code	% of Ownership
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%

8. Has anyone listed in 7d. had an ownership interest of 5% or more in a pharmacy or any other business permit which was disciplined, suspended, revoked, or closed involuntarily within the past 5 years? *If yes, please provide a signed statement disclosing the reason the entity was closed.*

Yes _____ No _____

8a. Has anyone listed in 7d. had an ownership interest of 5% or more in a pharmacy or any other business permit which was voluntarily relinquished or closed voluntarily within the past 5 years? *If yes, please provide a signed statement disclosing the reason the entity was closed.*

Yes _____ No _____

Pursuant to Section 465.022(5), Florida Statutes, questions 9 – 18 are being asked. If you answer "Yes" to any of the following questions, explain <u>on a separate sheet</u> providing accurate details and submit copies of supporting documentation.
9. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant obtained a permit by misrepresentation or fraud?
Yes _____ No_____
10. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation?
Yes _____ No _____
11. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy?
Yes _____ No_____
12. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud?
Yes_____ No_____
13. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009?
Yes _____ No_____
14. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009?
Yes _____ No _____
15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period?
Yes _____ No _____
16. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application?
Yes _____ No _____

17. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant currently listed on the United States Department of Health Human Services Office of Inspector General's List of Excluded Individuals and Entities? *(If yes, please submit proof.)*

Yes _____ No _____

18. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant 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?

Yes _____ No _____

19. Are you currently registered or permitted in any other states? (*If yes, provide the state, permit type, and permit number for each permit. Attach a separate sheet if necessary.)*

Yes _____ No _____

State	Permit Type	Permit Number

20. Has the applicant, affiliated person, partner, officer, directors, Prescription Department Manager or Consultant Pharmacist of Record ever owned a pharmacy? *(If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy. Attach a separate sheet if necessary.)*

Yes _____ No _____

Individual's Name	Pharmacy Name	State	Status

21. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, affiliated persons, partners, officers, directors, Prescription Department Manager, or Consultant Pharmacist of Record in this state or any other?

Yes _____ No _____

22. Has the applicant, affiliated person, partner, officer, or director ever been convicted of a felony or misdemeanor, excluding minor traffic convictions? You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction.

Yes _____ No _____

23. Does the applicant, affiliated person, partner, officer, or director have any outstanding fines, liens or overpayments assessed by a final order of the department? If yes please answer 23a.

Yes _____ No _____

23a. Does the applicant, affiliated person, partner, officer, or director have a repayment plan approved by the department?

Yes _____ No_____

24. Is the applicant, affiliated persons, partners, officers, or directors, under investigation or prosecution for a crime in any jurisdiction?
Yes _____ No_____
25. Is the applicant, affiliated persons, partners, officers, or directors, under investigation or pending administrative action by the licensing authority of any jurisdiction, including its agencies and subdivisions?
Yes _____ No_____
26. Has the applicant received an FDA Form 483 or Warning Letter following an inspection conducted by the FDA within the last 5 years? If yes, please submit the Form 483 or Warning Letter, any corrective action plan, and supporting documentation demonstrating how the corrective action plan was implemented. Supporting documentation may include but is not limited to pictures, facility diagrams and updated policies and procedures.
Yes _____ No_____

SECTION B. Please complete for Change of Location only.

1. Current Practice Location Address		
City	**State**	**Zip**

E-Mail Address** (see note below)	**Telephone Number**

2. New Practice Location Address		
City	**State**	**Zip**

E-Mail Address** (see note below)	**Telephone Number**

Please provide your existing Pharmacy Permit Number(s):
Please provide your existing Federal DEA Number:
NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.

SECTION C. Please complete for a Change of Ownership only.

1. Are you changing physical locations with this change of ownership?
Yes _____ No _____ *NOTE: If yes, please complete Section B above.*
2. Please provide date when business transaction for the change of ownership will be completed?
Date:
3. Do you have a signed letter from both the buyer and seller which indicates dates that pharmacy permit license should be transferred? *Note: A copy of the signed letter should be provided with your application.*
Yes _____ No _____

SECTION D. Please complete for a Stock Transfer of Ownership Interests only.
1. Please provide the date the transfer of ownership interest took place?
Date:
2. Did your company's FEIN change as a result of the transfer of ownership interest referenced in Section D, question 1 above?
Yes _____ No _____ *NOTE: If yes, please complete Section C above and include the necessary fee.*

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

****

Section 456.013(1), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application, which takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department.

I swear or affirm that the statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations that they deem appropriate and to secure any additional information concerning me, and I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, Board, or any municipal, county, state, or federal governmental agencies or units, and I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other item, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

Under penalty of perjury I have read the foregoing document and that the facts stated in it are true. I recognize that providing false information may result in disciplinary action against my license or criminal penalties.

SIGNATURE _____ DATE_____
(Owner or officer of establishment)

FLORIDA DEPARTMENT OF LAW ENFORCEMENT

NOTICE FOR APPLICANTS SUBMITTING FINGERPRINTS WHERE CRIMINAL RECORD RESULTS WILL BECOME PART OF THE CARE PROVIDER BACKGROUND SCREENING CLEARINGHOUSE

NOTICE OF:

- **SHARING OF CRIMINAL HISTORY RECORD INFORMATION WITH SPECIFIED AGENCIES,**
- **RETENTION OF FINGERPRINTS,**
- **PRIVACY POLICY, AND**
- **RIGHT TO CHALLENGE AN INCORRECT CRIMINAL HISTORY RECORD**

This notice is to inform you that when you submit a set of fingerprints to the Florida Department of Law Enforcement (FDLE) for the purpose of conducting a search for any Florida and national criminal history records that may pertain to you, the results of that search will be returned to the Care Provider Background Screening Clearinghouse. By submitting fingerprints, you are authorizing the dissemination of any state and national criminal history record that may pertain to you to the Specified Agency or Agencies from which you are seeking approval to be employed, licensed, work under contract, or to serve as a volunteer, pursuant to the National Child Protection Act of 1993, as amended, and Section 943.0542, Florida Statutes. "Specified agency" means the Department of Health, the Department of Children and Family Services, the Division of Vocational Rehabilitation within the Department of Education, the Agency for Health Care Administration, the Department of Elder Affairs, the Department of Juvenile Justice, and the Agency for Persons with Disabilities when these agencies are conducting state and national criminal history background screening on persons who provide care for children or persons who are elderly or disabled. The fingerprints submitted will be retained by FDLE and the Clearinghouse will be notified if FDLE receives Florida arrest information on you.

Your Social Security Number (SSN) is needed to keep records accurate because other people may have the same name and birth date. Disclosure of your SSN is imperative for the performance of the Clearinghouse agencies' duties in distinguishing your identity from that of other persons whose identification information may be the same as or similar to yours.
Licensing and employing agencies are allowed to release a copy of the state and national criminal record information to a person who requests a copy of his or her own record if the identification of the record was based on submission of the person's fingerprints. Therefore, if you wish to review your record, you may request that the agency that is screening the record provide you with a copy. After you have reviewed the criminal history record, if you believe it is incomplete or inaccurate, you may conduct a personal review as provided in s. 943.056, F.S., and Rule 11C8.001, F.A.C. If national information is believed to be in error, the FBI should be contacted at 304-625-2000. You can receive any national criminal history record that may pertain to you directly from the FBI, pursuant to 28 CFR Sections 16.30-16.34. You have the right to obtain a prompt determination as to the validity of your challenge before a final decision is made about your status as an employee, volunteer, contractor, or subcontractor.

Until the criminal history background check is completed, you may be denied unsupervised access to children, the elderly, or persons with disabilities.

The FBI's Privacy Statement follows on a separate page and contains additional information.

US Department of Justice, Federal Bureau of Investigation,
Criminal Justice Information Services Division

Privacy Statement

Authority: The FBI's acquisition, preservation and exchange of information requested by this form is generally authorized under 28 U.S.C. 534. Depending on the nature of your application, supplemental authorities include numerous Federal statutes, hundreds of State statutes pursuant to Pub.L.92-544, Presidential executive orders, regulations and/or orders of the Attorney General of the United States, or other authorized authorities. Examples include, but are not limited to: 5 U.S.C. 9101; Pub.L.94-29; Pub.L.101-604; and Executive Orders 10450 and 12968. Providing the requested information is voluntary; however, failure to furnish the information may affect timely completion of approval of your application.

Social Security Account Number (SSAN): Your SSAN is needed to keep records accurate because other people may have the same name and birth date. Pursuant to the Federal Privacy Act of 1974 (5 USC 552a), the requesting agency is responsible for informing you whether disclosure is mandatory or voluntary, by what statutory or other authority your SSAN is solicited, and what uses will be made of it. Executive Order 9397 also asks Federal Agencies to use this number to help identify individuals in agency records.

Principal Purpose: Certain determinations, such as employment, security, licensing and adoption, may be predicated on fingerprint based checks. Your fingerprints and other information contained on (and along with) this form may be submitted to the requesting agency, the agency conducting the application investigation, and/or FBI for the purpose of comparing the submitted information to available records in order to identify other information that may be pertinent to the application. During the processing of this application, and for as long hereafter as my be relevant to the activity for which this application is being submitted, the FBI(may disclose any potentially pertinent information to the requesting agency and/or to the agency conducting the investigation. The FBI may also retain the submitted information in the FBI's permanent collection of fingerprints and related information, where it will be subject to comparisons against other submissions received by the FBI. Depending on the nature of your application, the requesting agency and/or the agency conducting the application investigation may also retain the fingerprints and other submitted information for other authorized purposes of such agency(ies).

Routine Uses: The fingerprints and information reported on this form may be disclosed pursuant to your consent, and may also be disclosed by the FBI without your consent as permitted by the Federal Privacy Act of 1974 (5 USC 552a(b)) and all applicable routine uses as many be published at any time in the Federal Register, including the routine uses for the FBI Fingerprint Identification Records System (Justice, FBI-009) and the FBI's Blanket Routine Uses (Justice/FBI-BRU). Routine uses include, but are not limited to, disclosures to: appropriate governmental authorities responsible for civil or criminal law enforcement counterintelligence, national security or public safety matters to which the information may be relevant; to State and local governmental agencies and nongovernmental entities for application processing as authorized by Federal and State legislation, executive order, or regulation, including employment, security, licensing, and adoption checks; and as otherwise authorized by law , treaty, executive order, regulation, or other lawful authority. If other agencies are involved in processing the application, they may have additional routine uses.

Additional Information: The requesting agency and/or the agency conducting the application investigation will provide you additional information pertinent to the specific circumstances of this application, which may include identification of other authorities, purposes, uses, and consequences of not providing requested information. In addition, any such agency in the Federal Executive Branch has also published notice.

Electronic Fingerprinting

Take this form with you to the Live Scan service provider. Please check the service provider's requirements to see if you need to bring any additional items.

- Background screening results are obtained from the Florida Department of Law Enforcement and the Federal Bureau of Investigation by submitting to a fingerprint scan using the Livescan method;
- You can find a Livescan service provider at: http://www.floridahealth.gov/licensing-and-regulation/background-screening/livescan-service-providers.html
- Failure to submit background screening will delay your application;
- Applicants may use any Livescan service provider approved by the Florida Department of Law Enforcement to submit their background screening to the department;
- If you do not provide the correct Originating Agency Identification (ORI) number to the livescan service provider the Board office will not receive your background screening results;
- You must provide accurate demographic information to the livescan service provider at the time your fingerprints are taken, ***including your Social Security number (SSN)***;
- The ORI number for the Board of Pharmacy is **EDOH4680Z**.
- Typically background screening results submitted through a Livescan service provider are received by the Board within 24-72 hours of being processed.
- If you obtain your Livescan from a service provider who does not capture your photo you may be required to be reprinted by another agency in the future.

Name:_____ SSN#: _____ - ____ - _____

Aliases: _____

Address: _____Apt. Number: _____

City:_____ State_____Zip Code: _____

Date of Birth: _____/_____/_____ Place of Birth: _____
(MM/DD/YYYY)

Weight: _____ Height: _____ Eye Color:_____ Hair Color: _____

Race: _____ Sex: _____
(W-White/Latino(a); B-Black; A-Asian; NA-Native American; U-Unknown) (M=Male; F=Female)

Citizenship: _____

Transaction Control Number (TCN#):_____
(*This will be provided to you by the Livescan Service provider*.)

Keep this form for your records.

Item #1- Prescription Department Manager (PDM) or Consultant Pharmacist of Record (COR) Privacy Statement Acknowledgement

File # (if known):	License # (if applicable):

To: Florida Board of Pharmacy, Post Office Box 6320, Tallahassee, FL 32314-6320
(850) 245-4292- phone * (850) 413-6982 – fax * MQAPharmPDMAffiliate@flhealth.gov

Section A. Prescription Department Manager (PDM) or Consultant Pharmacist of Record (COR) Designation

Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailing Address:		
City	**State**	**Zip**
Incoming PDM / COR Name:		**License#:**
Date Beginning as PDM / COR:	**Incoming PDM / COR Signature**	
PDM / COR Transaction Control Number (TCN) – related to Livescan Fingerprints *(optional, if known)*: ** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs**		
*****Only provide following information if there is an Outgoing PDM or COR at current pharmacy location.*****		
Outgoing PDM / COR Name:		**License#:**
Date Ending as PDM / COR:	**Outgoing PDM/COR Signature** *(optional)*	

Section B. Incoming PDM / COR Privacy Statement Acknowledgement

Note: Acknowledgment should be completed by same person listed in Section A above as Incoming PDM or COR.

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

Date:	Incoming PDM / COR Signature

Item #2- Affiliate/Owner Privacy Statement Acknowledgement

To be completed by EACH Affiliate/Owner listed in the application.

To: **Florida Board of Pharmacy, Post Office Box 6320, Tallahassee, FL 32314-6320**
(850) 245-4292- phone * (850) 413-6982 – fax * MQAPharmPDMAffiliate@flhealth.gov

From:

Affiliate / Owner Name:		**File # (required):**
Applicant Name:		
Affiliate/Owner Mailing Address:		
City	**State**	**Zip**
Affiliate/Owner Email ** (see note below)	**Affiliate/Owner Telephone Number**	
Affiliate/Owner Transaction Control Number (TCN) *(optional, if known)***:** ** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs**		
NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.		

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

_____ _____

Affiliate/Owner Signature (Required) **Date (of signature)**

Item #3 - Policy and Procedure Questions

All Applicants Must Complete the Following Questions.

The Prescription Department Manager or Consultant Pharmacist of Record is responsible for developing and maintaining a current policy and procedure manual. A copy of the permittee's policy and procedure manual as provided herein shall accompany the permit application. The original policy and procedure manual shall be kept within the pharmacy and shall be available for inspection by the Department of Health. The Board office will approve the policy and procedure manual based upon answers submitted for the following questions, where applicable, by using excerpts or summaries from the policy and procedure manual.

List the following:
Firm Name:
Doing business as (d/b/a):
Telephone number:
Address:
Permit number:

1) Explain the practice setting of the proposed facility.

2) What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice.

3) What are the experience, qualifications, special education, and/or training of the compounding pharmacist? Please provide a resume.

4) What is the ratio of supportive personnel to each pharmacist? How will the supportive personnel be utilized? Include a job description for any such supportive personnel.

5) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.

6) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how products are protected from extreme temperature conditions.

7) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.

8) What are the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions? If this type of dispensing will not be performed, please state so accordingly.

9) What is the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.

10) What is the procedure for the annual review and updating of the policy and procedure manual?

11) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink, and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.

12) Include a sample copy of a patient profile.

13) What aseptic techniques are utilized?

14) Describe the Quality Assurance Program.

15) Describe with detail the policy and procedure for patient education, including the personnel involved.

16) What are the policy and procedures for handling waste and returns?

17) Describe the type of certified laminar flow hood(s) to be used and the frequency of certification.

18) Describe the refrigerator/freezer to be used.

19) Describe appropriate waste containers for:

    a. Used needles and syringes.

    b. Cytotoxic waste including disposable apparel used in preparation.

20) Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.

21) How will you utilize the following reference material to ensure patient safety?

    a. Chapters 465 and 893, F.S., and Rule Title 64B16, F.A.C.

    b. Authoritative Therapeutic Reference.

    c. Handbook of Injectable Drugs by American Society of Health-System Pharmacists.

22) What steps will be taken to ensure safe handling of cytotoxic drugs related to the Occupational Safety and Health Administration guidelines.

23) Describe the individual responsibilities of the Special- Parenteral/Enteral Extended Scope Permit and the supplied institutional pharmacy permits, if applicable.

24) What are the protocols for the maintenance of patient profiles and the offer to counsel if dispensing to outpatients?

25) Describe the system for the maintenance of compounding records.

26) What percentage of your business is related to sterile compounding?

27) Describe the types of sterile products you will compound.

28) Are the products you will be compounding:

    a. be pursuant to a patient-specific prescription

b. be prepared in bulk (compounding multiple doses from a single source or batch)

c. be prepared in bulk for office use.

30) Will your pharmacy ship sterile compounded products to other states?

If yes, provide a list of states to which your pharmacy will ship.

31) Provide the total number of pharmacy staff and indicate how many will be preparing sterile products;

a. Pharmacists

b. Pharmacy Interns

c. Pharmacy Technicians

32) Provide the number of clean rooms in your pharmacy.

33) Provide the number of laminar flow hoods in your pharmacy.

34) When was the last time your clean room was certified by an independent contractor for Controlled Environment Testing Association CAG 003-2006? Provide a copy of the most recent inspection and the name and address of the independent contractor.

35) When was the last time your laminar flow hood was certified by an independent contractor for National Sanitation Foundation Standard 49? Provide a copy of the most recent inspection and the name and address of the independent contractor.

36) Has your company ever recalled a sterile compounded product due to a compounding error? If yes, list the name (s) of the drug and the reason for the recall.

Prescription Department Manager (PDM) Designation and Privacy Statement Acknowledgement

Section 465.022, Florida Statutes, requires the permittee and newly designated Prescription Department Manager to notify the Board of Pharmacy within ten (10) days of any change.

Pursuant to section 465.022, F.S., a Prescription Department Manger is responsible for maintaining all drug records, providing for the security of the prescription department and following such other rules as relate to the practice of the profession of pharmacy.

File #: (if known)	**License#:** (required)
— — — — —	**PH**

Section A. Prescription Department Manager (PDM) Designation

Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailing Address:		
City	**State**	**Zip**
Incoming PDM Name:		**License#:**
		PS
Date Beginning as PDM:	**Incoming PDM Signature**	
PDM Transaction Control Number (TCN) – related to Livescan Fingerprints *(optional, if known)*: ** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs**		
****OPTIONAL: Only provide the following information if there is an Outgoing PDM at current pharmacy****		
Outgoing PDM Name:		**License#:**
		PS
Date Ending as PDM:	**Outgoing PDM Signature** *(optional)*	

Section B. Incoming PDM Privacy Statement Acknowledgement

Note: Acknowledgment should be completed by same person listed in Section A above as Incoming PDM.

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

Date:	**Incoming PDM Signature**

SEND TO: Florida Board of Pharmacy, Post Office Box 6320, Tallahassee, FL 32314-6320
(850) 245-4292 (phone) * (850) 413-6982 (fax) * *MQAPharmPDMAffiliate@flhealth.gov* - email

Consultant Pharmacist of Record (COR) Designation and Privacy Statement Acknowledgement

Section 465.022, Florida Statutes, requires the permittee and newly designated Consultant Pharmacist of Record (COR) to notify the Board of Pharmacy within ten (10) days of any change.

Rule 64B16-28.501, Florida Administrative Code, requires each facility holding a Class I, Class II, or a Modified Class II Institutional Pharmacy or Special Assisted Living Facility Permit to designate a COR to ensure compliance with the laws and rules governing the permit. The Board Office shall be notified in writing within ten (10) days of any change in the COR.

File #: (if known)	**License#:** (required)
— — — — —	**PH**

Section A. Consultant Pharmacist of Record (COR) Designation

Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailing Address:		
City	**State**	**Zip**
Incoming COR Name:		**License#:**
		PU
Date Beginning as COR:	**Incoming COR Signature**	
COR Transaction Control Number (TCN) – related to Livescan Fingerprints:*(optional, if known)***:** ** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs**		
****OPTIONAL: Only provide following information if there is an Outgoing COR at current pharmacy****		
Outgoing COR Name:		**License#:**
		PU
Date Ending as COR:	**Outgoing COR Signature** *(optional)*	

Section B. Incoming COR Privacy Statement Acknowledgement

Note: Acknowledgment should be completed by same person listed in Section A above as Incoming COR.

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

Date:	**Incoming COR Signature**

SEND TO: Florida Board of Pharmacy, Post Office Box 6320, Tallahassee, FL 32314-6320
(850) 245-4292 (phone) * (850) 413-6982 (fax) * *MQAPharmPDMAffiliate@flhealth.gov* - email

TAB #9

64B16-30.001 Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances.

(1) The board sets forth below a range of disciplinary guidelines from which disciplinary penalties will be imposed upon licensees guilty of violating Chapter 465 or Section 828.055, F.S. The purpose of the disciplinary guidelines is to give notice to licensees of the range of penalties which will normally be imposed upon violations of particular provisions of Chapter 465 or Section 828.055, F.S. The term license means any permit, registration, certificate, or license, including a provisional license, issued by the Department. Penalty ranges are shown as minimum and maximum guidelines as well as for first time single count violations and for multiple or repeated violations of the same provision of Chapter 465, F.S., or the rules promulgated thereunder. If an actual range of penalties is not provided, the listed penalty shall be the guideline penalty for the violation(s) unless aggravating or mitigating factors are shown. All penalties at the upper range of the sanctions set forth in the guidelines, e.g., suspension, revocation, etc., include lesser penalties, e.g., fine, continuing education, probation, or reprimand, which may be included in the final penalty at the board's discretion. Probation may be subject to conditions, including restriction from practice in certain settings, restricting the licensee to working only under designated conditions or in certain settings, requiring continuing or remedial education, or any other restriction found to be necessary for the protection of the public health, safety, and welfare. In addition to any other discipline imposed under these guidelines, the board shall assess costs relating to the investigation and prosecution of the case.

(2) The following disciplinary guidelines shall be followed by the board in imposing disciplinary penalties upon licensees and permittees for violation of the below mentioned statutes and rules. For the purposes of this rule, the descriptions of the violations are abbreviated and the full statute or rule cited should be consulted to determine the prohibited conduct.

VIOLATION	PENALTY RANGE MINIMUM, INCLUDING FIRST TIME OR SINGLE COUNT VIOLATIONS	MAXIMUM, INCLUDING MULTIPLE OR REPEATED VIOLATIONS OF THE SAME PROVISION
(a) Obtaining a license or permit by misrepresentation, fraud, or error. (Section 465.016(1)(a), F.S.); (Section 465.023(1)(a), F.S.)		
1. By negligent misrepresentation on original application or renewal.	$1,000 fine and 12 hour Laws and Rules course or MPJE and 3 hour ethics course.	$5,000 fine and one (1) year suspension, to Revocation.
2. By fraudulent misrepresentation on original application or renewal.	$10,000 fine for each count and Revocation.	$10,000 fine for each count and Revocation.
3. By error of the Department or Board on original application or renewal.	Revocation.	Revocation.
(b) Procuring or attempting to procure a license or permit for another person by false representation. (Section 465.016(1)(b), F.S.); (Section 465.023(1)(b), F.S.)	$10,000 fine for each count and Revocation.	$10,000 fine for each count and Revocation.
(c) Permitting any unlicensed persons, including owner or operator of pharmacy, to practice pharmacy. (Section 465.016(1)(c), F.S.)	$2,500 fine and 12 hour Laws & Rules course or Multistate Pharmacy Jurisprudence Exam (MPJE).	$5,000 to $10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
(d) Being unfit or incompetent to practice pharmacy by reason of habitual intoxication, medicinal drug abuse, or physical or mental condition that threatens public safety.	$250 fine, indefinite suspension with PRN review and board appearance.	Revocation.

(Sections 465.016(1)(d), (m), F.S.)		
(e) Violating laws governing the practice of pharmacy. (Section 465.016(1)(e), F.S.); (Section 465.023(1)(c), F.S.)		
1. Chapter 465, F.S.:		
a. Failure to supervise registered pharmacy technician. (Section 465.014, F.S.)	$250 fine and one (1) year probation and 12 hour Laws and Rules course or MPJE.	$1,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
b. Operating a pharmacy that is not registered. (Section 465.015(1)(a), F.S.)	$500 fine per month to maximum of $5,000 (penalty will require permittee to renew permit or cease practice).	$10,000 fine (penalty will require permittee to renew permit or cease practice), to Revocation.
c. Operating a pharmacy where an unlicensed, unregistered, or unsupervised person practices pharmacy. (Section 465.015(1)(b), F.S.)	$5,000 fine and one (1) year probation.	$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
d. Making a false or fraudulent statement to the board. (Section 465.015(2)(a), F.S.)	$10,000 fine.	$10,000 fine and Revocation.
e. Practicing pharmacy as an inactive licensee. (Section 465.015(2)(b), F.S.)	Fine based on length of time in practice while inactive; $500 fine per month.	$10,000 fine and two (2) years suspension, to Revocation.
f. Selling or dispensing drugs without a prescription. (Section 465.015(2)(c), F.S.)		
(I) Non-scheduled legend drugs.	$1,500 fine.	$5,000 fine and one (1) year probation, to Revocation.
(II) Scheduled (controlled substances) legend drugs.	$5,000 fine and (1) year probation.	$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
g. Selling samples or complimentary drugs. (Section 465.015(2)(d), F.S.)		
(I) Non-scheduled legend drugs.	$1,500 fine and (1) year probation.	$5,000 fine and one (1) year probation, to Revocation.
(II) Scheduled (controlled substances) legend drugs.	$5,000 fine and one (1) year probation.	$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
h. Failure to notify the board of, or failure to have, a prescription department manager or a supervising, a responsible, or a consultant pharmacist. (Section 465.018, .019, .0193, .0196, or .0197, F.S. and 465.022(10), (11), F.S.)		
(I) Failure to notify. (Section 465.018, F.S.)	Fine based on length of time prior to notifying board. $500 per month.	$7,500 maximum (penalty requires notification or ceasing practice).

(II) Failure to have prescription department manager or a supervising, a responsible, or a consultant pharmacist of record.	Fine based on length of time practicing without designated pharmacist, $750 fine per month and one (1) year probation.	$2,000 fine per month, to Revocation.
i. Failure to comply with substitution of legend drug requirements. (Sections 465.025(2), (3), (4), F.S.)	$500 fine and 12 hour Laws & Rules course or MPJE.	$2,500 fine, 12 hour Laws & Rules course or MPJE, and one (1) year probation.
j. Failure to follow negative formulary requirements. (Section 465.025(6), F.S.); (Rule 64B16-27.500, F.A.C.)	$1,000 fine and 12 hour Laws & Rules course or MPJE.	$2,500 fine, 12 hour Laws & Rules course or MPJE, and one (1) year probation.
k. Failure to follow emergency prescription requirements. (Section 465.0275, F.S.)	$500 fine.	$1,000 fine and one (1) year probation.
l. Engage in prohibited rebate scheme. (Section 465.185, F.S.)	$1,500 fine and 12 hour Laws & Rules course or MPJE.	$5,000 fine, 12 hour Laws & Rules course or MPJE, and one (1) year probation, to Revocation.
m. Failure to comply with pharmacist dispensing requirements. (Section 465.186, F.S.)		
(I) Failure to follow procedure, but dispense drug appearing on formulary. (Section 465.186(3), F.S.); (Rule 64B16-27.210, F.A.C.)	$500 fine.	$1000 fine and one (1) year probation to suspension of right to dispense.
(II) Dispensing drug not on the formulary. (Section 465.186(2), F.S.); (Rules 64B16-27.220, .230, F.A.C.)	$1,500 fine and 12 hour Laws & Rules course or MPJE.	$5,000 fine and one (1) year probation to $10,000 fine and Revocation.
n. Failure to timely report fraudulent obtaining or attempted obtaining of controlled substances from a pharmacy. (Section 465.015(3), F.S.)		
(I) Failure to timely report.	$500 fine.	$1,000 fine and one (1) year probation.
(II) Failure to report.	$1,000 fine and one (1) year probation.	$5,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
o. Violation of facsimile prescription requirements. (Section 465.035, F.S.)	$500 fine.	$1,000 fine and one (1) year probation.
p. Violation of requirements for administration of vaccines and epinephrine auto injection. (Section 465.189, F.S.); (Section 465.009(6)(a), F.S.)		
(I) Failure to enter into a written protocol.	$2,500 fine and 12 hour Laws & Rules course or MPJE.	$5,000 fine and one (1) year probation.
(II) Failure to maintain proper insurance.	$500 fine and suspension until insured.	$1,000 fine, suspension until insured, followed by one (1) year probation.

(III) Failure to maintain and make available patient records.	$500 fine.	$1,000 fine and one (1) year probation.
(IV) Uncertified administration of vaccine.	$5,000 fine and suspension until certified.	$7,500 fine and suspension until certified, followed by one (1) year probation, to Revocation.
(V) Failure to submit copy of protocol or written agreement to the board.	$500 fine.	$1,000 fine and one (1) year probation.
2. Chapter 499, F.S.:		
a. Adulteration or misbranding of a drug. (Sections 499.005(2), (3), F.S.); (Section 499.006, F.S.); (Section 499.007, F.S.)		
(I) Adulteration of a drug. (Section 499.005(2), F.S.); (Section 499.006, F.S.)	$1,000 fine and 12 hour Laws & Rules course or MPJE.	$5,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
(II) Receipt or delivery of any drug that is adulterated or misbranded. (Section 499.005(3), F.S.)	$1,000 fine and 12 hour Laws & Rules course or MPJE.	$5,000 fine and one (1) year probation, to Revocation.
(III) Incomplete or inaccurate labeling. (Section 499.007, F.S.); (Rule 64B16-28.108, F.A.C.)	$250 fine and 12 hour Laws & Rules course or MPJE.	$2,500 fine and one (1) year probation.
(IV) Fraudulent misbranding of legend drugs. (Section 499.007, F.S.)	$10,000 fine and one (1) year suspension followed by one (1) year probation.	$10,000 fine and two (2) years suspension followed by two (2) years probation, to Revocation.
b. Failure to obtain a permit or registration, or operating without a valid permit when it is required. (Section 499.005(22), F.S.)	$500 fine per month to maximum of $5,000 (penalty will require permittee to renew permit or cease practice).	$10,000 fine (penalty will require permittee to renew permit or cease practice), to Revocation.
c. Prescription drug pedigree violations. (Section 499.005(28), F.S.); (Section 499.0051, F.S.)	$500 fine and 12 hour Laws & Rules course or MPJE.	$5,000 fine and one (1) year probation, to Revocation.
d. Recordkeeping requirement. (Section 499.0121, F.S.); (Sections 499.005(18), (19), F.S.)	$500 fine and 12 hour Laws & Rules course or MPJE.	$5,000 fine and one (1) year probation, to Revocation.
e. Storage of drugs. (Section 499.0121, F.S.)	$500 fine and 12 hour Laws & Rules course or MPJE.	$5,000 fine and one (1) year probation, to Revocation.
3. Chapter 893, F.S. (Controlled Substances):		
a. Filling a written or oral prescription for controlled substances that does not meet the requirements of Chapter 893, F.S. (Sections 893.04(1)(a), (b), (c), F.S.)	$1,500 fine.	$5,000 fine and one (1) year probation, to Revocation.
b. Failing to retain prescription records for two (2) years. (Section 893.04(1)(d), F.S.)	$1,000 fine.	$5,000 fine and one (1) year probation, to Revocation.
c. Failing to appropriately label. (Section 893.04(1)(e), F.S.)	$250 fine and 12 hour Laws & Rules course or MPJE.	$2,500 fine and (1) year probation.

d. Dispensing a Schedule II drug inappropriately with a non-written prescription. (Section 893.04(1)(f), F.S.)	$5,000 fine and one (1) year probation.	$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
e. Inappropriate refilling of Schedule III, IV, or V drugs. (Section 893.04(1)(g), F.S.); (Section 893.04(2)(e), F.S.)	$1,750 fine and one (1) year probation.	$5,000 fine and one (1) year suspension.
f. Receiving controlled substances without an appropriate order form. (Section 893.06(1), F.S.)	$2,500 fine.	$5,000 fine and one (1) year probation, to Revocation.
g. Possession of controlled substances outside the regular course of business, occupation, profession, employment, or duty. (Section 893.06(2), F.S.)	$2,500 fine and one (1) year probation.	$5,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
h. Failure to take a biennial inventory. (Sections 893.07(1)(a), (2), (3), (4), (5), F.S.)	$1,000 fine.	$2,500 fine and one (1) year probation.
i. Failure to maintain a complete and accurate record of controlled substances. (Sections 893.07(1)(b), (2), (3), (4), (5), F.S.)	$1,000 fine and one (1) year probation.	$5,000 fine and two (2) years probation, to Revocation.
j. Dispensing Schedule V controlled substances in other than good faith. (Section 893.08(3)(b), F.S.)	$5,000 fine and one (1) year probation.	$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
k. Inappropriate selling of Schedule V controlled substance. (Section 893.08(3)(c), F.S.)	$1,500 fine and one (1) year probation.	$5,000 fine and one (1) year suspension.
l. Unlawful possession of controlled substance. (Section 893.13, F.S.)	$5,000 fine and two (2) years probation.	$10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
4. Violation of Federal Drug Abuse Act 21 U.S.C. 821 et seq. (Manufacture, Distribution, and Dispensing of Controlled Substances.)	$500 fine and one (1) year probation.	$2,000 fine up to $10,000 and one (1) year suspension followed by two (2) years probation, to Revocation.
5. Violation of Food and Drug Act 21 U.S.C. 301 – 392.	$2,500 fine and one (1) year suspension.	$7,500 fine and two (2) years suspension followed by two (2) years probation, to Revocation.
(f) Criminal conviction related to Pharmacy. (Section 465.016(1)(f), F.S.); (Section 465.023(1)(d), F.S.)		
1. Misdemeanor.	$1,000 fine.	$5,000 fine, one (1) year probation, to Revocation.
2. Felony.	$5,000 fine and one (1) year suspension followed by two (2) years probation.	$10,000 fine and two (2) years suspension followed by three (3) years probation, to Revocation.
(g) Using in the compounding of a	$250 fine without ingestion or	$500 fine without ingestion or harm,

prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed, except as authorized in Section 465.019(6), F.S. or Section 465.025, F.S. (Section 465.016(1)(g), F.S.); or, compounding, dispensing or distributing legend drugs outside professional practice of pharmacy. (Section 465.016(1)(i), F.S.)	harm, to $500 with ingestion, and complete approved CE course in the prevention of medication errors of no less than eight (8) hours.	to $1,000 with ingestion, complete approved CE course in the prevention of medication errors of no less than eight (8) hours, and two (2) years probation, to Revocation.
(h) Filing a false report or failing to file a report required by law. (Section 465.016(1)(j), F.S.)		
1. Knowing violation.	$10,000 fine and one (1) year probation.	$10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
2. Negligent violation.	Reprimand.	One (1) year probation and $1,000 fine.
(i) Failure to make prescription price information available. (Section 465.016(1)(k), F.S.)	$250 fine and 12 hour Laws & Rules course or MPJE.	$1,000 fine and one (1) year probation.
(j) Improperly placing returned drugs into the stock of a pharmacy. (Section 465.016(1)(l), F.S.)	$1,500 fine.	$3,000 fine and one (1) year probation.
(k) Violating a rule or order of the Board or Department. (Section 465.016(1)(n), F.S.)		
1. Rules of Board of Pharmacy.		
a. Rules 64B16-28.101 to 64B16-28.1035, F.A.C. Rule 64B16-27.100, F.A.C. Rule 64B16-28.109, F.A.C. Rule 64B16-27.103, F.A.C. Rule 64B16-27.104, F.A.C. Rule 64B16-26.400, F.A.C. Rule 64B16-26.2032 F.A.C. Rule 64B16-28.1081, F.A.C. Rule 64B16-27.105, F.A.C. Rule 64B16-27.211, F.A.C. Rule 64B16-28.113, F.A.C. Rule 64B16-28.2021, F.A.C. Rule 64B16-28.603, F.A.C.	$500 fine and 12 hour Laws & Rules course or MPJE.	One (1) year probation and $2,000 fine.
b. Sink and running water, sufficient space, refrigeration, sanitation, equipment. (Rule 64B16-28.102, F.A.C.)	Suspension until compliance.	$2,000 fine and Revocation.
c. Knowingly purchase, sell, possess, or distribute counterfeit drugs.	$5,000 fine, one (1) year suspension followed by one (1)	$10,000 fine and Revocation.

(Rule 64B16-27.101, F.A.C.)	year probation to Revocation.	
d. Failure to remove outdated pharmaceuticals, or dispensing of same. (Rule 64B16-28.110, F.A.C.)	$500 fine for possession, $1,000 fine for dispensing.	$2,500 – $5,000 fine and two (2) years probation, to Revocation.
e. Violation of destruction of controlled substances. (Rules 64B16-28.301 and .303 F.A.C.)	$500 fine and 12 hour Laws & Rules course or MPJE.	$5,000 fine and two (2) years probation, to Revocation.
f. Serving as consultant pharmacist without being licensed as a consultant pharmacist. (Rule 64B16-26.300, F.A.C.)	$500 per month up to $5,000 fine. (fine based upon the length of time the person is serving as a consultant without being licensed as a consultant pharmacist.)	$7,500 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
g. Violation of requirements for records maintained in a data processing system. (Rule 64B16-28.140, F.A.C.)	$1,000 fine and 12 hour Laws & Rules course or MPJE plus 8 hours CE course in record keeping.	$5,000 fine and two (2) years probation, to Revocation.
h. Failure to properly store legend drugs. (Rule 64B16-28.120, F.A.C.)	$1,000 fine and 12 hour Laws & Rules course or MPJE.	$5,000 fine and one (1) year probation, to Revocation.
i. Practicing nuclear pharmacy without being licensed as a nuclear pharmacist. (Rule 64B16-26.303, F.A.C.)	$500 per month up to $5,000 fine. (fine based upon the length of time the person is practicing without being licensed as a nuclear pharmacist.)	$10,000 fine and one (1) year suspension, to Revocation.
j. Failure to follow technical requirements for nuclear pharmacy. (Rules 64B16-28.901 and .902, F.A.C.)	One (1) year probation and $1,000 fine, to $2,500 fine and six (6) months suspension followed by one (1) year probation.	$5,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
k. Failure to properly transfer prescription files and medicinal drugs when closing pharmacy. (Rules 64B16-28.202 and .203, F.A.C.)	Revocation.	Revocation.
l. Failure to complete the required continuing education during the biennial licensure period. (Rule 64B16-26.103, F.A.C.)		
(I) Failure to complete less than ten (10) hours.	$500 fine and suspension until completed.	$1,500 fine and suspension until completed.
(II) Failure to complete ten (10) or more hours.	$1,000 fine. In addition, licensees shall take two (2) additional hours of continuing education for each of the continuing education deficiencies. Said hours shall not count for continuing education renewal requirements for the next biennium.	$2,500 fine and suspension until deficiency and penalty units are completed. In addition, licensees shall take two (2) additional hours of continuing education for each of the continuing education deficiencies. Said hours shall not count for continuing education renewal requirements for the next biennium.
m. Failure to retain continuing education records.	$250 fine.	$1,500 fine and suspension of license until undocumented courses are

(Rule 64B16-26.603, F.A.C.)		completed and documentation is submitted to the Department.
n. Failure to practice in accordance with established practice standards. (Rules 64B16-27.1001 and .104, F.A.C.)		
(I) Pharmacist.	$500 to $1,000 fine and 12 hour Laws & Rules course or MPJE to one (1) year probation.	$2,500 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
(II) Pharmacy Intern.	$250 to $500 fine and 12 hour Laws & Rules course or MPJE.	$1,000 to $5,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
(III) Permittee.	$500 to $1,000 fine and 12 hour Laws & Rules course or MPJE to one (1) year probation.	$2,500 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
o. Failure to have or maintain current policies and procedures for automated pharmacy system or central fill pharmacy. (Rules 64B16-28.141 and.450, F.A.C.)	$500 to $1000 fine and 12 hour Laws & Rules course or MPJE.	$2,500 to $5,000 fine and suspension of license/permit until current policies and procedures are in place, to Revocation.
p. Failure to have or maintain standards for an institutional pharmacy. (Rules 64B16-28.602, .6021, .605, .606, .702, F.A.C.)	$500 fine and 12 hour Laws & Rules course or MJPE.	$2,500 to $5,000 fine and suspension of license until policies and procedures are in place, to Revocation.
q. Failure to have or maintain standards for a special pharmacy. (Rules 64B16-28.800, .810, .820, .840, .850, .860, .870, F.A.C.)	$500 fine and 12 hour Laws & Rules course or MJPE.	$2,500 to $5,000 fine and suspension of license until policies and procedures are in place, to Revocation.
r. Failure to maintain standards for animal control shelters. (Rule Chapter 64B16-29, F.A.C.)	$500 fine and 12 hour Laws & Rules course or MJPE.	$2,500 to $5,000 fine and suspension of license until policies and procedures are in place, to Revocation.
s. Failure to comply with Board's rule on patient counseling. (Rules 64B16-27.800, .810, .820, F.A.C.)	$250 fine without ingestion or harm, to $500 with ingestion, and complete approved CE course in the prevention of medication errors of no less than eight (8) hours.	$500 fine without ingestion or harm, to $1,000 with ingestion, complete approved CE course in the prevention of medication errors of no less than eight (8) hours, and two (2) years probation, to Revocation.
t. Standards of practice for compounding CSPs. (Rules 64B16-27.700 and .797, F.A.C.)		
(I) No harm.	$500 fine, 12 hour Laws & Rules course, and course governing sterile compounds, to $2,000 fine and one (1) year probation.	$2,500 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
(II) Harm.	$2,000 fine, one (1) year probation, and 12 hour Laws & Rules course, to Revocation.	Revocation.
2. Violation of orders of the Board or Department.	$2,500 fine and one (1) year probation, to suspension until	$5,000 fine and one (1) year probation, to suspension until

	compliance with order.	compliance with order, to Revocation.
(l) License disciplined by another jurisdiction for an offense that would constitute a violation of this chapter. (Section 465.016(1)(h), F.S.); (Section 465.023(1)(e), F.S.)	Same penalty as imposed in other jurisdiction or as closely as possible to penalties set forth in Florida Statutes.	Same penalty as imposed in other jurisdiction or as closely as possible to penalties set forth in Florida Statutes to $10,000 fine and Revocation.
(m) Failing to report to the Department any Chapter 458 or 459, F.S., licensee violation. (Section 465.016(1)(o), F.S.)	$500 fine and 12 hour Laws & Rules course or MJPE.	$1,500 fine and 12 hour Laws & Rules course or MJPE.
(n) Abandoning or allowing permit to become null and void after notice of disciplinary proceedings. (Section 465.018(3), F.S.)	Revocation.	Revocation.
(o) Failing to notify the Board of commencement or cessation of practice due to discipline in another jurisdiction. (Section 465.016(1)(p), F.S.)	$500 fine and 12 hour Laws & Rules course or MJPE	$2,000 fine and two (2) years probation.
(p) Using or releasing patient records improperly. (Section 465.016(1)(q), F.S.)	$1,000 fine and 12 hour Laws & Rules course or MJPE.	$2,500 fine and one (1) year probation.
(q) Knowingly, or with reason to believe, dispensing based on purported prescription where patient-prescriber relationship is invalid. (Section 465.016(1)(s), F.S.); (Section 465.023(1)(h), F.S.)		
(I) Reason to believe.	$2,000 fine, 12 hour Laws & Rules course or MJPE, and one (1) year probation.	$2,500 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
(II) Knowingly.	Revocation.	Revocation.
(r) Committing an error or omission during prescription drug processing. (Section 465.016(1)(t), F.S.)	$250 fine without ingestion or harm, to $500 with ingestion, and complete approved CE course in the prevention of medication errors of no less than eight (8) hours.	$500 fine without ingestion or harm, to $1,000 with ingestion, complete approved CE course in the prevention of medication errors of no less than eight (8) hours, and two (2) years probation, to Revocation.
(s) Guilty of a felony involving moral turpitude. (Section 465.023(1)(d), F.S.)	$1,000 fine and 12 hour Laws & Rules course or MJPE.	$5,000 fine and one (1) year probation, to Revocation.
(t) Guilty of a crime related to health care fraud. (Section 465.023(1)(g), F.S.)	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license.	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license.
(u) Violating Section 456.072, F.S. (Section 465.016(1)(r), F.S.)		
1. Making misleading, deceptive, or fraudulent representation in or related to the practice of the licensee's profession.	$10,000 fine and one (1) year probation.	Revocation, and a fine of $10,000.

(Section 456.072(1)(a), F.S.)		
2. Intentionally violating any rule adopted by the Board or the Department. (Section 456.072(1)(b), F.S.)	$2,500 fine and two (2) years probation.	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
3. Being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession. (Section 456.072(1)(c), F.S.)		
a. Misdemeanor.	$1,000 fine and suspension until compliant.	$2,500 fine and suspension until compliant, followed by one (1) year probation, to Revocation.
b. Felony.	$3,000 fine and one (1) year probation.	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
4. Failing to comply with the educational course requirements for human immunodeficiency virus and acquired immune deficiency syndrome, or medical errors. (Section 456.072(1)(e), F.S.) (Rules 64B16-26.103(1)(c), (4)(e), F.A.C.)	$500 fine.	$1,000 fine.
5. Having a license or the authority to practice the regulated profession revoked, suspended, or otherwise acted against, including the denial of licensure, by the licensing authority of any jurisdiction, including its agencies or subdivisions, for a violation that would constitute a violation under Florida law. The licensing authority's acceptance of a relinquishment of licensure, stipulation, consent order, or other settlement, offered in response to or in anticipation of the filing of charges against the license, shall be construed as action against the license. (Section 456.072(1)(f), F.S.)	Same penalty as imposed in other jurisdiction or as closely as possible to penalties for similar violation.	Same penalty as imposed in other jurisdiction or as closely as possible to penalties for similar violation, to $10,000 fine and Revocation.
6. Having been found liable in a civil proceeding for knowingly filing a false report or complaint with the Department against another licensee. (Section 456.072(1)(g), F.S.)	$3,000 fine.	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
7. Attempting to obtain, obtaining, or renewing a license to practice a	$10,000 fine and Revocation or denial of license application.	$10,000 fine and Revocation or denial of license application.

profession by bribery, by fraudulent misrepresentation, or through an error of the Department or the Board. (Section 456.072(1)(h), F.S.)		
8. Except as provided in Section 465.016, F.S., failing to report to the Department any person who the licensee knows is in violation of this part, the chapter regulating the alleged violator, or the rules of the Department or the Board. (Section 456.072(1)(i), F.S.)	$500 fine and 12 hour Laws & Rules course or MJPE.	$1,500 fine and 12 hours Laws & Rules or MJPE, to one (1) year suspension or Revocation.
9. Aiding, assisting, procuring, employing, or advising any unlicensed person or entity to practice a profession contrary to this part, the chapter regulating the profession, or the rules of the Department or the Board. (Section 456.072(1)(j), F.S.)	$2,000 fine and 12 hour Laws & Rules course or MJPE, to one (1) year probation.	$2,500 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
10. Failing to perform any statutory or legal obligation placed upon a licensee, including failure to repay student loans or perform scholarship service obligations. (Section 456.072(1)(k), F.S.)		
a. Generally.	$2,000 fine.	$2,500 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
b. Student loans or scholarship service.	The minimum disciplinary action imposed shall be a suspension of the license until new payment terms are agreed upon or the scholarship obligation is resumed, followed by probation for the duration of the student loan or remaining scholarship obligation period, and a fine equal to 10 percent of the defaulted loan amount.	Suspension of the license until new payment terms are agreed upon or the scholarship obligation is resumed, followed by probation for the duration of the student loan or remaining scholarship obligation period, and a fine equal to 10 percent of the defaulted loan amount, to Revocation with a minimum total fine of $10,000.
11. Making or filing a report which the licensee knows to be false, intentionally or negligently failing to file a report or record required by state or federal law, or willfully impeding or obstructing another person to do so. Such reports or records shall include only those that are signed in the capacity of a licensee. (Section 456.072(1)(l), F.S.)		
a. Knowingly filing a false report or	$10,000 fine and two (2) years	$10,000 fine and one (1) year

willful obstruction.	probation.	suspension followed by two (2) years probation, to Revocation.
b. Negligently failing to file a report or record.	$2,500 fine.	$5,000 fine and one (1) year probation, to Revocation.
12. Making deceptive, untrue, or fraudulent representations in or related to the practice of a profession or employing a trick or a scheme in or related to the practice of a profession. (Section 456.072(1)(m), F.S.)	$10,000 fine and two (2) years probation.	$10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
13. Exercising influence on the patient or client for the purpose of financial gain of the licensee or a third party. (Section 456.072(1)(n), F.S.)	$3,000 fine and two (2) years probation.	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
14. Practicing or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities the licensee knows, or has reason to know, the licensee is not competent to perform. (Section 456.072(1)(o), F.S.)	$2,000 fine and two (2) years probation.	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
15. Delegating or contracting for the performance of professional responsibilities by a person when the licensee delegating or contracting for performance of such responsibilities knows, or has reason to know, such person is not qualified by training, experience, and authorization when required to perform them. (Section 456.072(1)(p), F.S.)	$2,000 fine and two (2) years probation.	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
16. Violating any provision of Chapter 456, F.S., the applicable professional practice act, a rule of the Department or the Board, or a lawful order of the Department or the Board, or failing to comply with a lawfully issued subpoena of the Department. (Section 456.072(1)(dd), F.S.); (Section 456.072(1)(q), F.S.)	$1,000 fine and 12 hour Laws & Rules course or MPJE, to one (1) year probation.	$5,000 to $10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
17. Improperly interfering with an investigation or inspection authorized by statute, or with any disciplinary proceeding. (Section 456.072(1)(r), F.S.)	$2,500 fine and two (2) years probation.	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
18. Engaging or attempting to engage in sexual misconduct as defined and prohibited in Section 456.063(1), F.S. (Section 456.072(1)(v), F.S.)	$10,000 fine and Revocation.	$10,000 fine and Revocation.

19. Being unable to practice with reasonable skill and safety by reason of illness or use of alcohol, drugs, narcotics, chemicals, or as a result of any mental or physical condition (board has authority to issue order to compel examination). (Section 456.072(1)(z), F.S.)	$500 fine, suspension until safe to practice with reasonable skill and safety, and appearance before the board.	$2,500 fine and Revocation.
20. Failing to report to the Board, or the Department if there is no Board, in writing within 30 days after the licensee has been convicted or found guilty of, or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction. (Section 456.072(1)(x), F.S.)	$1,000 fine.	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
21. Testing positive for any drug, as defined in Section 112.0455, F.S., on any confirmed preemployment or employer ordered drug screening when the practitioner does not have a lawful prescription and legitimate medical reason for using such drug. (Section 456.072(1)(aa), F.S.)	$500 fine, suspension until safe to practice with reasonable skill and safety and appearance before the board.	$2,500 fine and Revocation.
22. Being terminated from, or failing to successfully complete, an impaired practitioners treatment program. (Section 456.072(1)(hh), F.S.)	Suspension until successful completion or receipt of written confirmation of compliance with ongoing treatment and a fine of up to $1,000.	Revocation.
23. Being convicted of, or entering a plea of guilty or nolo contendere to, any misdemeanor or felony, regardless of adjudication, under 18 U.S.C. s. 669, ss. 285-287, s. 371, s. 1001, s. 1035, s. 1341, s. 1343, s. 1347, s. 1349, or s. 1518, or 42 U.S.C. ss. 1320a-7b, relating to the Medicaid program. (Section 456.072(1)(ii), F.S.)	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license.	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license.
24. Failing to remit the sum owed to the state for overpayment from the Medicaid program pursuant to a final order, judgment, or settlement. (Section 456.072(1)(jj), F.S.)	$500 to $5,000 fine and one (1) year probation.	$2,500 to $5,000 fine and suspension until amount owed is remitted, followed by two (2) years probation, to Revocation.
25. Being terminated from the state Medicaid program pursuant to Section 409.913, F.S., any other state Medicaid program, or the federal Medicare program, as a result of fraud and abuse unless eligibility to participate in the	$10,000 fine and one (1) year probation, to one (1) year suspension followed by one (1) year probation.	$10,000 fine and two (2) years suspension followed by two (2) years probation, to Revocation.

program from which the practitioner was terminated has been restored. (Section 456.072(1)(kk), F.S.)		
26. Being convicted of, or entering a plea of guilty or nolo contendere to, any misdemeanor or felony, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud. (Section 456.072(1)(ll), F.S.)	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license.	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license.
27. Willfully failing to comply with Section 627.64194 or 641.513, F.S., with such frequency as to indicate a general business practice. (Section 456.072(1)(oo), F.S.)	Reprimand and a fine of $250.	$500 fine and one (1) year probation, to Revocation.
(v) Violation of Section 828.055, F.S. by a permitted county or municipal animal control agency or humane society.		
1. Using drugs for animal euthanasia for an improper use. (Section 828.055(3)(a), F.S.)	Reprimand and a fine of $250.	$500 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
2. Failing to take reasonable precautions against misuse, theft, loss, or diversion. (Section 828.055(3)(b), F.S.)	Reprimand and a fine of $250.	$500 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
3. Failing to detect or to report a significant loss, theft, or inventory shortage of drugs. (Section 828.055(3)(c), F.S.)	Reprimand, $500 fine, and one (1) year probation.	$1,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
4. Failing to follow the rules of the Board regarding proper storage and handling of drugs. (Section 828.055(3)(d), F.S.)	Reprimand and a fine of $250.	$500 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
5. Violating any provision of Section 828.055, Chapter 465, and 499, F.S., or any rule adopted under those chapters. (Section 828.055(3)(e), F.S.)	Reprimand and a fine of $250.	$500 fine and one (1) year suspension followed by one (1) year probation, to Revocation.

(3) The board shall be entitled to deviate from the above-mentioned guidelines upon a showing of aggravating or mitigating circumstances by clear and convincing evidence presented to the board prior to the imposition of a final penalty.

(a) Aggravating circumstances; circumstances which may justify deviating from the above set forth disciplinary guidelines and cause the enhancement of a penalty beyond the maximum level of discipline in the guidelines shall include but not be limited to the following:

1. History of previous violations of the practice act and the rules promulgated thereto.

2. In the case of negligent acts, the magnitude and scope of the damage or potential damage inflicted upon the patient or the general public by the licensee's misfeasance.

3. Evidence of violation of professional practice acts in other jurisdictions wherein the licensee has been disciplined by the appropriate regulatory authority.

4. Harm occurred.

(b) Mitigating circumstances; circumstances which may justify deviating from the above set forth disciplinary guidelines and cause the lessening of a penalty beyond the minimum level of discipline in the guidelines shall include but not be limited to the

following:

1. In cases of negligent acts, the minor nature of the damage or potential damage to the patient's or the public's health, safety, and welfare resulting from the licensee's misfeasance.

2. Lack of previous disciplinary history in this or any other jurisdiction wherein the licensee practices his profession.

3. Restitution of any monetary damage suffered by the patient.

4. The licensee's professional standing among his peers.

5. Steps already taken by the licensee to insure the non-occurrence of similar violations in the future, including continuing education.

6. The degree of financial hardship incurred by a licensee as a result of the imposition of fines or the suspension of his practice.

(4) All fines imposed by the Board shall be paid within a period of ninety (90) days from the date of the final order entered by the Board. This time limitation may be modified by the Board for good cause shown in order to prevent undue hardship.

Rulemaking Authority 456.072, 456.079, 465.005 FS. Law Implemented 456.072, 456.079, 465.016, 465.023 FS. History–New 3-1-87, Amended 5-11-88, Formerly 21S-17.001, 21S-30.001, 61F10-30.001, Amended 6-26-95, 1-30-96, Formerly 59X-30.001, Amended 12-3-97, 11-15-98, 5-3-00, 1-2-02, 11-29-06, 9-26-12, 2-14-13, 2-5-14, 1-10-17.

TAB #10

BOARD COUNSEL SUGGESTED AMENDMENTS
APRIL 2018

64B16-30.002 Minor Violations.

(1) The Board sets forth the following guidelines for use by Department investigators when a licensee is in noncompliance of an initial offense of a minor violation. The Board deems the following violations, depending upon severity, to be consistent with Section 456.073(3), F.S.

(a) Outdated pharmaceuticals – Rule 64B16-28.110, F.A.C.

(b) Failure to meet regulation of daily operating hours – Rule 64B16-28.404, F.A.C.

(c) Generic substitution sign not displayed – Section 465.025(7), F.S.

(d) Information required on controlled substance prescriptions: practitioner's address, practitioner's DEA registration number, patient's address – Section 893.04, F.S.

(e) Failure to have certified by dispensing pharmacists the daily hard-copy printout or daily log – paragraph 64B16-28.140(3)(c) or (e), F.A.C.

(f) Failure to have pharmacy minimally equipped i.e. references, compounding equipment, and a current copy of the laws and rules governing the practice of pharmacy in the State of Florida – Rule 64B16-28.107, F.A.C.

(g) Failure to properly identify pharmacy technicians – Rule 64B16-27.410, F.A.C.

(h) Results of P&E quality assurance program not documented or available for inspection – paragraph 64B16-28.820(3)(d), F.A.C.

(i) Improper storage of legend drugs – Rule 64B16-28.120, F.A.C.

(j) Improper documentation of destruction of controlled substances – Rules 64B16-28.301, 64B16-28.303, F.A.C.

(k) Consultant pharmacist's monthly reports not current or available for inspection – Rule 64B16-28.501, subsection 64B16-28.702(2), F.A.C.

(l) Controlled substance prescription labels lack transfer crime warning labeling – paragraph 64B16-28.502(2)(c), F.A.C.

(m) Failure to maintain proof of licensure, display licenses/registrations or notices, or to properly identify pharmacy staff – Rule 64B16-27.100, F.A.C.

(n) Failure to notify the have a continuously designated Prescription Department Manager or Consultant Pharamcist of Record, if the gap between designations is less than fourteen (14) days – Rules 64B16-27.450 and 64B16-28.501, F.A.C.

(2) The Department's investigator may issue a Notice of Deficiencies when the above conditions occur and the requirements of Section 456.073(3), F.S., are met. In such cases licensees shall correct the violation and respond to the investigator on forms provided by the Department and with other evidence of compliance as may be necessary, within 30 days, to certify current compliance. Failure to do so shall subject the licensee to further proceedings.

Rulemaking Authority 456.073(3), 465.005 FS. Law Implemented 456.073(3) FS. History–New 11-12-90, Formerly 21S-17.002, 21S-30.002, 61F10-30.002, 59X-30.002, Amended 12-9-98, 8-26-02, 11-7-17.

TAB #11

1
2 An act relating to controlled substances; creating s.
3 456.0301, F.S.; requiring certain boards to require
4 certain registered practitioners to complete a
5 specified board-approved continuing education course
6 to obtain authorization to prescribe controlled
7 substances as part of biennial license renewal and
8 before a specified date; providing course
9 requirements; providing that the course may be offered
10 in a distance learning format and requiring that it be
11 included within required continuing education hours;
12 prohibiting the Department of Health from renewing the
13 license of a prescriber under specified circumstances;
14 specifying a deadline for course completion; providing
15 an exception from the course requirements for certain
16 licensees; requiring such licensees to submit
17 confirmation of course completion; authorizing certain
18 boards to adopt rules; amending s. 456.072, F.S.;
19 authorizing disciplinary action against practitioners
20 for violating specified provisions relating to
21 controlled substances; amending s. 456.44, F.S.;
22 defining the term "acute pain"; requiring the
23 applicable boards to adopt rules establishing certain
24 guidelines for prescribing controlled substances for
25 acute pain; providing that the failure of a prescriber

26 to follow specified guidelines is grounds for
27 disciplinary action; limiting opioid drug
28 prescriptions for the treatment of acute pain to a
29 specified period under certain circumstances;
30 authorizing such prescriptions for an extended period
31 if specified requirements are met; requiring a
32 prescriber who prescribes an opioid drug for the
33 treatment of pain other than acute pain to include a
34 specific indication on the prescription; requiring a
35 prescriber who prescribes an opioid drug for the
36 treatment of pain related to a traumatic injury with a
37 specified Injury Severity Score to concurrently
38 prescribe an emergency opioid antagonist; amending ss.
39 458.3265 and 459.0137, F.S.; requiring pain management
40 clinics to register with the department or hold a
41 valid certificate of exemption; requiring certain
42 clinics to apply to the department for a certificate
43 of exemption; providing requirements for such
44 certificates; requiring the department to adopt rules
45 necessary to administer such exemptions; amending s.
46 465.0155, F.S.; providing requirements for pharmacists
47 for the dispensing of controlled substances to persons
48 not known to them; defining the term "proper
49 identification"; amending s. 465.0276, F.S.;
50 prohibiting the dispensing of certain controlled

51 substances in an amount that exceeds a 3-day supply
52 unless certain criteria are met; providing an
53 exception for the dispensing of certain controlled
54 substances by a practitioner to the practitioner's own
55 patients for the medication-assisted treatment of
56 opiate addiction; providing requirements for
57 practitioners for the dispensing of controlled
58 substances to persons not known to them; defining the
59 term "proper identification"; amending s. 893.03,
60 F.S.; correcting a cross-reference; conforming the
61 state controlled substances schedule to the federal
62 controlled substances schedule; amending s. 893.04,
63 F.S.; authorizing a pharmacist to dispense controlled
64 substances upon receipt of an electronic prescription
65 if certain conditions are met; amending s. 893.055,
66 F.S.; revising and providing definitions; revising
67 requirements for the prescription drug monitoring
68 program; authorizing rulemaking; requiring dispensers
69 to report information to the department for each
70 controlled substance dispensed; providing
71 applicability; requiring the department to maintain an
72 electronic system for certain purposes which meets
73 specified requirements; requiring certain information
74 to be reported to the system by a specified time;
75 specifying direct access to system information;

76 authorizing the department to enter into reciprocal
77 agreements or contracts to share prescription drug
78 monitoring information with certain entities;
79 providing requirements for such agreements;
80 authorizing the department to enter into agreements or
81 contracts for secure connections with practitioner
82 electronic systems; requiring specified persons to
83 consult the system for certain purposes within a
84 specified time; providing exceptions to the duty of
85 specified persons to consult the system under certain
86 circumstances; requiring the department to issue
87 citations to prescribers or dispensers who fail to
88 meet specified requirements relating to consulting the
89 system; providing a system for discipline of specified
90 persons for failing to meet such requirements;
91 prohibiting a person from failing to report the
92 dispensing of a controlled substance when required to
93 do so; specifying penalties; authorizing the
94 department to enter into agreements or contracts for
95 specified purposes; providing for the release of
96 information obtained by the system; allowing specified
97 persons to have direct access to information for the
98 purpose of reviewing the controlled drug prescription
99 history of a patient; providing prescriber or
100 dispenser immunity from liability for review of

101 patient history when acting in good faith; providing
102 construction; prohibiting the department from
103 specified uses of funds; requiring the department to
104 conduct or participate in studies for specified
105 purposes; requiring an annual report to be submitted
106 to the Governor and Legislature by a specified date;
107 providing report requirements; authorizing the
108 department to establish a certain direct-support
109 organization for specified purposes; defining the term
110 "direct-support organization"; requiring a direct-
111 support organization to operate under written contract
112 with the department; providing contract requirements;
113 requiring the direct-support organization to obtain
114 written approval from the department for specified
115 purposes; providing for an independent annual
116 financial audit by the direct-support organization;
117 providing that copies of such audit be provided to
118 specified entities; authorizing the department to
119 adopt certain rules relating to resources used by the
120 direct-support organization; providing for future
121 repeal of provisions relating to the direct-support
122 organization; requiring the department to adopt rules
123 to implement the system; amending s. 893.0551, F.S.;
124 revising provisions concerning the release of
125 information held by the prescription drug monitoring

126 program; amending s. 893.13, F.S.; correcting cross-
127 references; increasing the severity of a felony for a
128 health care practitioner who provides or a person who
129 obtains certain controlled substances that are not
130 medically necessary under certain circumstances;
131 amending s. 893.147, F.S.; prohibiting any person from
132 possessing, purchasing, delivering, selling, or
133 possessing with intent to sell or deliver a tableting
134 machine, an encapsulating machine, or controlled
135 substance counterfeiting materials with knowledge,
136 intent, or reasonable cause to believe that it will be
137 used to manufacture a controlled substance or
138 counterfeit controlled substance; providing an
139 exception for persons who meet certain criteria;
140 defining terms; providing criminal penalties for
141 persons who violate specified provisions relating to
142 tableting machines, encapsulating machines, and
143 controlled substance counterfeiting materials;
144 amending ss. 458.331, 459.015, 463.0055, 782.04,
145 893.135, and 921.0022, F.S.; correcting cross-
146 references; conforming provisions to changes made by
147 the act; providing appropriations; providing effective
148 dates.
149
150 Be It Enacted by the Legislature of the State of Florida:

151

152 Section 1. Section 456.0301, Florida Statutes, is created
153 to read:
154 456.0301 Requirement for instruction on controlled
155 substance prescribing.-
156 (1)(a) The appropriate board shall require each person
157 registered with the United States Drug Enforcement
158 Administration and authorized to prescribe controlled substances
159 pursuant to 21 U.S.C. s. 822 to complete a board-approved 2-hour
160 continuing education course on prescribing controlled substances
161 offered by a statewide professional association of physicians in
162 this state that is accredited to provide educational activities
163 designated for the American Medical Association Physician's
164 Recognition Award Category 1 Credit or the American Osteopathic
165 Category 1-A continuing medical education credit as part of
166 biennial license renewal. The course must include information on
167 the current standards for prescribing controlled substances,
168 particularly opiates; alternatives to these standards;
169 nonpharmacological therapies; prescribing emergency opioid
170 antagonists; and the risks of opioid addiction following all
171 stages of treatment in the management of acute pain. The course
172 may be offered in a distance learning format and must be
173 included within the number of continuing education hours
174 required by law. The department may not renew the license of any
175 prescriber registered with the United States Drug Enforcement

176 Administration to prescribe controlled substances who has failed
177 to complete the course. The course must be completed by January
178 31, 2019, and at each subsequent renewal. This paragraph does
179 not apply to a licensee who is required by his or her applicable
180 practice act to complete a minimum of 2 hours of continuing
181 education on the safe and effective prescribing of controlled
182 substances.
183 (b) Each practitioner required to complete the course
184 required in paragraph (a) shall submit confirmation of having
185 completed such course when applying for biennial license
186 renewal.
187 (c) Each licensing board that requires a licensee to
188 complete an educational course pursuant to this subsection must
189 include the hours required for completion of the course in the
190 total hours of continuing education required by law for such
191 profession unless the continuing education requirements for such
192 profession consist of fewer than 30 hours biennially.
193 (2) Each board may adopt rules to administer this section.
194 Section 2. Paragraph (gg) of subsection (1) of section
195 456.072, Florida Statutes, is amended to read:
196 456.072 Grounds for discipline; penalties; enforcement.—
197 (1) The following acts shall constitute grounds for which
198 the disciplinary actions specified in subsection (2) may be
199 taken:
200 (gg) Engaging in a pattern of practice when prescribing

201 medicinal drugs or controlled substances which demonstrates a
202 lack of reasonable skill or safety to patients, a violation of
203 ~~any provision of~~ this chapter or ss. 893.055 and 893.0551, a
204 violation of the applicable practice act, or a violation of any
205 rules adopted under this chapter or the applicable practice act
206 of the prescribing practitioner. Notwithstanding s. 456.073(13),
207 the department may initiate an investigation and establish such
208 a pattern from billing records, data, or any other information
209 obtained by the department.
210 Section 3. Paragraphs (a) through (g) of subsection (1) of
211 section 456.44, Florida Statutes, are redesignated as paragraphs
212 (b) through (h), respectively, a new paragraph (a) is added to
213 that subsection, subsection (3) of that section is amended, and
214 subsections (4), (5), and (6) are added to that section, to
215 read:
216 456.44 Controlled substance prescribing.—
217 (1) DEFINITIONS.—As used in this section, the term:
218 (a) "Acute pain" means the normal, predicted,
219 physiological, and time-limited response to an adverse chemical,
220 thermal, or mechanical stimulus associated with surgery, trauma,
221 or acute illness. The term does not include pain related to:
222 1. Cancer.
223 2. A terminal condition. For purposes of this
224 subparagraph, the term "terminal condition" means a progressive
225 disease or medical or surgical condition that causes significant

226 functional impairment, is not considered by a treating physician
227 to be reversible without the administration of life-sustaining
228 procedures, and will result in death within 1 year after
229 diagnosis if the condition runs its normal course.
230 3. Palliative care to provide relief of symptoms related
231 to an incurable, progressive illness or injury.
232 4. A traumatic injury with an Injury Severity Score of 9
233 or greater.
234 (3) STANDARDS OF PRACTICE FOR TREATMENT OF CHRONIC
235 NONMALIGNANT PAIN.—The standards of practice in this section do
236 not supersede the level of care, skill, and treatment recognized
237 in general law related to health care licensure.
238 (a) A complete medical history and a physical examination
239 must be conducted before beginning any treatment and must be
240 documented in the medical record. The exact components of the
241 physical examination shall be left to the judgment of the
242 registrant who is expected to perform a physical examination
243 proportionate to the diagnosis that justifies a treatment. The
244 medical record must, at a minimum, document the nature and
245 intensity of the pain, current and past treatments for pain,
246 underlying or coexisting diseases or conditions, the effect of
247 the pain on physical and psychological function, a review of
248 previous medical records, previous diagnostic studies, and
249 history of alcohol and substance abuse. The medical record shall
250 also document the presence of one or more recognized medical

251 indications for the use of a controlled substance. Each
252 registrant must develop a written plan for assessing each
253 patient's risk of aberrant drug-related behavior, which may
254 include patient drug testing. Registrants must assess each
255 patient's risk for aberrant drug-related behavior and monitor
256 that risk on an ongoing basis in accordance with the plan.
257 (b) Each registrant must develop a written individualized
258 treatment plan for each patient. The treatment plan shall state
259 objectives that will be used to determine treatment success,
260 such as pain relief and improved physical and psychosocial
261 function, and shall indicate if any further diagnostic
262 evaluations or other treatments are planned. After treatment
263 begins, the registrant shall adjust drug therapy to the
264 individual medical needs of each patient. Other treatment
265 modalities, including a rehabilitation program, shall be
266 considered depending on the etiology of the pain and the extent
267 to which the pain is associated with physical and psychosocial
268 impairment. The interdisciplinary nature of the treatment plan
269 shall be documented.
270 (c) The registrant shall discuss the risks and benefits of
271 the use of controlled substances, including the risks of abuse
272 and addiction, as well as physical dependence and its
273 consequences, with the patient, persons designated by the
274 patient, or the patient's surrogate or guardian if the patient
275 is incompetent. The registrant shall use a written controlled

276 substance agreement between the registrant and the patient
277 outlining the patient's responsibilities, including, but not
278 limited to:
279 1. Number and frequency of controlled substance
280 prescriptions and refills.
281 2. Patient compliance and reasons for which drug therapy
282 may be discontinued, such as a violation of the agreement.
283 3. An agreement that controlled substances for the
284 treatment of chronic nonmalignant pain shall be prescribed by a
285 single treating registrant unless otherwise authorized by the
286 treating registrant and documented in the medical record.
287 (d) The patient shall be seen by the registrant at regular
288 intervals, not to exceed 3 months, to assess the efficacy of
289 treatment, ensure that controlled substance therapy remains
290 indicated, evaluate the patient's progress toward treatment
291 objectives, consider adverse drug effects, and review the
292 etiology of the pain. Continuation or modification of therapy
293 shall depend on the registrant's evaluation of the patient's
294 progress. If treatment goals are not being achieved, despite
295 medication adjustments, the registrant shall reevaluate the
296 appropriateness of continued treatment. The registrant shall
297 monitor patient compliance in medication usage, related
298 treatment plans, controlled substance agreements, and
299 indications of substance abuse or diversion at a minimum of 3-
300 month intervals.

301 (e) The registrant shall refer the patient as necessary
302 for additional evaluation and treatment in order to achieve
303 treatment objectives. Special attention shall be given to those
304 patients who are at risk for misusing their medications and
305 those whose living arrangements pose a risk for medication
306 misuse or diversion. The management of pain in patients with a
307 history of substance abuse or with a comorbid psychiatric
308 disorder requires extra care, monitoring, and documentation and
309 requires consultation with or referral to an addiction medicine
310 specialist or a psychiatrist.
311 (f) A registrant must maintain accurate, current, and
312 complete records that are accessible and readily available for
313 review and comply with the requirements of this section, the
314 applicable practice act, and applicable board rules. The medical
315 records must include, but are not limited to:
316 1. The complete medical history and a physical
317 examination, including history of drug abuse or dependence.
318 2. Diagnostic, therapeutic, and laboratory results.
319 3. Evaluations and consultations.
320 4. Treatment objectives.
321 5. Discussion of risks and benefits.
322 6. Treatments.
323 7. Medications, including date, type, dosage, and quantity
324 prescribed.
325 8. Instructions and agreements.

326 9. Periodic reviews.
327 10. Results of any drug testing.
328 11. A photocopy of the patient's government-issued photo
329 identification.
330 12. If a written prescription for a controlled substance
331 is given to the patient, a duplicate of the prescription.
332 13. The registrant's full name presented in a legible
333 manner.
334 (g) A registrant shall immediately refer patients with
335 signs or symptoms of substance abuse to a board-certified pain
336 management physician, an addiction medicine specialist, or a
337 mental health addiction facility as it pertains to drug abuse or
338 addiction unless the registrant is a physician who is board-
339 certified or board-eligible in pain management. Throughout the
340 period of time before receiving the consultant's report, a
341 prescribing registrant shall clearly and completely document
342 medical justification for continued treatment with controlled
343 substances and those steps taken to ensure medically appropriate
344 use of controlled substances by the patient. Upon receipt of the
345 consultant's written report, the prescribing registrant shall
346 incorporate the consultant's recommendations for continuing,
347 modifying, or discontinuing controlled substance therapy. The
348 resulting changes in treatment shall be specifically documented
349 in the patient's medical record. Evidence or behavioral
350 indications of diversion shall be followed by discontinuation of

351 controlled substance therapy, and the patient shall be
352 discharged, and all results of testing and actions taken by the
353 registrant shall be documented in the patient's medical record.
354
355 This subsection does not apply to a board-eligible or board-
356 certified anesthesiologist, physiatrist, rheumatologist, or
357 neurologist, or to a board-certified physician who has surgical
358 privileges at a hospital or ambulatory surgery center and
359 primarily provides surgical services. This subsection does not
360 apply to a board-eligible or board-certified medical specialist
361 who has also completed a fellowship in pain medicine approved by
362 the Accreditation Council for Graduate Medical Education or the
363 American Osteopathic Association, or who is board eligible or
364 board certified in pain medicine by the American Board of Pain
365 Medicine, the American Board of Interventional Pain Physicians,
366 the American Association of Physician Specialists, or a board
367 approved by the American Board of Medical Specialties or the
368 American Osteopathic Association and performs interventional
369 pain procedures of the type routinely billed using surgical
370 codes. This subsection does not apply to a registrant who
371 prescribes medically necessary controlled substances for a
372 patient during an inpatient stay in a hospital licensed under
373 chapter 395.
374 (4) STANDARDS OF PRACTICE FOR TREATMENT OF ACUTE PAIN.—The
375 applicable boards shall adopt rules establishing guidelines for

376 prescribing controlled substances for acute pain, including
377 evaluation of the patient, creation and maintenance of a
378 treatment plan, obtaining informed consent and agreement for
379 treatment, periodic review of the treatment plan, consultation,
380 medical record review, and compliance with controlled substance
381 laws and regulations. Failure of a prescriber to follow such
382 guidelines constitutes grounds for disciplinary action pursuant
383 to s. 456.072(1)(gg), punishable as provided in s. 456.072(2).
384 (5) PRESCRIPTION SUPPLY.—
385 (a) For the treatment of acute pain, a prescription for an
386 opioid drug listed as a Schedule II controlled substance in s.
387 893.03 or 21 U.S.C. s. 812 may not exceed a 3-day supply, except
388 that up to a 7-day supply may be prescribed if:
389 1. The prescriber, in his or her professional judgment,
390 believes that more than a 3-day supply of such an opioid is
391 medically necessary to treat the patient's pain as an acute
392 medical condition;
393 2. The prescriber indicates "ACUTE PAIN EXCEPTION" on the
394 prescription; and
395 3. The prescriber adequately documents in the patient's
396 medical records the acute medical condition and lack of
397 alternative treatment options that justify deviation from the 3-
398 day supply limit established in this subsection.
399 (b) For the treatment of pain other than acute pain, a
400 prescriber must indicate "NONACUTE PAIN" on a prescription for

401 an opioid drug listed as a Schedule II controlled substance in
402 s. 893.03 or 21 U.S.C. s. 812.
403 (6) EMERGENCY OPIOID ANTAGONIST.—For the treatment of pain
404 related to a traumatic injury with an Injury Severity Score of 9
405 or greater, a prescriber who prescribes a Schedule II controlled
406 substance listed in s. 893.03 or 21 U.S.C. s. 812 must
407 concurrently prescribe an emergency opioid antagonist, as
408 defined in s. 381.887(1).
409 Section 4. Effective January 1, 2019, present subsections
410 (2) through (5) of section 458.3265, Florida Statutes, are
411 renumbered as subsections (3) through (6), respectively,
412 paragraphs (a) and (g) of subsection (1), paragraph (a) of
413 present subsection (2), paragraph (a) of present subsection (3),
414 and paragraph (a) of present subsection (4) of that section are
415 amended, and a new subsection (2) is added to that section, to
416 read:
417 458.3265 Pain-management clinics.—
418 (1) REGISTRATION.—
419 (a)1. As used in this section, the term:
420 a. "Board eligible" means successful completion of an
421 anesthesia, physical medicine and rehabilitation, rheumatology,
422 or neurology residency program approved by the Accreditation
423 Council for Graduate Medical Education or the American
424 Osteopathic Association for a period of 6 years from successful
425 completion of such residency program.

426 b. "Chronic nonmalignant pain" means pain unrelated to
427 cancer which persists beyond the usual course of disease or the
428 injury that is the cause of the pain or more than 90 days after
429 surgery.
430 c. "Pain-management clinic" or "clinic" means any publicly
431 or privately owned facility:
432 (I) That advertises in any medium for any type of pain-
433 management services; or
434 (II) Where in any month a majority of patients are
435 prescribed opioids, benzodiazepines, barbiturates, or
436 carisoprodol for the treatment of chronic nonmalignant pain.
437 2. Each pain-management clinic must register with the
438 department or hold a valid certificate of exemption pursuant to
439 subsection (2).
440 3. The following clinics are exempt from the registration
441 requirement of paragraphs (c)-(m) and must apply to the
442 department for a certificate of exemption ~~unless~~:
443 a. A ~~That~~ clinic ~~is~~ licensed as a facility pursuant to
444 chapter 395;
445 b. A clinic in which the majority of the physicians who
446 provide services in the clinic primarily provide surgical
447 services;
448 c. A ~~The~~ clinic ~~is~~ owned by a publicly held corporation
449 whose shares are traded on a national exchange or on the over-
450 the-counter market and whose total assets at the end of the

451 corporation's most recent fiscal quarter exceeded $50 million;
452 d. A ~~The~~ clinic ~~is~~ affiliated with an accredited medical
453 school at which training is provided for medical students,
454 residents, or fellows;
455 e. A ~~The~~ clinic that does not prescribe controlled
456 substances for the treatment of pain;
457 f. A ~~The~~ clinic ~~is~~ owned by a corporate entity exempt from
458 federal taxation under 26 U.S.C. s. 501(c)(3);
459 g. A ~~The~~ clinic ~~is~~ wholly owned and operated by one or
460 more board-eligible or board-certified anesthesiologists,
461 physiatrists, rheumatologists, or neurologists; or
462 h. A ~~The~~ clinic ~~is~~ wholly owned and operated by a
463 physician multispecialty practice where one or more board-
464 eligible or board-certified medical specialists, who have also
465 completed fellowships in pain medicine approved by the
466 Accreditation Council for Graduate Medical Education or who are
467 also board-certified in pain medicine by the American Board of
468 Pain Medicine or a board approved by the American Board of
469 Medical Specialties, the American Association of Physician
470 Specialists, or the American Osteopathic Association, perform
471 interventional pain procedures of the type routinely billed
472 using surgical codes.
473 (g) The department may revoke the clinic's certificate of
474 registration and prohibit all physicians associated with that
475 pain-management clinic from practicing at that clinic location

476 based upon an annual inspection and evaluation of the factors
477 described in subsection (4) ~~(3)~~.
478 (2) CERTIFICATE OF EXEMPTION.—
479 (a) A pain management clinic claiming an exemption from
480 the registration requirements of subsection (1) must apply for a
481 certificate of exemption on a form adopted in rule by the
482 department. The form must require the applicant to provide:
483 1. The name or names under which the applicant does
484 business.
485 2. The address at which the pain management clinic is
486 located.
487 3. The specific exemption the applicant is claiming with
488 supporting documentation.
489 4. Any other information deemed necessary by the
490 department.
491 (b) The department must approve or deny the certificate
492 within 30 days after the receipt of a complete application.
493 (c) The certificate of exemption must be renewed
494 biennially, except that the department may issue the initial
495 certificates of exemption for up to 3 years in order to stagger
496 renewal dates.
497 (d) A certificateholder must prominently display the
498 certificate of exemption and make it available to the department
499 or the board upon request.
500 (e) A new certificate of exemption is required for a

501 change of address and is not transferable. A certificate of
502 exemption is valid only for the applicant, qualifying owners,
503 licenses, registrations, certifications, and services provided
504 under a specific statutory exemption and is valid only to the
505 specific exemption claimed and granted.
506 (f) A certificateholder must notify the department at
507 least 60 days before any anticipated relocation or name change
508 of the pain management clinic or a change of ownership.
509 (g) If a pain management clinic no longer qualifies for a
510 certificate of exemption, the certificateholder must notify the
511 department within 3 days after becoming aware that the clinic no
512 longer qualifies for a certificate of exemption and register as
513 a pain management clinic under subsection (1) or cease
514 operations.
515 (3) ~~(2)~~ PHYSICIAN RESPONSIBILITIES.—These responsibilities
516 apply to any physician who provides professional services in a
517 pain-management clinic that is required to be registered in
518 subsection (1).
519 (a) A physician may not practice medicine in a pain-
520 management clinic, as described in subsection (5) ~~(4)~~, if the
521 pain-management clinic is not registered with the department as
522 required by this section. Any physician who qualifies to
523 practice medicine in a pain-management clinic pursuant to rules
524 adopted by the Board of Medicine as of July 1, 2012, may
525 continue to practice medicine in a pain-management clinic as

526 long as the physician continues to meet the qualifications set
527 forth in the board rules. A physician who violates this
528 paragraph is subject to disciplinary action by his or her
529 appropriate medical regulatory board.
530 (4) ~~(3)~~ INSPECTION.—
531 (a) The department shall inspect the pain-management
532 clinic annually, including a review of the patient records, to
533 ensure that it complies with this section and the rules of the
534 Board of Medicine adopted pursuant to subsection (5) ~~(4)~~ unless
535 the clinic is accredited by a nationally recognized accrediting
536 agency approved by the Board of Medicine.
537 (5) ~~(4)~~ RULEMAKING.—
538 (a) The department shall adopt rules necessary to
539 administer the registration, exemption, and inspection of pain-
540 management clinics which establish the specific requirements,
541 procedures, forms, and fees.
542 Section 5. Effective January 1, 2019, present subsections
543 (2) through (5) of section 459.0137, Florida Statutes, are
544 renumbered as subsections (3) through (6), respectively,
545 paragraphs (a) and (g) of subsection (1), paragraph (a) of
546 present subsection (2), paragraph (a) of present subsection (3),
547 and paragraph (a) of present subsection (4) of that section are
548 amended, and a new subsection (2) is added to that section, to
549 read:
550 459.0137 Pain-management clinics.—

551 (1) REGISTRATION.—
552 (a)1. As used in this section, the term:
553 a. "Board eligible" means successful completion of an
554 anesthesia, physical medicine and rehabilitation, rheumatology,
555 or neurology residency program approved by the Accreditation
556 Council for Graduate Medical Education or the American
557 Osteopathic Association for a period of 6 years from successful
558 completion of such residency program.
559 b. "Chronic nonmalignant pain" means pain unrelated to
560 cancer which persists beyond the usual course of disease or the
561 injury that is the cause of the pain or more than 90 days after
562 surgery.
563 c. "Pain-management clinic" or "clinic" means any publicly
564 or privately owned facility:
565 (I) That advertises in any medium for any type of pain-
566 management services; or
567 (II) Where in any month a majority of patients are
568 prescribed opioids, benzodiazepines, barbiturates, or
569 carisoprodol for the treatment of chronic nonmalignant pain.
570 2. Each pain-management clinic must register with the
571 department or hold a valid certificate of exemption pursuant to
572 subsection (2).
573 3. The following clinics are exempt from the registration
574 requirement of paragraphs (c)-(m) and must apply to the
575 department for a certificate of exemption ~~unless~~:

576 a. A ~~That~~ clinic ~~is~~ licensed as a facility pursuant to
577 chapter 395;
578 b. A clinic in which the majority of the physicians who
579 provide services in the clinic primarily provide surgical
580 services;
581 c. A ~~The~~ clinic ~~is~~ owned by a publicly held corporation
582 whose shares are traded on a national exchange or on the over-
583 the-counter market and whose total assets at the end of the
584 corporation's most recent fiscal quarter exceeded $50 million;
585 d. A ~~The~~ clinic ~~is~~ affiliated with an accredited medical
586 school at which training is provided for medical students,
587 residents, or fellows;
588 e. A ~~The~~ clinic that does not prescribe controlled
589 substances for the treatment of pain;
590 f. A ~~The~~ clinic ~~is~~ owned by a corporate entity exempt from
591 federal taxation under 26 U.S.C. s. 501(c)(3);
592 g. A ~~The~~ clinic ~~is~~ wholly owned and operated by one or
593 more board-eligible or board-certified anesthesiologists,
594 physiatrists, rheumatologists, or neurologists; or
595 h. A ~~The~~ clinic ~~is~~ wholly owned and operated by a
596 physician multispecialty practice where one or more board-
597 eligible or board-certified medical specialists, who have also
598 completed fellowships in pain medicine approved by the
599 Accreditation Council for Graduate Medical Education or the
600 American Osteopathic Association or who are also board-certified

601 in pain medicine by the American Board of Pain Medicine or a
602 board approved by the American Board of Medical Specialties, the
603 American Association of Physician Specialists, or the American
604 Osteopathic Association, perform interventional pain procedures
605 of the type routinely billed using surgical codes.
606 (g) The department may revoke the clinic's certificate of
607 registration and prohibit all physicians associated with that
608 pain-management clinic from practicing at that clinic location
609 based upon an annual inspection and evaluation of the factors
610 described in subsection (4) ~~(3)~~.
611 (2) CERTIFICATE OF EXEMPTION.—
612 (a) A pain management clinic claiming an exemption from
613 the registration requirements of subsection (1) must apply for a
614 certificate of exemption on a form adopted in rule by the
615 department. The form must require the applicant to provide:
616 1. The name or names under which the applicant does
617 business.
618 2. The address at which the pain management clinic is
619 located.
620 3. The specific exemption the applicant is claiming with
621 supporting documentation.
622 4. Any other information deemed necessary by the
623 department.
624 (b) The department must approve or deny the certificate
625 within 30 days after the receipt of a complete application.

626 (c) The certificate of exemption must be renewed
627 biennially, except that the department may issue the initial
628 certificates of exemption for up to 3 years in order to stagger
629 renewal dates.
630 (d) A certificateholder must prominently display the
631 certificate of exemption and make it available to the department
632 or the board upon request.
633 (e) A new certificate of exemption is required for a
634 change of address and is not transferable. A certificate of
635 exemption is valid only for the applicant, qualifying owners,
636 licenses, registrations, certifications, and services provided
637 under a specific statutory exemption and is valid only to the
638 specific exemption claimed and granted.
639 (f) A certificateholder must notify the department at
640 least 60 days before any anticipated relocation or name change
641 of the pain management clinic or a change of ownership.
642 (g) If a pain management clinic no longer qualifies for a
643 certificate of exemption, the certificateholder must notify the
644 department within 3 days after becoming aware that the clinic no
645 longer qualifies for a certificate of exemption and register as
646 a pain management clinic under subsection (1) or cease
647 operations.
648 (3) ~~(2)~~ PHYSICIAN RESPONSIBILITIES.—These responsibilities
649 apply to any osteopathic physician who provides professional
650 services in a pain-management clinic that is required to be

651 registered in subsection (1).
652 (a) An osteopathic physician may not practice medicine in
653 a pain-management clinic, as described in subsection (5) ~~(4)~~, if
654 the pain-management clinic is not registered with the department
655 as required by this section. Any physician who qualifies to
656 practice medicine in a pain-management clinic pursuant to rules
657 adopted by the Board of Osteopathic Medicine as of July 1, 2012,
658 may continue to practice medicine in a pain-management clinic as
659 long as the physician continues to meet the qualifications set
660 forth in the board rules. An osteopathic physician who violates
661 this paragraph is subject to disciplinary action by his or her
662 appropriate medical regulatory board.
663 (4) ~~(3)~~ INSPECTION.—
664 (a) The department shall inspect the pain-management
665 clinic annually, including a review of the patient records, to
666 ensure that it complies with this section and the rules of the
667 Board of Osteopathic Medicine adopted pursuant to subsection (5)
668 ~~(4)~~ unless the clinic is accredited by a nationally recognized
669 accrediting agency approved by the Board of Osteopathic
670 Medicine.
671 (5) ~~(4)~~ RULEMAKING.—
672 (a) The department shall adopt rules necessary to
673 administer the registration, exemption, and inspection of pain-
674 management clinics which establish the specific requirements,
675 procedures, forms, and fees.

676 Section 6. Section 465.0155, Florida Statutes, is amended
677 to read:
678 465.0155 Standards of practice.—
679 (1) Consistent with the provisions of this act, the board
680 shall adopt by rule standards of practice relating to the
681 practice of pharmacy which shall be binding on every state
682 agency and shall be applied by such agencies when enforcing or
683 implementing any authority granted by any applicable statute,
684 rule, or regulation, whether federal or state.
685 (2)(a) Before dispensing a controlled substance to a
686 person not known to the pharmacist, the pharmacist must require
687 the person purchasing, receiving, or otherwise acquiring the
688 controlled substance to present valid photographic
689 identification or other verification of his or her identity. If
690 the person does not have proper identification, the pharmacist
691 may verify the validity of the prescription and the identity of
692 the patient with the prescriber or his or her authorized agent.
693 Verification of health plan eligibility through a real-time
694 inquiry or adjudication system is considered to be proper
695 identification.
696 (b) This subsection does not apply in an institutional
697 setting or to a long-term care facility, including, but not
698 limited to, an assisted living facility or a hospital to which
699 patients are admitted.
700 (c) As used in this subsection, the term "proper

701 identification" means an identification that is issued by a
702 state or the Federal Government containing the person's
703 photograph, printed name, and signature or a document considered
704 acceptable under 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).
705 Section 7. Paragraph (b) of subsection (1) of section
706 465.0276, Florida Statutes, is amended, and paragraph (d) is
707 added to subsection (2) of that section, to read:
708 465.0276 Dispensing practitioner.—
709 (1)
710 (b) A practitioner registered under this section may not
711 dispense a controlled substance listed in Schedule II or
712 Schedule III as provided in s. 893.03. This paragraph does not
713 apply to:
714 1. The dispensing of complimentary packages of medicinal
715 drugs which are labeled as a drug sample or complimentary drug
716 as defined in s. 499.028 to the practitioner's own patients in
717 the regular course of her or his practice without the payment of
718 a fee or remuneration of any kind, whether direct or indirect,
719 as provided in subsection (4).
720 2. The dispensing of controlled substances in the health
721 care system of the Department of Corrections.
722 3. The dispensing of a controlled substance listed in
723 Schedule II or Schedule III in connection with the performance
724 of a surgical procedure.
725 a. For an opioid drug listed as a Schedule II controlled

726 substance in s. 893.03 or 21 U.S.C. s. 812:
727 (I) For the treatment of acute pain, the amount dispensed
728 pursuant to this subparagraph may not exceed a 3-day supply, or
729 a 7-day supply if the criteria in s. 456.44(5)(a) are met.
730 (II) For the treatment of pain other than acute pain, a
731 practitioner must indicate "NONACUTE PAIN" on a prescription.
732 (III) For the treatment of pain related to a traumatic
733 injury with an Injury Severity Score of 9 or greater, a
734 practitioner must concurrently prescribe an emergency opioid
735 antagonist, as defined in s. 381.887(1).
736 b. For a controlled substance listed in Schedule III, the
737 amount dispensed pursuant to this ~~the~~ subparagraph may not
738 exceed a 14-day supply.
739 c. The exception in this subparagraph ~~exception~~ does not
740 allow for the dispensing of a controlled substance listed in
741 Schedule II or Schedule III more than 14 days after the
742 performance of the surgical procedure.
743 d. For purposes of this subparagraph, the term "surgical
744 procedure" means any procedure in any setting which involves, or
745 reasonably should involve:
746 (I)~~a.~~ Perioperative medication and sedation that allows
747 the patient to tolerate unpleasant procedures while maintaining
748 adequate cardiorespiratory function and the ability to respond
749 purposefully to verbal or tactile stimulation and makes intra-
750 and postoperative monitoring necessary; or

751 (II)~~b.~~ The use of general anesthesia or major conduction
752 anesthesia and preoperative sedation.
753 4. The dispensing of a controlled substance listed in
754 Schedule II or Schedule III pursuant to an approved clinical
755 trial. For purposes of this subparagraph, the term "approved
756 clinical trial" means a clinical research study or clinical
757 investigation that, in whole or in part, is state or federally
758 funded or is conducted under an investigational new drug
759 application that is reviewed by the United States Food and Drug
760 Administration.
761 5. The dispensing of methadone in a facility licensed
762 under s. 397.427 where medication-assisted treatment for opiate
763 addiction is provided.
764 6. The dispensing of a controlled substance listed in
765 Schedule II or Schedule III to a patient of a facility licensed
766 under part IV of chapter 400.
767 7. The dispensing of controlled substances listed in
768 Schedule II or Schedule III which have been approved by the
769 United States Food and Drug Administration for the purpose of
770 treating opiate addictions, including, but not limited to,
771 buprenorphine and buprenorphine combination products, by a
772 practitioner authorized under 21 U.S.C. s. 823, as amended, to
773 the practitioner's own patients for the medication-assisted
774 treatment of opiate addiction.
775 (2) A practitioner who dispenses medicinal drugs for human

776 consumption for fee or remuneration of any kind, whether direct
777 or indirect, must:
778 (d)1. Before dispensing a controlled substance to a person
779 not known to the dispenser, require the person purchasing,
780 receiving, or otherwise acquiring the controlled substance to
781 present valid photographic identification or other verification
782 of his or her identity. If the person does not have proper
783 identification, the dispenser may verify the validity of the
784 prescription and the identity of the patient with the prescriber
785 or his or her authorized agent. Verification of health plan
786 eligibility through a real-time inquiry or adjudication system
787 is considered to be proper identification.
788 2. This paragraph does not apply in an institutional
789 setting or to a long-term care facility, including, but not
790 limited to, an assisted living facility or a hospital to which
791 patients are admitted.
792 3. As used in this paragraph, the term "proper
793 identification" means an identification that is issued by a
794 state or the Federal Government containing the person's
795 photograph, printed name, and signature or a document considered
796 acceptable under 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).
797 Section 8. Paragraph (c) of subsection (1) and subsections
798 (2) through (5) of section 893.03, Florida Statutes, are amended
799 to read:
800 893.03 Standards and schedules.—The substances enumerated

801 in this section are controlled by this chapter. The controlled
802 substances listed or to be listed in Schedules I, II, III, IV,
803 and V are included by whatever official, common, usual,
804 chemical, trade name, or class designated. The provisions of
805 this section shall not be construed to include within any of the
806 schedules contained in this section any excluded drugs listed
807 within the purview of 21 C.F.R. s. 1308.22, styled "Excluded
808 Substances"; 21 C.F.R. s. 1308.24, styled "Exempt Chemical
809 Preparations"; 21 C.F.R. s. 1308.32, styled "Exempted
810 Prescription Products"; or 21 C.F.R. s. 1308.34, styled "Exempt
811 Anabolic Steroid Products."
812 (1) SCHEDULE I.—A substance in Schedule I has a high
813 potential for abuse and has no currently accepted medical use in
814 treatment in the United States and in its use under medical
815 supervision does not meet accepted safety standards. The
816 following substances are controlled in Schedule I:
817 (c) Unless specifically excepted or unless listed in
818 another schedule, any material, compound, mixture, or
819 preparation that contains any quantity of the following
820 hallucinogenic substances or that contains any of their salts,
821 isomers, including optical, positional, or geometric isomers,
822 homologues, nitrogen-heterocyclic analogs, esters, ethers, and
823 salts of isomers, homologues, nitrogen-heterocyclic analogs,
824 esters, or ethers, if the existence of such salts, isomers, and
825 salts of isomers is possible within the specific chemical

826 designation or class description:
827 1. Alpha-Ethyltryptamine.
828 2. 4-Methylaminorex (2-Amino-4-methyl-5-phenyl-2-
829 oxazoline).
830 3. Aminorex (2-Amino-5-phenyl-2-oxazoline).
831 4. DOB (4-Bromo-2,5-dimethoxyamphetamine).
832 5. 2C-B (4-Bromo-2,5-dimethoxyphenethylamine).
833 6. Bufotenine.
834 7. Cannabis.
835 8. Cathinone.
836 9. DET (Diethyltryptamine).
837 10. 2,5-Dimethoxyamphetamine.
838 11. DOET (4-Ethyl-2,5-Dimethoxyamphetamine).
839 12. DMT (Dimethyltryptamine).
840 13. PCE (N-Ethyl-1-phenylcyclohexylamine)(Ethylamine
841 analog of phencyclidine).
842 14. JB-318 (N-Ethyl-3-piperidyl benzilate).
843 15. N-Ethylamphetamine.
844 16. Fenethylline.
845 17. 3,4-Methylenedioxy-N-hydroxyamphetamine.
846 18. Ibogaine.
847 19. LSD (Lysergic acid diethylamide).
848 20. Mescaline.
849 21. Methcathinone.
850 22. 5-Methoxy-3,4-methylenedioxyamphetamine.

851 23. PMA (4-Methoxyamphetamine).
852 24. PMMA (4-Methoxymethamphetamine).
853 25. DOM (4-Methyl-2,5-dimethoxyamphetamine).
854 26. MDEA (3,4-Methylenedioxy-N-ethylamphetamine).
855 27. MDA (3,4-Methylenedioxyamphetamine).
856 28. JB-336 (N-Methyl-3-piperidyl benzilate).
857 29. N,N-Dimethylamphetamine.
858 30. Parahexyl.
859 31. Peyote.
860 32. PCPY (N-(1-Phenylcyclohexyl)-pyrrolidine) (Pyrrolidine
861 analog of phencyclidine).
862 33. Psilocybin.
863 34. Psilocyn.
864 35. *Salvia divinorum*, except for any drug product approved
865 by the United States Food and Drug Administration which contains
866 *Salvia divinorum* or its isomers, esters, ethers, salts, and
867 salts of isomers, esters, and ethers, if the existence of such
868 isomers, esters, ethers, and salts is possible within the
869 specific chemical designation.
870 36. Salvinorin A, except for any drug product approved by
871 the United States Food and Drug Administration which contains
872 Salvinorin A or its isomers, esters, ethers, salts, and salts of
873 isomers, esters, and ethers, if the existence of such isomers,
874 esters, ethers, and salts is possible within the specific
875 chemical designation.

876 37. Xylazine.
877 38. TCP (1-[1-(2-Thienyl)-cyclohexyl]-piperidine)
878 (Thiophene analog of phencyclidine).
879 39. 3,4,5-Trimethoxyamphetamine.
880 40. Methylone (3,4-Methylenedioxymethcathinone).
881 41. MDPV (3,4-Methylenedioxypyrovalerone).
882 42. Methylmethcathinone.
883 43. Methoxymethcathinone.
884 44. Fluoromethcathinone.
885 45. Methylethcathinone.
886 46. CP 47,497 (2-(3-Hydroxycyclohexyl)-5-(2-methyloctan-2-
887 yl)phenol) and its dimethyloctyl (C8) homologue.
888 47. HU-210 [(6aR,10aR)-9-(Hydroxymethyl)-6,6-dimethyl-3-
889 (2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-
890 ol].
891 48. JWH-018 (1-Pentyl-3-(1-naphthoyl)indole).
892 49. JWH-073 (1-Butyl-3-(1-naphthoyl)indole).
893 50. JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-
894 naphthoyl)indole).
895 51. BZP (Benzylpiperazine).
896 52. Fluorophenylpiperazine.
897 53. Methylphenylpiperazine.
898 54. Chlorophenylpiperazine.
899 55. Methoxyphenylpiperazine.
900 56. DBZP (1,4-Dibenzylpiperazine).

901 57. TFMPP (Trifluoromethylphenylpiperazine).
902 58. MBDB (Methylbenzodioxolylbutanamine) or (3,4-
903 Methylenedioxy-N-methylbutanamine).
904 59. 5-Hydroxy-AMT (5-Hydroxy-alpha-methyltryptamine).
905 60. 5-Hydroxy-N-methyltryptamine.
906 61. 5-MeO-MiPT (5-Methoxy-N-methyl-N-isopropyltryptamine).
907 62. 5-MeO-AMT (5-Methoxy-alpha-methyltryptamine).
908 63. Methyltryptamine.
909 64. 5-MeO-DMT (5-Methoxy-N,N-dimethyltryptamine).
910 65. 5-Me-DMT (5-Methyl-N,N-dimethyltryptamine).
911 66. Tyramine (4-Hydroxyphenethylamine).
912 67. 5-MeO-DiPT (5-Methoxy-N,N-Diisopropyltryptamine).
913 68. DiPT (N,N-Diisopropyltryptamine).
914 69. DPT (N,N-Dipropyltryptamine).
915 70. 4-Hydroxy-DiPT (4-Hydroxy-N,N-diisopropyltryptamine).
916 71. 5-MeO-DALT (5-Methoxy-N,N-Diallyltryptamine).
917 72. DOI (4-Iodo-2,5-dimethoxyamphetamine).
918 73. DOC (4-Chloro-2,5-dimethoxyamphetamine).
919 74. 2C-E (4-Ethyl-2,5-dimethoxyphenethylamine).
920 75. 2C-T-4 (4-Isopropylthio-2,5-dimethoxyphenethylamine).
921 76. 2C-C (4-Chloro-2,5-dimethoxyphenethylamine).
922 77. 2C-T (4-Methylthio-2,5-dimethoxyphenethylamine).
923 78. 2C-T-2 (4-Ethylthio-2,5-dimethoxyphenethylamine).
924 79. 2C-T-7 (4-(n)-Propylthio-2,5-dimethoxyphenethylamine).
925 80. 2C-I (4-Iodo-2,5-dimethoxyphenethylamine).

926 81. Butylone (3,4-Methylenedioxy-alpha-
927 methylaminobutyrophenone).
928 82. Ethcathinone.
929 83. Ethylone (3,4-Methylenedioxy-N-ethylcathinone).
930 84. Naphyrone (Naphthylpyrovalerone).
931 85. Dimethylone (3,4-Methylenedioxy-N,N-
932 dimethylcathinone).
933 86. 3,4-Methylenedioxy-N,N-diethylcathinone.
934 87. 3,4-Methylenedioxy-propiophenone.
935 88. 3,4-Methylenedioxy-alpha-bromopropiophenone.
936 89. 3,4-Methylenedioxy-propiophenone-2-oxime.
937 90. 3,4-Methylenedioxy-N-acetylcathinone.
938 91. 3,4-Methylenedioxy-N-acetylmethcathinone.
939 92. 3,4-Methylenedioxy-N-acetylethcathinone.
940 93. Bromomethcathinone.
941 94. Buphedrone (alpha-Methylamino-butyrophenone).
942 95. Eutylone (3,4-Methylenedioxy-alpha-
943 ethylaminobutyrophenone).
944 96. Dimethylcathinone.
945 97. Dimethylmethcathinone.
946 98. Pentylone (3,4-Methylenedioxy-alpha-
947 methylaminovalerophenone).
948 99. MDPPP (3,4-Methylenedioxy-alpha-
949 pyrrolidinopropiophenone).
950 100. MDPBP (3,4-Methylenedioxy-alpha-

951 pyrrolidinobutyrophenone).
952 101. MOPPP (Methoxy-alpha-pyrrolidinopropiophenone).
953 102. MPHP (Methyl-alpha-pyrrolidinohexanophenone).
954 103. BTCP (Benzothiophenylcyclohexylpiperidine) or BCP
955 (Benocyclidine).
956 104. F-MABP (Fluoromethylaminobutyrophenone).
957 105. MeO-PBP (Methoxypyrrolidinobutyrophenone).
958 106. Et-PBP (Ethylpyrrolidinobutyrophenone).
959 107. 3-Me-4-MeO-MCAT (3-Methyl-4-Methoxymethcathinone).
960 108. Me-EABP (Methylethylaminobutyrophenone).
961 109. Etizolam.
962 110. PPP (Pyrrolidinopropiophenone).
963 111. PBP (Pyrrolidinobutyrophenone).
964 112. PVP (Pyrrolidinovalerophenone) or
965 (Pyrrolidinopentiophenone).
966 113. MPPP (Methyl-alpha-pyrrolidinopropiophenone).
967 114. JWH-007 (1-Pentyl-2-methyl-3-(1-naphthoyl)indole).
968 115. JWH-015 (1-Propyl-2-methyl-3-(1-naphthoyl)indole).
969 116. JWH-019 (1-Hexyl-3-(1-naphthoyl)indole).
970 117. JWH-020 (1-Heptyl-3-(1-naphthoyl)indole).
971 118. JWH-072 (1-Propyl-3-(1-naphthoyl)indole).
972 119. JWH-081 (1-Pentyl-3-(4-methoxy-1-naphthoyl)indole).
973 120. JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole).
974 121. JWH-133 ((6aR,10aR)-6,6,9-Trimethyl-3-(2-
975 methylpentan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromene).

976 122. JWH-175 (1-Pentyl-3-(1-naphthylmethyl)indole).
977 123. JWH-201 (1-Pentyl-3-(4-methoxyphenylacetyl)indole).
978 124. JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl)indole).
979 125. JWH-210 (1-Pentyl-3-(4-ethyl-1-naphthoyl)indole).
980 126. JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole).
981 127. JWH-251 (1-Pentyl-3-(2-methylphenylacetyl)indole).
982 128. JWH-302 (1-Pentyl-3-(3-methoxyphenylacetyl)indole).
983 129. JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole).
984 130. HU-211 ((6aS,10aS)-9-(Hydroxymethyl)-6,6-dimethyl-3-
985 (2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-
986 ol).
987 131. HU-308 ([(1R,2R,5R)-2-[2,6-Dimethoxy-4-(2-
988 methyloctan-2-yl)phenyl]-7,7-dimethyl-4-bicyclo[3.1.1]hept-3-
989 enyl] methanol).
990 132. HU-331 (3-Hydroxy-2-[(1R,6R)-3-methyl-6-(1-
991 methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-2,5-cyclohexadiene-
992 1,4-dione).
993 133. CB-13 (4-Pentyloxy-1-(1-naphthoyl)naphthalene).
994 134. CB-25 (N-Cyclopropyl-11-(3-hydroxy-5-pentylphenoxy)-
995 undecanamide).
996 135. CB-52 (N-Cyclopropyl-11-(2-hexyl-5-hydroxyphenoxy)-
997 undecanamide).
998 136. CP 55,940 (2-[3-Hydroxy-6-propanol-cyclohexyl]-5-(2-
999 methyloctan-2-yl)phenol).
1000 137. AM-694 (1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole).

1001 138. AM-2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl)indole).
1002 139. RCS-4 (1-Pentyl-3-(4-methoxybenzoyl)indole).
1003 140. RCS-8 (1-(2-Cyclohexylethyl)-3-(2-
1004 methoxyphenylacetyl)indole).
1005 141. WIN55,212-2 ((R)-(+)-[2,3-Dihydro-5-methyl-3-(4-
1006 morpholinylmethyl)pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl]-1-
1007 naphthalenylmethanone).
1008 142. WIN55,212-3 ([(3S)-2,3-Dihydro-5-methyl-3-(4-
1009 morpholinylmethyl)pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl]-1-
1010 naphthalenylmethanone).
1011 143. Pentedrone (alpha-Methylaminovalerophenone).
1012 144. Fluoroamphetamine.
1013 145. Fluoromethamphetamine.
1014 146. Methoxetamine.
1015 147. Methiopropamine.
1016 148. Methylbuphedrone (Methyl-alpha-
1017 methylaminobutyrophenone).
1018 149. APB ((2-Aminopropyl)benzofuran).
1019 150. APDB ((2-Aminopropyl)-2,3-dihydrobenzofuran).
1020 151. UR-144 (1-Pentyl-3-(2,2,3,3-
1021 tetramethylcyclopropanoyl)indole).
1022 152. XLR11 (1-(5-Fluoropentyl)-3-(2,2,3,3-
1023 tetramethylcyclopropanoyl)indole).
1024 153. Chloro UR-144 (1-(Chloropentyl)-3-(2,2,3,3-
1025 tetramethylcyclopropanoyl)indole).

1026 154. AKB48 (N-Adamant-1-yl 1-pentylindazole-3-
1027 carboxamide).
1028 155. AM-2233(1-[(N-Methyl-2-piperidinyl)methyl]-3-(2-
1029 iodobenzoyl)indole).
1030 156. STS-135 (N-Adamant-1-yl 1-(5-fluoropentyl)indole-3-
1031 carboxamide).
1032 157. URB-597 ((3'-(Aminocarbonyl)[1,1'-biphenyl]-3-yl)-
1033 cyclohexylcarbamate).
1034 158. URB-602 ([1,1'-Biphenyl]-3-yl-carbamic acid,
1035 cyclohexyl ester).
1036 159. URB-754 (6-Methyl-2-[(4-methylphenyl)amino]-1-
1037 benzoxazin-4-one).
1038 160. 2C-D (4-Methyl-2,5-dimethoxyphenethylamine).
1039 161. 2C-H (2,5-Dimethoxyphenethylamine).
1040 162. 2C-N (4-Nitro-2,5-dimethoxyphenethylamine).
1041 163. 2C-P (4-(n)-Propyl-2,5-dimethoxyphenethylamine).
1042 164. 25I-NBOMe (4-Iodo-2,5-dimethoxy-[N-(2-
1043 methoxybenzyl)]phenethylamine).
1044 165. MDMA (3,4-Methylenedioxymethamphetamine).
1045 166. PB-22 (8-Quinolinyl 1-pentylindole-3-carboxylate).
1046 167. Fluoro PB-22 (8-Quinolinyl 1-(fluoropentyl)indole-3-
1047 carboxylate).
1048 168. BB-22 (8-Quinolinyl 1-(cyclohexylmethyl)indole-3-
1049 carboxylate).
1050 169. Fluoro AKB48 (N-Adamant-1-yl 1-

1051 (fluoropentyl)indazole-3-carboxamide).
1052 170. AB-PINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-
1053 pentylindazole-3-carboxamide).
1054 171. AB-FUBINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-
1055 (4-fluorobenzyl)indazole-3-carboxamide).
1056 172. ADB-PINACA (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-
1057 1-pentylindazole-3-carboxamide).
1058 173. Fluoro ADBICA (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-
1059 yl)-1-(fluoropentyl)indole-3-carboxamide).
1060 174. 25B-NBOMe (4-Bromo-2,5-dimethoxy-[N-(2-
1061 methoxybenzyl)]phenethylamine).
1062 175. 25C-NBOMe (4-Chloro-2,5-dimethoxy-[N-(2-
1063 methoxybenzyl)]phenethylamine).
1064 176. AB-CHMINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-
1065 (cyclohexylmethyl)indazole-3-carboxamide).
1066 177. FUB-PB-22 (8-Quinolinyl 1-(4-fluorobenzyl)indole-3-
1067 carboxylate).
1068 178. Fluoro-NNEI (N-Naphthalen-1-yl 1-
1069 (fluoropentyl)indole-3-carboxamide).
1070 179. Fluoro-AMB (N-(1-Methoxy-3-methyl-1-oxobutan-2-yl)-1-
1071 (fluoropentyl)indazole-3-carboxamide).
1072 180. THJ-2201 (1-(5-Fluoropentyl)-3-(1-
1073 naphthoyl)indazole).
1074 181. AM-855 ((4aR,12bR)-8-Hexyl-2,5,5-trimethyl-
1075 1,4,4a,8,9,10,11,12b-octahydronaphtho[3,2-c]isochromen-12-ol).

1076 182. AM-905 ((6aR,9R,10aR)-3-[(E)-Hept-1-enyl]-9-
1077 (hydroxymethyl)-6,6-dimethyl-6a,7,8,9,10,10a-
1078 hexahydrobenzo[c]chromen-1-ol).
1079 183. AM-906 ((6aR,9R,10aR)-3-[(Z)-Hept-1-enyl]-9-
1080 (hydroxymethyl)-6,6-dimethyl-6a,7,8,9,10,10a-
1081 hexahydrobenzo[c]chromen-1-ol).
1082 184. AM-2389 ((6aR,9R,10aR)-3-(1-Hexyl-cyclobut-1-yl)-
1083 6a,7,8,9,10,10a-hexahydro-6,6-dimethyl-6H-dibenzo[b,d]pyran-1,9
1084 diol).
1085 185. HU-243 ((6aR,8S,9S,10aR)-9-(Hydroxymethyl)-6,6-
1086 dimethyl-3-(2-methyloctan-2-yl)-8,9-ditritio-7,8,10,10a-
1087 tetrahydro-6aH-benzo[c]chromen-1-ol).
1088 186. HU-336 ((6aR,10aR)-6,6,9-Trimethyl-3-pentyl-
1089 6a,7,10,10a-tetrahydro-1H-benzo[c]chromene-1,4(6H)-dione).
1090 187. MAPB ((2-Methylaminopropyl)benzofuran).
1091 188. 5-IT (2-(1H-Indol-5-yl)-1-methyl-ethylamine).
1092 189. 6-IT (2-(1H-Indol-6-yl)-1-methyl-ethylamine).
1093 190. Synthetic Cannabinoids.—Unless specifically excepted
1094 or unless listed in another schedule or contained within a
1095 pharmaceutical product approved by the United States Food and
1096 Drug Administration, any material, compound, mixture, or
1097 preparation that contains any quantity of a synthetic
1098 cannabinoid found to be in any of the following chemical class
1099 descriptions, or homologues, nitrogen-heterocyclic analogs,
1100 isomers (including optical, positional, or geometric), esters,

1101 ethers, salts, and salts of homologues, nitrogen-heterocyclic
1102 analogs, isomers, esters, or ethers, whenever the existence of
1103 such homologues, nitrogen-heterocyclic analogs, isomers, esters,
1104 ethers, salts, and salts of isomers, esters, or ethers is
1105 possible within the specific chemical class or designation.
1106 Since nomenclature of these synthetically produced cannabinoids
1107 is not internationally standardized and may continually evolve,
1108 these structures or the compounds of these structures shall be
1109 included under this subparagraph, regardless of their specific
1110 numerical designation of atomic positions covered, if it can be
1111 determined through a recognized method of scientific testing or
1112 analysis that the substance contains properties that fit within
1113 one or more of the following categories:
1114 a. Tetrahydrocannabinols.—Any tetrahydrocannabinols
1115 naturally contained in a plant of the genus *Cannabis*, the
1116 synthetic equivalents of the substances contained in the plant
1117 or in the resinous extracts of the genus *Cannabis*, or synthetic
1118 substances, derivatives, and their isomers with similar chemical
1119 structure and pharmacological activity, including, but not
1120 limited to, Delta 9 tetrahydrocannabinols and their optical
1121 isomers, Delta 8 tetrahydrocannabinols and their optical
1122 isomers, Delta 6a,10a tetrahydrocannabinols and their optical
1123 isomers, or any compound containing a tetrahydrobenzo[c]chromene
1124 structure with substitution at either or both the 3-position or
1125 9-position, with or without substitution at the 1-position with

1126 hydroxyl or alkoxy groups, including, but not limited to:
1127 (I) Tetrahydrocannabinol.
1128 (II) HU-210 ((6aR,10aR)-9-(Hydroxymethyl)-6,6-dimethyl-3-
1129 (2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-
1130 ol).
1131 (III) HU-211 ((6aS,10aS)-9-(Hydroxymethyl)-6,6-dimethyl-3-
1132 (2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-
1133 ol).
1134 (IV) JWH-051 ((6aR,10aR)-9-(Hydroxymethyl)-6,6-dimethyl-3-
1135 (2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromene).
1136 (V) JWH-133 ((6aR,10aR)-6,6,9-Trimethyl-3-(2-methylpentan-
1137 2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromene).
1138 (VI) JWH-057 ((6aR,10aR)-6,6,9-Trimethyl-3-(2-methyloctan-
1139 2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromene).
1140 (VII) JWH-359 ((6aR,10aR)-1-Methoxy-6,6,9-trimethyl-3-
1141 (2,3-dimethylpentan-2-yl)-6a,7,10,10a-
1142 tetrahydrobenzo[c]chromene).
1143 (VIII) AM-087 ((6aR,10aR)-3-(2-Methyl-6-bromohex-2-yl)-
1144 6,6,9-trimethyl-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol).
1145 (IX) AM-411 ((6aR,10aR)-3-(1-Adamantyl)-6,6,9-trimethyl-
1146 6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol).
1147 (X) Parahexyl.
1148 b. Naphthoylindoles, Naphthoylindazoles,
1149 Naphthoylcarbazoles, Naphthylmethylindoles,
1150 Naphthylmethylindazoles, and Naphthylmethylcarbazoles.—Any

1151 compound containing a naphthoylindole, naphthoylindazole,
1152 naphthoylcarbazole, naphthylmethylindole,
1153 naphthylmethylindazole, or naphthylmethylcarbazole structure,
1154 with or without substitution on the indole, indazole, or
1155 carbazole ring to any extent, whether or not substituted on the
1156 naphthyl ring to any extent, including, but not limited to:
1157 (I) JWH-007 (1-Pentyl-2-methyl-3-(1-naphthoyl)indole).
1158 (II) JWH-011 (1-(1-Methylhexyl)-2-methyl-3-(1-
1159 naphthoyl)indole).
1160 (III) JWH-015 (1-Propyl-2-methyl-3-(1-naphthoyl)indole).
1161 (IV) JWH-016 (1-Butyl-2-methyl-3-(1-naphthoyl)indole).
1162 (V) JWH-018 (1-Pentyl-3-(1-naphthoyl)indole).
1163 (VI) JWH-019 (1-Hexyl-3-(1-naphthoyl)indole).
1164 (VII) JWH-020 (1-Heptyl-3-(1-naphthoyl)indole).
1165 (VIII) JWH-022 (1-(4-Pentenyl)-3-(1-naphthoyl)indole).
1166 (IX) JWH-071 (1-Ethyl-3-(1-naphthoyl)indole).
1167 (X) JWH-072 (1-Propyl-3-(1-naphthoyl)indole).
1168 (XI) JWH-073 (1-Butyl-3-(1-naphthoyl)indole).
1169 (XII) JWH-080 (1-Butyl-3-(4-methoxy-1-naphthoyl)indole).
1170 (XIII) JWH-081 (1-Pentyl-3-(4-methoxy-1-naphthoyl)indole).
1171 (XIV) JWH-098 (1-Pentyl-2-methyl-3-(4-methoxy-1-
1172 naphthoyl)indole).
1173 (XV) JWH-116 (1-Pentyl-2-ethyl-3-(1-naphthoyl)indole).
1174 (XVI) JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole).
1175 (XVII) JWH-149 (1-Pentyl-2-methyl-3-(4-methyl-1-

1176 naphthoyl)indole).
1177 (XVIII) JWH-164 (1-Pentyl-3-(7-methoxy-1-
1178 naphthoyl)indole).
1179 (XIX) JWH-175 (1-Pentyl-3-(1-naphthylmethyl)indole).
1180 (XX) JWH-180 (1-Propyl-3-(4-propyl-1-naphthoyl)indole).
1181 (XXI) JWH-182 (1-Pentyl-3-(4-propyl-1-naphthoyl)indole).
1182 (XXII) JWH-184 (1-Pentyl-3-[(4-methyl)-1-
1183 naphthylmethyl]indole).
1184 (XXIII) JWH-193 (1-[2-(4-Morpholinyl)ethyl]-3-(4-methyl-1-
1185 naphthoyl)indole).
1186 (XXIV) JWH-198 (1-[2-(4-Morpholinyl)ethyl]-3-(4-methoxy-1-
1187 naphthoyl)indole).
1188 (XXV) JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-
1189 naphthoyl)indole).
1190 (XXVI) JWH-210 (1-Pentyl-3-(4-ethyl-1-naphthoyl)indole).
1191 (XXVII) JWH-387 (1-Pentyl-3-(4-bromo-1-naphthoyl)indole).
1192 (XXVIII) JWH-398 (1-Pentyl-3-(4-chloro-1-
1193 naphthoyl)indole).
1194 (XXIX) JWH-412 (1-Pentyl-3-(4-fluoro-1-naphthoyl)indole).
1195 (XXX) JWH-424 (1-Pentyl-3-(8-bromo-1-naphthoyl)indole).
1196 (XXXI) AM-1220 (1-[(1-Methyl-2-piperidinyl)methyl]-3-(1-
1197 naphthoyl)indole).
1198 (XXXII) AM-1235 (1-(5-Fluoropentyl)-6-nitro-3-(1-
1199 naphthoyl)indole).
1200 (XXXIII) AM-2201 (1-(5-Fluoropentyl)-3-(1-

1201 naphthoyl)indole).
1202 (XXXIV) Chloro JWH-018 (1-(Chloropentyl)-3-(1-
1203 naphthoyl)indole).
1204 (XXXV) Bromo JWH-018 (1-(Bromopentyl)-3-(1-
1205 naphthoyl)indole).
1206 (XXXVI) AM-2232 (1-(4-Cyanobutyl)-3-(1-naphthoyl)indole).
1207 (XXXVII) THJ-2201 (1-(5-Fluoropentyl)-3-(1-
1208 naphthoyl)indazole).
1209 (XXXVIII) MAM-2201 (1-(5-Fluoropentyl)-3-(4-methyl-1-
1210 naphthoyl)indole).
1211 (XXXIX) EAM-2201 (1-(5-Fluoropentyl)-3-(4-ethyl-1-
1212 naphthoyl)indole).
1213 (XL) EG-018 (9-Pentyl-3-(1-naphthoyl)carbazole).
1214 (XLI) EG-2201 (9-(5-Fluoropentyl)-3-(1-
1215 naphthoyl)carbazole).
1216 c. Naphthoylpyrroles.—Any compound containing a
1217 naphthoylpyrrole structure, with or without substitution on the
1218 pyrrole ring to any extent, whether or not substituted on the
1219 naphthyl ring to any extent, including, but not limited to:
1220 (I) JWH-030 (1-Pentyl-3-(1-naphthoyl)pyrrole).
1221 (II) JWH-031 (1-Hexyl-3-(1-naphthoyl)pyrrole).
1222 (III) JWH-145 (1-Pentyl-5-phenyl-3-(1-naphthoyl)pyrrole).
1223 (IV) JWH-146 (1-Heptyl-5-phenyl-3-(1-naphthoyl)pyrrole).
1224 (V) JWH-147 (1-Hexyl-5-phenyl-3-(1-naphthoyl)pyrrole).
1225 (VI) JWH-307 (1-Pentyl-5-(2-fluorophenyl)-3-(1-

1226 naphthoyl)pyrrole).
1227 (VII) JWH-309 (1-Pentyl-5-(1-naphthalenyl)-3-(1-
1228 naphthoyl)pyrrole).
1229 (VIII) JWH-368 (1-Pentyl-5-(3-fluorophenyl)-3-(1-
1230 naphthoyl)pyrrole).
1231 (IX) JWH-369 (1-Pentyl-5-(2-chlorophenyl)-3-(1-
1232 naphthoyl)pyrrole).
1233 (X) JWH-370 (1-Pentyl-5-(2-methylphenyl)-3-(1-
1234 naphthoyl)pyrrole).
1235 d. Naphthylmethylenindenes.—Any compound containing a
1236 naphthylmethylenindene structure, with or without substitution
1237 at the 3-position of the indene ring to any extent, whether or
1238 not substituted on the naphthyl ring to any extent, including,
1239 but not limited to, JWH-176 (3-Pentyl-1-
1240 (naphthylmethylene)indene).
1241 e. Phenylacetylindoles and Phenylacetylindazoles.—Any
1242 compound containing a phenylacetylindole or phenylacetylindazole
1243 structure, with or without substitution on the indole or
1244 indazole ring to any extent, whether or not substituted on the
1245 phenyl ring to any extent, including, but not limited to:
1246 (I) JWH-167 (1-Pentyl-3-(phenylacetyl)indole).
1247 (II) JWH-201 (1-Pentyl-3-(4-methoxyphenylacetyl)indole).
1248 (III) JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl)indole).
1249 (IV) JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole).
1250 (V) JWH-251 (1-Pentyl-3-(2-methylphenylacetyl)indole).

1251 (VI) JWH-302 (1-Pentyl-3-(3-methoxyphenylacetyl)indole).
1252 (VII) Cannabipiperidiethanone.
1253 (VIII) RCS-8 (1-(2-Cyclohexylethyl)-3-(2-
1254 methoxyphenylacetyl)indole).
1255 f. Cyclohexylphenols.—Any compound containing a
1256 cyclohexylphenol structure, with or without substitution at the
1257 5-position of the phenolic ring to any extent, whether or not
1258 substituted on the cyclohexyl ring to any extent, including, but
1259 not limited to:
1260 (I) CP 47,497 (2-(3-Hydroxycyclohexyl)-5-(2-methyloctan-2-
1261 yl)phenol).
1262 (II) Cannabicyclohexanol (CP 47,497 dimethyloctyl (C8)
1263 homologue).
1264 (III) CP-55,940 (2-(3-Hydroxy-6-propanol-cyclohexyl)-5-(2-
1265 methyloctan-2-yl)phenol).
1266 g. Benzoylindoles and Benzoylindazoles.—Any compound
1267 containing a benzoylindole or benzoylindazole structure, with or
1268 without substitution on the indole or indazole ring to any
1269 extent, whether or not substituted on the phenyl ring to any
1270 extent, including, but not limited to:
1271 (I) AM-679 (1-Pentyl-3-(2-iodobenzoyl)indole).
1272 (II) AM-694 (1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole).
1273 (III) AM-1241 (1-[(N-Methyl-2-piperidinyl)methyl]-3-(2-
1274 iodo-5-nitrobenzoyl)indole).
1275 (IV) Pravadoline (1-[2-(4-Morpholinyl)ethyl]-2-methyl-3-

1276 (4-methoxybenzoyl)indole).
1277 (V) AM-2233 (1-[(N-Methyl-2-piperidinyl)methyl]-3-(2-
1278 iodobenzoyl)indole).
1279 (VI) RCS-4 (1-Pentyl-3-(4-methoxybenzoyl)indole).
1280 (VII) RCS-4 C4 homologue (1-Butyl-3-(4-
1281 methoxybenzoyl)indole).
1282 (VIII) AM-630 (1-[2-(4-Morpholinyl)ethyl]-2-methyl-6-iodo-
1283 3-(4-methoxybenzoyl)indole).
1284 h. Tetramethylcyclopropanoylindoles and
1285 Tetramethylcyclopropanoylindazoles.—Any compound containing a
1286 tetramethylcyclopropanoylindole or
1287 tetramethylcyclopropanoylindazole structure, with or without
1288 substitution on the indole or indazole ring to any extent,
1289 whether or not substituted on the tetramethylcyclopropyl group
1290 to any extent, including, but not limited to:
1291 (I) UR-144 (1-Pentyl-3-(2,2,3,3-
1292 tetramethylcyclopropanoyl)indole).
1293 (II) XLR11 (1-(5-Fluoropentyl)-3-(2,2,3,3-
1294 tetramethylcyclopropanoyl)indole).
1295 (III) Chloro UR-144 (1-(Chloropentyl)-3-(2,2,3,3-
1296 tetramethylcyclopropanoyl)indole).
1297 (IV) A-796,260 (1-[2-(4-Morpholinyl)ethyl]-3-(2,2,3,3-
1298 tetramethylcyclopropanoyl)indole).
1299 (V) A-834,735 (1-[4-(Tetrahydropyranyl)methyl]-3-(2,2,3,3-
1300 tetramethylcyclopropanoyl)indole).

1301 (VI) M-144 (1-(5-Fluoropentyl)-2-methyl-3-(2,2,3,3-
1302 tetramethylcyclopropanoyl)indole).
1303 (VII) FUB-144 (1-(4-Fluorobenzyl)-3-(2,2,3,3-
1304 tetramethylcyclopropanoyl)indole).
1305 (VIII) FAB-144 (1-(5-Fluoropentyl)-3-(2,2,3,3-
1306 tetramethylcyclopropanoyl)indazole).
1307 (IX) XLR12 (1-(4,4,4-Trifluorobutyl)-3-(2,2,3,3-
1308 tetramethylcyclopropanoyl)indole).
1309 (X) AB-005 (1-[(1-Methyl-2-piperidinyl)methyl]-3-(2,2,3,3-
1310 tetramethylcyclopropanoyl)indole).
1311 i. Adamantoylindoles, Adamantoylindazoles, Adamantylindole
1312 carboxamides, and Adamantylindazole carboxamides.—Any compound
1313 containing an adamantoyl indole, adamantoyl indazole, adamantyl
1314 indole carboxamide, or adamantyl indazole carboxamide structure,
1315 with or without substitution on the indole or indazole ring to
1316 any extent, whether or not substituted on the adamantyl ring to
1317 any extent, including, but not limited to:
1318 (I) AKB48 (N-Adamant-1-yl 1-pentylindazole-3-carboxamide).
1319 (II) Fluoro AKB48 (N-Adamant-1-yl 1-
1320 (fluoropentyl)indazole-3-carboxamide).
1321 (III) STS-135 (N-Adamant-1-yl 1-(5-fluoropentyl)indole-3-
1322 carboxamide).
1323 (IV) AM-1248 (1-(1-Methylpiperidine)methyl-3-(1-
1324 adamantoyl)indole).
1325 (V) AB-001 (1-Pentyl-3-(1-adamantoyl)indole).

1326 (VI) APICA (N-Adamant-1-yl 1-pentylindole-3-carboxamide).
1327 (VII) Fluoro AB-001 (1-(Fluoropentyl)-3-(1-
1328 adamantoyl)indole).
1329 j. Quinolinylindolecarboxylates,
1330 Quinolinylindazolecarboxylates, Quinolinylindolecarboxamides,
1331 and Quinolinylindazolecarboxamides.—Any compound containing a
1332 quinolinylindole carboxylate, quinolinylindazole carboxylate,
1333 isoquinolinylindole carboxylate, isoquinolinylindazole
1334 carboxylate, quinolinylindole carboxamide, quinolinylindazole
1335 carboxamide, isoquinolinylindole carboxamide, or
1336 isoquinolinylindazole carboxamide structure, with or without
1337 substitution on the indole or indazole ring to any extent,
1338 whether or not substituted on the quinoline or isoquinoline ring
1339 to any extent, including, but not limited to:
1340 (I) PB-22 (8-Quinolinyl 1-pentylindole-3-carboxylate).
1341 (II) Fluoro PB-22 (8-Quinolinyl 1-(fluoropentyl)indole-3-
1342 carboxylate).
1343 (III) BB-22 (8-Quinolinyl 1-(cyclohexylmethyl)indole-3-
1344 carboxylate).
1345 (IV) FUB-PB-22 (8-Quinolinyl 1-(4-fluorobenzyl)indole-3-
1346 carboxylate).
1347 (V) NPB-22 (8-Quinolinyl 1-pentylindazole-3-carboxylate).
1348 (VI) Fluoro NPB-22 (8-Quinolinyl 1-(fluoropentyl)indazole-
1349 3-carboxylate).
1350 (VII) FUB-NPB-22 (8-Quinolinyl 1-(4-fluorobenzyl)indazole-

1351 3-carboxylate).
1352 (VIII) THJ (8-Quinolinyl 1-pentylindazole-3-carboxamide).
1353 (IX) Fluoro THJ (8-Quinolinyl 1-(fluoropentyl)indazole-3-
1354 carboxamide).
1355 k. Naphthylindolecarboxylates and
1356 Naphthylindazolecarboxylates.—Any compound containing a
1357 naphthylindole carboxylate or naphthylindazole carboxylate
1358 structure, with or without substitution on the indole or
1359 indazole ring to any extent, whether or not substituted on the
1360 naphthyl ring to any extent, including, but not limited to:
1361 (I) NM-2201 (1-Naphthalenyl 1-(5-fluoropentyl)indole-3-
1362 carboxylate).
1363 (II) SDB-005 (1-Naphthalenyl 1-pentylindazole-3-
1364 carboxylate).
1365 (III) Fluoro SDB-005 (1-Naphthalenyl 1-
1366 (fluoropentyl)indazole-3-carboxylate).
1367 (IV) FDU-PB-22 (1-Naphthalenyl 1-(4-fluorobenzyl)indole-3-
1368 carboxylate).
1369 (V) 3-CAF (2-Naphthalenyl 1-(2-fluorophenyl)indazole-3-
1370 carboxylate).
1371 l. Naphthylindole carboxamides and Naphthylindazole
1372 carboxamides.—Any compound containing a naphthylindole
1373 carboxamide or naphthylindazole carboxamide structure, with or
1374 without substitution on the indole or indazole ring to any
1375 extent, whether or not substituted on the naphthyl ring to any

1376 extent, including, but not limited to:
1377 (I) NNEI (N-Naphthalen-1-yl 1-pentylindole-3-carboxamide).
1378 (II) Fluoro-NNEI (N-Naphthalen-1-yl 1-
1379 (fluoropentyl)indole-3-carboxamide).
1380 (III) Chloro-NNEI (N-Naphthalen-1-yl 1-
1381 (chloropentyl)indole-3-carboxamide).
1382 (IV) MN-18 (N-Naphthalen-1-yl 1-pentylindazole-3-
1383 carboxamide).
1384 (V) Fluoro MN-18 (N-Naphthalen-1-yl 1-
1385 (fluoropentyl)indazole-3-carboxamide).
1386 m. Alkylcarbonyl indole carboxamides, Alkylcarbonyl
1387 indazole carboxamides, Alkylcarbonyl indole carboxylates, and
1388 Alkylcarbonyl indazole carboxylates.—Any compound containing an
1389 alkylcarbonyl group, including 1-amino-3-methyl-1-oxobutan-2-yl,
1390 1-methoxy-3-methyl-1-oxobutan-2-yl, 1-amino-1-oxo-3-
1391 phenylpropan-2-yl, 1-methoxy-1-oxo-3-phenylpropan-2-yl, with an
1392 indole carboxamide, indazole carboxamide, indole carboxylate, or
1393 indazole carboxylate, with or without substitution on the indole
1394 or indazole ring to any extent, whether or not substituted on
1395 the alkylcarbonyl group to any extent, including, but not
1396 limited to:
1397 (I) ADBICA, (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-
1398 pentylindole-3-carboxamide).
1399 (II) Fluoro ADBICA (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-
1400 yl)-1-(fluoropentyl)indole-3-carboxamide).

1401 (III) Fluoro ABICA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-
1402 1-(fluoropentyl)indole-3-carboxamide).
1403 (IV) AB-PINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-
1404 pentylindazole-3-carboxamide).
1405 (V) Fluoro AB-PINACA (N-(1-Amino-3-methyl-1-oxobutan-2-
1406 yl)-1-(fluoropentyl)indazole-3-carboxamide).
1407 (VI) ADB-PINACA (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-
1408 1-pentylindazole-3-carboxamide).
1409 (VII) Fluoro ADB-PINACA (N-(1-Amino-3,3-dimethyl-1-
1410 oxobutan-2-yl)-1-(fluoropentyl)indazole-3-carboxamide).
1411 (VIII) AB-FUBINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-
1412 1-(4-fluorobenzyl)indazole-3-carboxamide).
1413 (IX) ADB-FUBINACA (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-
1414 yl)-1-(4-fluorobenzyl)indazole-3-carboxamide).
1415 (X) AB-CHMINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-
1416 (cyclohexylmethyl)indazole-3-carboxamide).
1417 (XI) MA-CHMINACA (N-(1-Methoxy-3-methyl-1-oxobutan-2-yl)-
1418 1-(cyclohexylmethyl)indazole-3-carboxamide).
1419 (XII) MAB-CHMINACA (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-
1420 yl)-1-(cyclohexylmethyl)indazole-3-carboxamide).
1421 (XIII) AMB (N-(1-Methoxy-3-methyl-1-oxobutan-2-yl)-1-
1422 pentylindazole-3-carboxamide).
1423 (XIV) Fluoro-AMB (N-(1-Methoxy-3-methyl-1-oxobutan-2-yl)-
1424 1-(fluoropentyl)indazole-3-carboxamide).
1425 (XV) FUB-AMB (N-(1-Methoxy-3-methyl-1-oxobutan-2-yl)-1-(4-

1426 fluorobenzyl)indazole-3-carboxamide).
1427 (XVI) MDMB-CHMINACA (N-(1-Methoxy-3,3-dimethyl-1-oxobutan-
1428 2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide).
1429 (XVII) MDMB-FUBINACA (N-(1-Methoxy-3,3-dimethyl-1-
1430 oxobutan-2-yl)-1-(4-fluorobenzyl)indazole-3-carboxamide).
1431 (XVIII) MDMB-CHMICA (N-(1-Methoxy-3,3-dimethyl-1-oxobutan-
1432 2-yl)-1-(cyclohexylmethyl)indole-3-carboxamide).
1433 (XIX) PX-1 (N-(1-Amino-1-oxo-3-phenylpropan-2-yl)-1-(5-
1434 fluoropentyl)indole-3-carboxamide).
1435 (XX) PX-2 (N-(1-Amino-1-oxo-3-phenylpropan-2-yl)-1-(5-
1436 fluoropentyl)indazole-3-carboxamide).
1437 (XXI) PX-3 (N-(1-Amino-1-oxo-3-phenylpropan-2-yl)-1-
1438 (cyclohexylmethyl)indazole-3-carboxamide).
1439 (XXII) PX-4 (N-(1-Amino-1-oxo-3-phenylpropan-2-yl)-1-(4-
1440 fluorobenzyl)indazole-3-carboxamide).
1441 (XXIII) MO-CHMINACA (N-(1-Methoxy-3,3-dimethyl-1-oxobutan-
1442 2-yl)-1-(cyclohexylmethyl)indazole-3-carboxylate).
1443 n. Cumylindolecarboxamides and Cumylindazolecarboxamides.—
1444 Any compound containing a N-(2-phenylpropan-2-yl) indole
1445 carboxamide or N-(2-phenylpropan-2-yl) indazole carboxamide
1446 structure, with or without substitution on the indole or
1447 indazole ring to any extent, whether or not substituted on the
1448 phenyl ring of the cumyl group to any extent, including, but not
1449 limited to:
1450 (I) CUMYL-PICA (N-(2-Phenylpropan-2-yl)-1-pentylindole-3-

1451 carboxamide).
1452 (II) Fluoro CUMYL-PICA (N-(2-Phenylpropan-2-yl)-1-
1453 (fluoropentyl)indole-3-carboxamide).
1454 o. Other Synthetic Cannabinoids.—Any material, compound,
1455 mixture, or preparation that contains any quantity of a
1456 Synthetic Cannabinoid, as described in sub-subparagraphs a.-n.:
1457 (I) With or without modification or replacement of a
1458 carbonyl, carboxamide, alkylene, alkyl, or carboxylate linkage
1459 between either two core rings, or linkage between a core ring
1460 and group structure, with or without the addition of a carbon or
1461 replacement of a carbon;
1462 (II) With or without replacement of a core ring or group
1463 structure, whether or not substituted on the ring or group
1464 structures to any extent; and
1465 (III) Is a cannabinoid receptor agonist, unless
1466 specifically excepted or unless listed in another schedule or
1467 contained within a pharmaceutical product approved by the United
1468 States Food and Drug Administration.
1469 191. Substituted Cathinones.—Unless specifically excepted,
1470 listed in another schedule, or contained within a pharmaceutical
1471 product approved by the United States Food and Drug
1472 Administration, any material, compound, mixture, or preparation,
1473 including its salts, isomers, esters, or ethers, and salts of
1474 isomers, esters, or ethers, whenever the existence of such salts
1475 is possible within any of the following specific chemical

1476 designations:
1477 a. Any compound containing a 2-amino-1-phenyl-1-propanone
1478 structure;
1479 b. Any compound containing a 2-amino-1-naphthyl-1-
1480 propanone structure; or
1481 c. Any compound containing a 2-amino-1-thiophenyl-1-
1482 propanone structure,
1483
1484 whether or not the compound is further modified:
1485 (I) With or without substitution on the ring system to any
1486 extent with alkyl, alkylthio, thio, fused alkylenedioxy, alkoxy,
1487 haloalkyl, hydroxyl, nitro, fused furan, fused benzofuran, fused
1488 dihydrofuran, fused tetrahydropyran, fused alkyl ring, or halide
1489 substituents;
1490 (II) With or without substitution at the 3-propanone
1491 position with an alkyl substituent or removal of the methyl
1492 group at the 3-propanone position;
1493 (III) With or without substitution at the 2-amino nitrogen
1494 atom with alkyl, dialkyl, acetyl, or benzyl groups, whether or
1495 not further substituted in the ring system; or
1496 (IV) With or without inclusion of the 2-amino nitrogen
1497 atom in a cyclic structure, including, but not limited to:
1498 (A) Methcathinone.
1499 (B) Ethcathinone.
1500 (C) Methylone (3,4-Methylenedioxymethcathinone).

1501 (D) 2,3-Methylenedioxymethcathinone.
1502 (E) MDPV (3,4-Methylenedioxypyrovalerone).
1503 (F) Methylmethcathinone.
1504 (G) Methoxymethcathinone.
1505 (H) Fluoromethcathinone.
1506 (I) Methylethcathinone.
1507 (J) Butylone (3,4-Methylenedioxy-alpha-
1508 methylaminobutyrophenone).
1509 (K) Ethylone (3,4-Methylenedioxy-N-ethylcathinone).
1510 (L) BMDP (3,4-Methylenedioxy-N-benzylcathinone).
1511 (M) Naphyrone (Naphthylpyrovalerone).
1512 (N) Bromomethcathinone.
1513 (O) Buphedrone (alpha-Methylaminobutyrophenone).
1514 (P) Eutylone (3,4-Methylenedioxy-alpha-
1515 ethylaminobutyrophenone).
1516 (Q) Dimethylcathinone.
1517 (R) Dimethylmethcathinone.
1518 (S) Pentylone (3,4-Methylenedioxy-alpha-
1519 methylaminovalerophenone).
1520 (T) Pentedrone (alpha-Methylaminovalerophenone).
1521 (U) MDPPP (3,4-Methylenedioxy-alpha-
1522 pyrrolidinopropiophenone).
1523 (V) MDPBP (3,4-Methylenedioxy-alpha-
1524 pyrrolidinobutyrophenone).
1525 (W) MPPP (Methyl-alpha-pyrrolidinopropiophenone).

1526 (X) PPP (Pyrrolidinopropiophenone).
1527 (Y) PVP (Pyrrolidinovalerophenone) or
1528 (Pyrrolidinopentiophenone).
1529 (Z) MOPPP (Methoxy-alpha-pyrrolidinopropiophenone).
1530 (AA) MPHP (Methyl-alpha-pyrrolidinohexanophenone).
1531 (BB) F-MABP (Fluoromethylaminobutyrophenone).
1532 (CC) Me-EABP (Methylethylaminobutyrophenone).
1533 (DD) PBP (Pyrrolidinobutyrophenone).
1534 (EE) MeO-PBP (Methoxypyrrolidinobutyrophenone).
1535 (FF) Et-PBP (Ethylpyrrolidinobutyrophenone).
1536 (GG) 3-Me-4-MeO-MCAT (3-Methyl-4-Methoxymethcathinone).
1537 (HH) Dimethylone (3,4-Methylenedioxy-N,N-
1538 dimethylcathinone).
1539 (II) 3,4-Methylenedioxy-N,N-diethylcathinone.
1540 (JJ) 3,4-Methylenedioxy-N-acetylcathinone.
1541 (KK) 3,4-Methylenedioxy-N-acetylmethcathinone.
1542 (LL) 3,4-Methylenedioxy-N-acetylethcathinone.
1543 (MM) Methylbuphedrone (Methyl-alpha-
1544 methylaminobutyrophenone).
1545 (NN) Methyl-alpha-methylaminohexanophenone.
1546 (OO) N-Ethyl-N-methylcathinone.
1547 (PP) PHP (Pyrrolidinohexanophenone).
1548 (QQ) PV8 (Pyrrolidinoheptanophenone).
1549 (RR) Chloromethcathinone.
1550 (SS) 4-Bromo-2,5-dimethoxy-alpha-aminoacetophenone.

1551 192. Substituted Phenethylamines.—Unless specifically
1552 excepted or unless listed in another schedule, or contained
1553 within a pharmaceutical product approved by the United States
1554 Food and Drug Administration, any material, compound, mixture,
1555 or preparation, including its salts, isomers, esters, or ethers,
1556 and salts of isomers, esters, or ethers, whenever the existence
1557 of such salts is possible within any of the following specific
1558 chemical designations, any compound containing a phenethylamine
1559 structure, without a beta-keto group, and without a benzyl group
1560 attached to the amine group, whether or not the compound is
1561 further modified with or without substitution on the phenyl ring
1562 to any extent with alkyl, alkylthio, nitro, alkoxy, thio,
1563 halide, fused alkylenedioxy, fused furan, fused benzofuran,
1564 fused dihydrofuran, or fused tetrahydropyran substituents,
1565 whether or not further substituted on a ring to any extent, with
1566 or without substitution at the alpha or beta position by any
1567 alkyl substituent, with or without substitution at the nitrogen
1568 atom, and with or without inclusion of the 2-amino nitrogen atom
1569 in a cyclic structure, including, but not limited to:
1570 a. 2C-B (4-Bromo-2,5-dimethoxyphenethylamine).
1571 b. 2C-E (4-Ethyl-2,5-dimethoxyphenethylamine).
1572 c. 2C-T-4 (4-Isopropylthio-2,5-dimethoxyphenethylamine).
1573 d. 2C-C (4-Chloro-2,5-dimethoxyphenethylamine).
1574 e. 2C-T (4-Methylthio-2,5-dimethoxyphenethylamine).
1575 f. 2C-T-2 (4-Ethylthio-2,5-dimethoxyphenethylamine).

1576 g. 2C-T-7 (4-(n)-Propylthio-2,5-dimethoxyphenethylamine).
1577 h. 2C-I (4-Iodo-2,5-dimethoxyphenethylamine).
1578 i. 2C-D (4-Methyl-2,5-dimethoxyphenethylamine).
1579 j. 2C-H (2,5-Dimethoxyphenethylamine).
1580 k. 2C-N (4-Nitro-2,5-dimethoxyphenethylamine).
1581 l. 2C-P (4-(n)-Propyl-2,5-dimethoxyphenethylamine).
1582 m. MDMA (3,4-Methylenedioxymethamphetamine).
1583 n. MBDB (Methylbenzodioxolylbutanamine) or (3,4-
1584 Methylenedioxy-N-methylbutanamine).
1585 o. MDA (3,4-Methylenedioxyamphetamine).
1586 p. 2,5-Dimethoxyamphetamine.
1587 q. Fluoroamphetamine.
1588 r. Fluoromethamphetamine.
1589 s. MDEA (3,4-Methylenedioxy-N-ethylamphetamine).
1590 t. DOB (4-Bromo-2,5-dimethoxyamphetamine).
1591 u. DOC (4-Chloro-2,5-dimethoxyamphetamine).
1592 v. DOET (4-Ethyl-2,5-dimethoxyamphetamine).
1593 w. DOI (4-Iodo-2,5-dimethoxyamphetamine).
1594 x. DOM (4-Methyl-2,5-dimethoxyamphetamine).
1595 y. PMA (4-Methoxyamphetamine).
1596 z. N-Ethylamphetamine.
1597 aa. 3,4-Methylenedioxy-N-hydroxyamphetamine.
1598 bb. 5-Methoxy-3,4-methylenedioxyamphetamine.
1599 cc. PMMA (4-Methoxymethamphetamine).
1600 dd. N,N-Dimethylamphetamine.

1601 ee. 3,4,5-Trimethoxyamphetamine.
1602 ff. 4-APB (4-(2-Aminopropyl)benzofuran).
1603 gg. 5-APB (5-(2-Aminopropyl)benzofuran).
1604 hh. 6-APB (6-(2-Aminopropyl)benzofuran).
1605 ii. 7-APB (7-(2-Aminopropyl)benzofuran).
1606 jj. 4-APDB (4-(2-Aminopropyl)-2,3-dihydrobenzofuran).
1607 kk. 5-APDB (5-(2-Aminopropyl)-2,3-dihydrobenzofuran).
1608 ll. 6-APDB (6-(2-Aminopropyl)-2,3-dihydrobenzofuran).
1609 mm. 7-APDB (7-(2-Aminopropyl)-2,3-dihydrobenzofuran).
1610 nn. 4-MAPB (4-(2-Methylaminopropyl)benzofuran).
1611 oo. 5-MAPB (5-(2-Methylaminopropyl)benzofuran).
1612 pp. 6-MAPB (6-(2-Methylaminopropyl)benzofuran).
1613 qq. 7-MAPB (7-(2-Methylaminopropyl)benzofuran).
1614 rr. 5-EAPB (5-(2-Ethylaminopropyl)benzofuran).
1615 ss. 5-MAPDB (5-(2-Methylaminopropyl)-2,3-
1616 dihydrobenzofuran),
1617
1618 which does not include phenethylamine, mescaline as described in
1619 subparagraph 20., substituted cathinones as described in
1620 subparagraph 191., N-Benzyl phenethylamine compounds as
1621 described in subparagraph 193., or methamphetamine as described
1622 in subparagraph (2)(c)5. ~~(2)(c)4.~~
1623 193. N-Benzyl Phenethylamine Compounds.—Unless
1624 specifically excepted or unless listed in another schedule, or
1625 contained within a pharmaceutical product approved by the United

1626 States Food and Drug Administration, any material, compound,
1627 mixture, or preparation, including its salts, isomers, esters,
1628 or ethers, and salts of isomers, esters, or ethers, whenever the
1629 existence of such salts is possible within any of the following
1630 specific chemical designations, any compound containing a
1631 phenethylamine structure without a beta-keto group, with
1632 substitution on the nitrogen atom of the amino group with a
1633 benzyl substituent, with or without substitution on the phenyl
1634 or benzyl ring to any extent with alkyl, alkoxy, thio,
1635 alkylthio, halide, fused alkylenedioxy, fused furan, fused
1636 benzofuran, or fused tetrahydropyran substituents, whether or
1637 not further substituted on a ring to any extent, with or without
1638 substitution at the alpha position by any alkyl substituent,
1639 including, but not limited to:
1640 a. 25B-NBOMe (4-Bromo-2,5-dimethoxy-[N-(2-
1641 methoxybenzyl)]phenethylamine).
1642 b. 25B-NBOH (4-Bromo-2,5-dimethoxy-[N-(2-
1643 hydroxybenzyl)]phenethylamine).
1644 c. 25B-NBF (4-Bromo-2,5-dimethoxy-[N-(2-
1645 fluorobenzyl)]phenethylamine).
1646 d. 25B-NBMD (4-Bromo-2,5-dimethoxy-[N-(2,3-
1647 methylenedioxybenzyl)]phenethylamine).
1648 e. 25I-NBOMe (4-Iodo-2,5-dimethoxy-[N-(2-
1649 methoxybenzyl)]phenethylamine).
1650 f. 25I-NBOH (4-Iodo-2,5-dimethoxy-[N-(2-

1651 hydroxybenzyl)]phenethylamine).
1652 g. 25I-NBF (4-Iodo-2,5-dimethoxy-[N-(2-
1653 fluorobenzyl)]phenethylamine).
1654 h. 25I-NBMD (4-Iodo-2,5-dimethoxy-[N-(2,3-
1655 methylenedioxybenzyl)]phenethylamine).
1656 i. 25T2-NBOMe (4-Methylthio-2,5-dimethoxy-[N-(2-
1657 methoxybenzyl)]phenethylamine).
1658 j. 25T4-NBOMe (4-Isopropylthio-2,5-dimethoxy-[N-(2-
1659 methoxybenzyl)]phenethylamine).
1660 k. 25T7-NBOMe (4-(n)-Propylthio-2,5-dimethoxy-[N-(2-
1661 methoxybenzyl)]phenethylamine).
1662 l. 25C-NBOMe (4-Chloro-2,5-dimethoxy-[N-(2-
1663 methoxybenzyl)]phenethylamine).
1664 m. 25C-NBOH (4-Chloro-2,5-dimethoxy-[N-(2-
1665 hydroxybenzyl)]phenethylamine).
1666 n. 25C-NBF (4-Chloro-2,5-dimethoxy-[N-(2-
1667 fluorobenzyl)]phenethylamine).
1668 o. 25C-NBMD (4-Chloro-2,5-dimethoxy-[N-(2,3-
1669 methylenedioxybenzyl)]phenethylamine).
1670 p. 25H-NBOMe (2,5-Dimethoxy-[N-(2-
1671 methoxybenzyl)]phenethylamine).
1672 q. 25H-NBOH (2,5-Dimethoxy-[N-(2-
1673 hydroxybenzyl)]phenethylamine).
1674 r. 25H-NBF (2,5-Dimethoxy-[N-(2-
1675 fluorobenzyl)]phenethylamine).

1676 s. 25D-NBOMe (4-Methyl-2,5-dimethoxy-[N-(2-
1677 methoxybenzyl)]phenethylamine),
1678
1679 which does not include substituted cathinones as described in
1680 subparagraph 191.
1681 194. Substituted Tryptamines.—Unless specifically excepted
1682 or unless listed in another schedule, or contained within a
1683 pharmaceutical product approved by the United States Food and
1684 Drug Administration, any material, compound, mixture, or
1685 preparation containing a 2-(1H-indol-3-yl)ethanamine, for
1686 example tryptamine, structure with or without mono- or di-
1687 substitution of the amine nitrogen with alkyl or alkenyl groups,
1688 or by inclusion of the amino nitrogen atom in a cyclic
1689 structure, whether or not substituted at the alpha position with
1690 an alkyl group, whether or not substituted on the indole ring to
1691 any extent with any alkyl, alkoxy, halo, hydroxyl, or acetoxy
1692 groups, including, but not limited to:
1693 a. Alpha-Ethyltryptamine.
1694 b. Bufotenine.
1695 c. DET (Diethyltryptamine).
1696 d. DMT (Dimethyltryptamine).
1697 e. MET (N-Methyl-N-ethyltryptamine).
1698 f. DALT (N,N-Diallyltryptamine).
1699 g. EiPT (N-Ethyl-N-isopropyltryptamine).
1700 h. MiPT (N-Methyl-N-isopropyltryptamine).

1701 i. 5-Hydroxy-AMT (5-Hydroxy-alpha-methyltryptamine).
1702 j. 5-Hydroxy-N-methyltryptamine.
1703 k. 5-MeO-MiPT (5-Methoxy-N-methyl-N-isopropyltryptamine).
1704 l. 5-MeO-AMT (5-Methoxy-alpha-methyltryptamine).
1705 m. Methyltryptamine.
1706 n. 5-MeO-DMT (5-Methoxy-N,N-dimethyltryptamine).
1707 o. 5-Me-DMT (5-Methyl-N,N-dimethyltryptamine).
1708 p. 5-MeO-DiPT (5-Methoxy-N,N-Diisopropyltryptamine).
1709 q. DiPT (N,N-Diisopropyltryptamine).
1710 r. DPT (N,N-Dipropyltryptamine).
1711 s. 4-Hydroxy-DiPT (4-Hydroxy-N,N-diisopropyltryptamine).
1712 t. 5-MeO-DALT (5-Methoxy-N,N-Diallyltryptamine).
1713 u. 4-AcO-DMT (4-Acetoxy-N,N-dimethyltryptamine).
1714 v. 4-AcO-DiPT (4-Acetoxy-N,N-diisopropyltryptamine).
1715 w. 4-Hydroxy-DET (4-Hydroxy-N,N-diethyltryptamine).
1716 x. 4-Hydroxy-MET (4-Hydroxy-N-methyl-N-ethyltryptamine).
1717 y. 4-Hydroxy-MiPT (4-Hydroxy-N-methyl-N-
1718 isopropyltryptamine).
1719 z. Methyl-alpha-ethyltryptamine.
1720 aa. Bromo-DALT (Bromo-N,N-diallyltryptamine),
1721
1722 which does not include tryptamine, psilocyn as described in
1723 subparagraph 34., or psilocybin as described in subparagraph 33.
1724 195. Substituted Phenylcyclohexylamines.—Unless
1725 specifically excepted or unless listed in another schedule, or

1726 contained within a pharmaceutical product approved by the United
1727 States Food and Drug Administration, any material, compound,
1728 mixture, or preparation containing a phenylcyclohexylamine
1729 structure, with or without any substitution on the phenyl ring,
1730 any substitution on the cyclohexyl ring, any replacement of the
1731 phenyl ring with a thiophenyl or benzothiophenyl ring, with or
1732 without substitution on the amine with alkyl, dialkyl, or alkoxy
1733 substituents, inclusion of the nitrogen in a cyclic structure,
1734 or any combination of the above, including, but not limited to:
1735 a. BTCP (Benzothiophenylcyclohexylpiperidine) or BCP
1736 (Benocyclidine).
1737 b. PCE (N-Ethyl-1-phenylcyclohexylamine)(Ethylamine analog
1738 of phencyclidine).
1739 c. PCPY (N-(1-Phenylcyclohexyl)-pyrrolidine)(Pyrrolidine
1740 analog of phencyclidine).
1741 d. PCPr (Phenylcyclohexylpropylamine).
1742 e. TCP (1-[1-(2-Thienyl)-cyclohexyl]-piperidine)(Thiophene
1743 analog of phencyclidine).
1744 f. PCEEA (Phenylcyclohexyl(ethoxyethylamine)).
1745 g. PCMPA (Phenylcyclohexyl(methoxypropylamine)).
1746 h. Methoxetamine.
1747 i. 3-Methoxy-PCE ((3-Methoxyphenyl)cyclohexylethylamine).
1748 j. Bromo-PCP ((Bromophenyl)cyclohexylpiperidine).
1749 k. Chloro-PCP ((Chlorophenyl)cyclohexylpiperidine).
1750 l. Fluoro-PCP ((Fluorophenyl)cyclohexylpiperidine).

1751 m. Hydroxy-PCP ((Hydroxyphenyl)cyclohexylpiperidine).
1752 n. Methoxy-PCP ((Methoxyphenyl)cyclohexylpiperidine).
1753 o. Methyl-PCP ((Methylphenyl)cyclohexylpiperidine).
1754 p. Nitro-PCP ((Nitrophenyl)cyclohexylpiperidine).
1755 q. Oxo-PCP ((Oxophenyl)cyclohexylpiperidine).
1756 r. Amino-PCP ((Aminophenyl)cyclohexylpiperidine).
1757 196. W-15, 4-chloro-N-[1-(2-phenylethyl)-2-
1758 piperidinylidene]-benzenesulfonamide.
1759 197. W-18, 4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]-2-
1760 piperidinylidene]-benzenesulfonamide.
1761 198. AH-7921, 3,4-dichloro-N-[[1-
1762 (dimethylamino)cyclohexyl]methyl]-benzamide.
1763 199. U47700, trans-3,4-dichloro-N-[2-
1764 (dimethylamino)cyclohexyl]-N-methyl-benzamide.
1765 200. MT-45, 1-cyclohexyl-4-(1,2-diphenylethyl)-piperazine,
1766 dihydrochloride.
1767 (2) SCHEDULE II.—A substance in Schedule II has a high
1768 potential for abuse and has a currently accepted but severely
1769 restricted medical use in treatment in the United States, and
1770 abuse of the substance may lead to severe psychological or
1771 physical dependence. The following substances are controlled in
1772 Schedule II:
1773 (a) Unless specifically excepted or unless listed in
1774 another schedule, any of the following substances, whether
1775 produced directly or indirectly by extraction from substances of

1776 vegetable origin or independently by means of chemical
1777 synthesis:
1778 1. Opium and any salt, compound, derivative, or
1779 preparation of opium, except nalmefene or isoquinoline alkaloids
1780 of opium, including, but not limited to the following:
1781 a. Raw opium.
1782 b. Opium extracts.
1783 c. Opium fluid extracts.
1784 d. Powdered opium.
1785 e. Granulated opium.
1786 f. Tincture of opium.
1787 g. Codeine.
1788 h. Dihydroetorphine.
1789 i.~~h.~~ Ethylmorphine.
1790 j.~~i.~~ Etorphine hydrochloride.
1791 k.~~j.~~ Hydrocodone and hydrocodone combination products.
1792 l.~~k.~~ Hydromorphone.
1793 m.~~l.~~ Levo-alphacetylmethadol (also known as levo-alpha-
1794 acetylmethadol, levomethadyl acetate, or LAAM).
1795 n.~~m.~~ Metopon (methyldihydromorphinone).
1796 o.~~n.~~ Morphine.
1797 p. Oripavine.
1798 q.~~o.~~ Oxycodone.
1799 r.~~p.~~ Oxymorphone.
1800 s.~~q.~~ Thebaine.

1801 2. Any salt, compound, derivative, or preparation of a
1802 substance which is chemically equivalent to or identical with
1803 any of the substances referred to in subparagraph 1., except
1804 that these substances shall not include the isoquinoline
1805 alkaloids of opium.
1806 3. Any part of the plant of the species *Papaver*
1807 *somniferum, L.*
1808 4. Cocaine or ecgonine, including any of their
1809 stereoisomers, and any salt, compound, derivative, or
1810 preparation of cocaine or ecgonine, except that these substances
1811 shall not include ioflupane I 123.
1812 (b) Unless specifically excepted or unless listed in
1813 another schedule, any of the following substances, including
1814 their isomers, esters, ethers, salts, and salts of isomers,
1815 esters, and ethers, whenever the existence of such isomers,
1816 esters, ethers, and salts is possible within the specific
1817 chemical designation:
1818 1. Alfentanil.
1819 2. Alphaprodine.
1820 3. Anileridine.
1821 4. Bezitramide.
1822 5. Bulk propoxyphene (nondosage forms).
1823 6. Carfentanil.
1824 7. Dihydrocodeine.
1825 8. Diphenoxylate.

1826 9. Fentanyl.
1827 10. Isomethadone.
1828 11. Levomethorphan.
1829 12. Levorphanol.
1830 13. Metazocine.
1831 14. Methadone.
1832 15. Methadone-Intermediate,4-cyano-2-
1833 dimethylamino-4,4-diphenylbutane.
1834 16. Moramide-Intermediate,2-methyl-
1835 3-morpholoino-1,1-diphenylpropane-carboxylic acid.
1836 17. Nabilone.
1837 18. Pethidine (meperidine).
1838 19. Pethidine-Intermediate-A,4-cyano-1-
1839 methyl-4-phenylpiperidine.
1840 20. Pethidine-Intermediate-B,ethyl-4-
1841 phenylpiperidine-4-carboxylate.
1842 21. Pethidine-Intermediate-C,1-methyl-4- phenylpiperidine-
1843 4-carboxylic acid.
1844 22. Phenazocine.
1845 23. Phencyclidine.
1846 24. 1-Phenylcyclohexylamine.
1847 25. Piminodine.
1848 26. 1-Piperidinocyclohexanecarbonitrile.
1849 27. Racemethorphan.
1850 28. Racemorphan.

1851 29. Remifentanil.
1852 30.~~29.~~ Sufentanil.
1853 31. Tapentadol.
1854 32. Thiafentanil.
1855 (c) Unless specifically excepted or unless listed in
1856 another schedule, any material, compound, mixture, or
1857 preparation which contains any quantity of the following
1858 substances, including their salts, isomers, optical isomers,
1859 salts of their isomers, and salts of their optical isomers:
1860 1. Amobarbital.
1861 2. Amphetamine.
1862 3. Glutethimide.
1863 4. Lisdexamfetamine.
1864 5.~~4.~~ Methamphetamine.
1865 6.~~5.~~ Methylphenidate.
1866 7.~~6.~~ Pentobarbital.
1867 8.~~7.~~ Phenmetrazine.
1868 9.~~8.~~ Phenylacetone.
1869 10.~~9.~~ Secobarbital.
1870 (d) Dronabinol (synthetic THC) in oral solution in a drug
1871 product approved by the United States Food and Drug
1872 Administration.
1873 (3) SCHEDULE III.—A substance in Schedule III has a
1874 potential for abuse less than the substances contained in
1875 Schedules I and II and has a currently accepted medical use in

1876 treatment in the United States, and abuse of the substance may
1877 lead to moderate or low physical dependence or high
1878 psychological dependence or, in the case of anabolic steroids,
1879 may lead to physical damage. The following substances are
1880 controlled in Schedule III:
1881 (a) Unless specifically excepted or unless listed in
1882 another schedule, any material, compound, mixture, or
1883 preparation which contains any quantity of the following
1884 substances having a depressant or stimulant effect on the
1885 nervous system:
1886 1. Any substance which contains any quantity of a
1887 derivative of barbituric acid, including thiobarbituric acid, or
1888 any salt of a derivative of barbituric acid or thiobarbituric
1889 acid, including, but not limited to, butabarbital and
1890 butalbital.
1891 2. Benzphetamine.
1892 3. Buprenorphine.
1893 4.~~3.~~ Chlorhexadol.
1894 5.~~4.~~ Chlorphentermine.
1895 6.~~5.~~ Clortermine.
1896 7. Embutramide.
1897 8.~~6.~~ Lysergic acid.
1898 9.~~7.~~ Lysergic acid amide.
1899 10.~~8.~~ Methyprylon.
1900 11. Perampanel.

1901 12.~~9.~~ Phendimetrazine.
1902 13.~~10.~~ Sulfondiethylmethane.
1903 14.~~11.~~ Sulfonethylmethane.
1904 15.~~12.~~ Sulfonmethane.
1905 16.~~13.~~ Tiletamine and zolazepam or any salt thereof.
1906 (b) Nalorphine.
1907 (c) Unless specifically excepted or unless listed in
1908 another schedule, any material, compound, mixture, or
1909 preparation containing limited quantities of any of the
1910 following controlled substances or any salts thereof:
1911 1. Not more than 1.8 grams of codeine per 100 milliliters
1912 or not more than 90 milligrams per dosage unit, with an equal or
1913 greater quantity of an isoquinoline alkaloid of opium.
1914 2. Not more than 1.8 grams of codeine per 100 milliliters
1915 or not more than 90 milligrams per dosage unit, with recognized
1916 therapeutic amounts of one or more active ingredients which are
1917 not controlled substances.
1918 3. Not more than 300 milligrams of hydrocodone per 100
1919 milliliters or not more than 15 milligrams per dosage unit, with
1920 a fourfold or greater quantity of an isoquinoline alkaloid of
1921 opium.
1922 4. Not more than 300 milligrams of hydrocodone per 100
1923 milliliters or not more than 15 milligrams per dosage unit, with
1924 recognized therapeutic amounts of one or more active ingredients
1925 that are not controlled substances.

1926 5. Not more than 1.8 grams of dihydrocodeine per 100
1927 milliliters or not more than 90 milligrams per dosage unit, with
1928 recognized therapeutic amounts of one or more active ingredients
1929 which are not controlled substances.
1930 6. Not more than 300 milligrams of ethylmorphine per 100
1931 milliliters or not more than 15 milligrams per dosage unit, with
1932 one or more active, nonnarcotic ingredients in recognized
1933 therapeutic amounts.
1934 7. Not more than 50 milligrams of morphine per 100
1935 milliliters or per 100 grams, with recognized therapeutic
1936 amounts of one or more active ingredients which are not
1937 controlled substances.
1938
1939 For purposes of charging a person with a violation of s. 893.135
1940 involving any controlled substance described in subparagraph 3.
1941 or subparagraph 4., the controlled substance is a Schedule III
1942 controlled substance pursuant to this paragraph but the weight
1943 of the controlled substance per milliliters or per dosage unit
1944 is not relevant to the charging of a violation of s. 893.135.
1945 The weight of the controlled substance shall be determined
1946 pursuant to s. 893.135(6).
1947 (d) Anabolic steroids.
1948 1. The term "anabolic steroid" means any drug or hormonal
1949 substance, chemically and pharmacologically related to
1950 testosterone, other than estrogens, progestins, and

1951 corticosteroids, that promotes muscle growth and includes:
1952 a. Androsterone.
1953 b. Androsterone acetate.
1954 c. Boldenone.
1955 d. Boldenone acetate.
1956 e. Boldenone benzoate.
1957 f. Boldenone undecylenate.
1958 g. Chlorotestosterone (Clostebol).
1959 h. Dehydrochlormethyltestosterone.
1960 i. Dihydrotestosterone (Stanolone).
1961 j. Drostanolone.
1962 k. Ethylestrenol.
1963 l. Fluoxymesterone.
1964 m. Formebulone (Formebolone).
1965 n. Mesterolone.
1966 o. Methandrostenolone (Methandienone).
1967 p. Methandranone.
1968 q. Methandriol.
1969 r. Methenolone.
1970 s. Methyltestosterone.
1971 t. Mibolerone.
1972 u. Nortestosterone (Nandrolone).
1973 v. Norethandrolone.
1974 w. Nortestosterone decanoate.
1975 x. Nortestosterone phenylpropionate.

1976 y. Nortestosterone propionate.
1977 z. Oxandrolone.
1978 aa. Oxymesterone.
1979 bb. Oxymetholone.
1980 cc. Stanozolol.
1981 dd. Testolactone.
1982 ee. Testosterone.
1983 ff. Testosterone acetate.
1984 gg. Testosterone benzoate.
1985 hh. Testosterone cypionate.
1986 ii. Testosterone decanoate.
1987 jj. Testosterone enanthate.
1988 kk. Testosterone isocaproate.
1989 ll. Testosterone oleate.
1990 mm. Testosterone phenylpropionate.
1991 nn. Testosterone propionate.
1992 oo. Testosterone undecanoate.
1993 pp. Trenbolone.
1994 qq. Trenbolone acetate.
1995 rr. Any salt, ester, or isomer of a drug or substance
1996 described or listed in this subparagraph if that salt, ester, or
1997 isomer promotes muscle growth.
1998 2. The term does not include an anabolic steroid that is
1999 expressly intended for administration through implants to cattle
2000 or other nonhuman species and that has been approved by the

2001 United States Secretary of Health and Human Services for such
2002 administration. However, any person who prescribes, dispenses,
2003 or distributes such a steroid for human use is considered to
2004 have prescribed, dispensed, or distributed an anabolic steroid
2005 within the meaning of this paragraph.
2006 (e) Ketamine, including any isomers, esters, ethers,
2007 salts, and salts of isomers, esters, and ethers, whenever the
2008 existence of such isomers, esters, ethers, and salts is possible
2009 within the specific chemical designation.
2010 (f) Dronabinol (synthetic THC) in sesame oil and
2011 encapsulated in a soft gelatin capsule in a drug product
2012 approved by the United States Food and Drug Administration.
2013 (g) Any drug product containing gamma-hydroxybutyric acid,
2014 including its salts, isomers, and salts of isomers, for which an
2015 application is approved under s. 505 of the Federal Food, Drug,
2016 and Cosmetic Act.
2017 (4)(a) SCHEDULE IV.—A substance in Schedule IV has a low
2018 potential for abuse relative to the substances in Schedule III
2019 and has a currently accepted medical use in treatment in the
2020 United States, and abuse of the substance may lead to limited
2021 physical or psychological dependence relative to the substances
2022 in Schedule III.
2023 (b) Unless specifically excepted or unless listed in
2024 another schedule, any material, compound, mixture, or
2025 preparation which contains any quantity of the following

2026 substances, including its salts, isomers, and salts of isomers
2027 whenever the existence of such salts, isomers, and salts of
2028 isomers is possible within the specific chemical designation,
2029 are controlled in Schedule IV:
2030 1. Alfaxalone.
2031 2.~~(a)~~ Alprazolam.
2032 3.~~(b)~~ Barbital.
2033 4.~~(c)~~ Bromazepam.
2034 5.~~(iii)~~ Butorphanol tartrate.
2035 6.~~(d)~~ Camazepam.
2036 7.~~(jjj)~~ Carisoprodol.
2037 8.~~(e)~~ Cathine.
2038 9.~~(f)~~ Chloral betaine.
2039 10.~~(g)~~ Chloral hydrate.
2040 11.~~(h)~~ Chlordiazepoxide.
2041 12.~~(i)~~ Clobazam.
2042 13.~~(j)~~ Clonazepam.
2043 14.~~(k)~~ Clorazepate.
2044 15.~~(l)~~ Clotiazepam.
2045 16.~~(m)~~ Cloxazolam.
2046 17. Dexfenfluramine.
2047 18.~~(n)~~ Delorazepam.
2048 19. Dichloralphenazone.
2049 20.~~(p)~~ Diazepam.
2050 21.~~(q)~~ Diethylpropion.

2051 22. Eluxadoline.
2052 23.~~(r)~~ Estazolam.
2053 24. Eszopiclone.
2054 25.~~(s)~~ Ethchlorvynol.
2055 26.~~(t)~~ Ethinamate.
2056 27.~~(u)~~ Ethyl loflazepate.
2057 28.~~(v)~~ Fencamfamin.
2058 29.~~(w)~~ Fenfluramine.
2059 30.~~(x)~~ Fenproporex.
2060 31.~~(y)~~ Fludiazepam.
2061 32.~~(z)~~ Flurazepam.
2062 33. Fospropofol.
2063 34.~~(aa)~~ Halazepam.
2064 35.~~(bb)~~ Haloxazolam.
2065 36.~~(cc)~~ Ketazolam.
2066 37.~~(dd)~~ Loprazolam.
2067 38.~~(ee)~~ Lorazepam.
2068 39. Lorcaserin.
2069 40.~~(ff)~~ Lormetazepam.
2070 41.~~(gg)~~ Mazindol.
2071 42.~~(hh)~~ Mebutamate.
2072 43.~~(ii)~~ Medazepam.
2073 44.~~(jj)~~ Mefenorex.
2074 45.~~(kk)~~ Meprobamate.
2075 46.~~(ll)~~ Methohexital.

2076 47. ~~(mm)~~ Methylphenobarbital.
2077 48. ~~(nn)~~ Midazolam.
2078 49. Modafinil.
2079 50. ~~(oo)~~ Nimetazepam.
2080 51. ~~(pp)~~ Nitrazepam.
2081 52. ~~(qq)~~ Nordiazepam.
2082 53. ~~(rr)~~ Oxazepam.
2083 54. ~~(ss)~~ Oxazolam.
2084 55. ~~(tt)~~ Paraldehyde.
2085 56. ~~(uu)~~ Pemoline.
2086 57. ~~(vv)~~ Pentazocine.
2087 58. Petrichloral.
2088 59. ~~(ww)~~ Phenobarbital.
2089 60. ~~(xx)~~ Phentermine.
2090 61. ~~(yy)~~ Pinazepam.
2091 62. ~~(zz)~~ Pipradrol.
2092 63. ~~(aaa)~~ Prazepam.
2093 64. ~~(o)~~ Propoxyphene (dosage forms).
2094 65. ~~(bbb)~~ Propylhexedrine, excluding any patent or
2095 proprietary preparation containing propylhexedrine, unless
2096 otherwise provided by federal law.
2097 66. ~~(ccc)~~ Quazepam.
2098 67. Sibutramine.
2099 68. ~~(ccc)~~ SPA[(-)-1 dimethylamino-1, 2
2100 diphenylethane].

2101 69. Suvorexant.
2102 70.~~(fff)~~ Temazepam.
2103 71.~~(ddd)~~ Tetrazepam.
2104 72. Tramadol.
2105 73.~~(ggg)~~ Triazolam.
2106 74. Zaleplon.
2107 75. Zolpidem.
2108 76. Zopiclone.
2109 77.~~(hhh)~~ Not more than 1 milligram of difenoxin and not
2110 less than 25 micrograms of atropine sulfate per dosage unit.
2111 (5) SCHEDULE V.—A substance, compound, mixture, or
2112 preparation of a substance in Schedule V has a low potential for
2113 abuse relative to the substances in Schedule IV and has a
2114 currently accepted medical use in treatment in the United
2115 States, and abuse of such compound, mixture, or preparation may
2116 lead to limited physical or psychological dependence relative to
2117 the substances in Schedule IV.
2118 (a) Substances controlled in Schedule V include any
2119 compound, mixture, or preparation containing any of the
2120 following limited quantities of controlled substances, which
2121 must ~~shall~~ include one or more active medicinal ingredients that
2122 ~~which~~ are not controlled substances in sufficient proportion to
2123 confer upon the compound, mixture, or preparation valuable
2124 medicinal qualities other than those possessed by the controlled
2125 substance alone:

2126 1. Not more than 200 milligrams of codeine per 100
2127 milliliters or per 100 grams.
2128 2. Not more than 100 milligrams of dihydrocodeine per 100
2129 milliliters or per 100 grams.
2130 3. Not more than 100 milligrams of ethylmorphine per 100
2131 milliliters or per 100 grams.
2132 4. Not more than 2.5 milligrams of diphenoxylate and not
2133 less than 25 micrograms of atropine sulfate per dosage unit.
2134 5. Not more than 100 milligrams of opium per 100
2135 milliliters or per 100 grams.
2136 6. Not more than 0.5 milligrams of difenoxin and not less
2137 than 25 micrograms of atropine sulfate per dosage unit.
2138 (b) Unless a specific exception exists or unless listed in
2139 another schedule, any material, compound, mixture, or
2140 preparation that contains any quantity of the following
2141 substances is controlled in Schedule V:
2142 1. Brivaracetam.
2143 2. Ezogabine.
2144 3. Lacosamide.
2145 4. Pregabalin ~~Narcotic drugs. Unless specifically excepted~~
2146 ~~or unless listed in another schedule, any material, compound,~~
2147 ~~mixture, or preparation containing any of the following narcotic~~
2148 ~~drugs and their salts: Buprenorphine~~.
2149 (c) Stimulants. Unless specifically excepted or unless
2150 listed in another schedule, any material, compound, mixture, or

2151 preparation which contains any quantity of the following
2152 substances having a stimulant effect on the central nervous
2153 system, including its salts, isomers, and salts of isomers:
2154 Pyrovalerone.
2155 Section 9. Subsection (1) of section 893.04, Florida
2156 Statutes, is amended to read:
2157 893.04 Pharmacist and practitioner.—
2158 (1) A pharmacist, in good faith and in the course of
2159 professional practice only, may dispense controlled substances
2160 upon a written, ~~or~~ oral, or electronic prescription of a
2161 practitioner, under the following conditions:
2162 (a) Oral prescriptions must be promptly reduced to writing
2163 by the pharmacist or recorded electronically if permitted by
2164 federal law.
2165 (b) The written prescription must be dated and signed by
2166 the prescribing practitioner on the day when issued.
2167 (c) There shall appear on the face of the prescription or
2168 written record thereof for the controlled substance the
2169 following information:
2170 1. The full name and address of the person for whom, or
2171 the owner of the animal for which, the controlled substance is
2172 dispensed.
2173 2. The full name and address of the prescribing
2174 practitioner and the practitioner's federal controlled substance
2175 registry number shall be printed thereon.

2176 3. If the prescription is for an animal, the species of
2177 animal for which the controlled substance is prescribed.
2178 4. The name of the controlled substance prescribed and the
2179 strength, quantity, and directions for use thereof.
2180 5. The number of the prescription, as recorded in the
2181 prescription files of the pharmacy in which it is filled.
2182 6. The initials of the pharmacist filling the prescription
2183 and the date filled.
2184 (d) The prescription shall be retained on file by the
2185 proprietor of the pharmacy in which it is filled for a period of
2186 2 years.
2187 (e) Affixed to the original container in which a
2188 controlled substance is delivered upon a prescription or
2189 authorized refill thereof, as hereinafter provided, there shall
2190 be a label bearing the following information:
2191 1. The name and address of the pharmacy from which such
2192 controlled substance was dispensed.
2193 2. The date on which the prescription for such controlled
2194 substance was filled.
2195 3. The number of such prescription, as recorded in the
2196 prescription files of the pharmacy in which it is filled.
2197 4. The name of the prescribing practitioner.
2198 5. The name of the patient for whom, or of the owner and
2199 species of the animal for which, the controlled substance is
2200 prescribed.

2201 6. The directions for the use of the controlled substance
2202 prescribed in the prescription.
2203 7. A clear, concise warning that it is a crime to transfer
2204 the controlled substance to any person other than the patient
2205 for whom prescribed.
2206 (f) A prescription for a controlled substance listed in
2207 Schedule II may be dispensed only upon a written or electronic
2208 prescription of a practitioner, except that in an emergency
2209 situation, as defined by regulation of the Department of Health,
2210 such controlled substance may be dispensed upon oral
2211 prescription but is limited to a 72-hour supply. A prescription
2212 for a controlled substance listed in Schedule II may not be
2213 refilled.
2214 (g) A prescription for a controlled substance listed in
2215 Schedule III, Schedule IV, or Schedule V may not be filled or
2216 refilled more than five times within a period of 6 months after
2217 the date on which the prescription was written unless the
2218 prescription is renewed by a practitioner.
2219 Section 10. Section 893.055, Florida Statutes, is amended
2220 to read:
2221 (Substantial rewording of section. See
2222 s. 893.055, F.S., for present text.)
2223 893.055 Prescription drug monitoring program.—
2224 (1) As used in this section, the term:
2225 (a) "Active investigation" means an investigation that is

2226 being conducted with a reasonable, good faith belief that it
2227 could lead to the filing of administrative, civil, or criminal
2228 proceedings, or that is ongoing and continuing and for which
2229 there is a reasonable, good faith anticipation of securing an
2230 arrest or prosecution in the foreseeable future.
2231 (b) "Administration" means the obtaining and giving of a
2232 single dose of a controlled substance by a legally authorized
2233 person to a patient for her or his consumption.
2234 (c) "Controlled substance" means a controlled substance
2235 listed in Schedule II, Schedule III, Schedule IV, or Schedule V
2236 of s. 893.03 or 21 U.S.C. s. 812.
2237 (d) "Dispense" means the transfer of possession of one or
2238 more doses of a controlled substance by a dispenser to the
2239 ultimate consumer or to his or her agent.
2240 (e) "Dispenser" means a dispensing health care
2241 practitioner, pharmacy, or pharmacist licensed to dispense
2242 controlled substances in or into this state.
2243 (f) "Health care practitioner" or "practitioner" means any
2244 practitioner licensed under chapter 458, chapter 459, chapter
2245 461, chapter 463, chapter 464, chapter 465, or chapter 466.
2246 (g) "Health care regulatory board" has the same meaning as
2247 in s. 456.001(1).
2248 (h) "Law enforcement agency" means the Department of Law
2249 Enforcement, a sheriff's office in this state, a police
2250 department in this state, or a law enforcement agency of the

2251 Federal Government which enforces the laws of this state or the
2252 United States relating to controlled substances and whose agents
2253 and officers are empowered by law to conduct criminal
2254 investigations and make arrests.
2255 (i) "Pharmacy" includes a community pharmacy, an
2256 institutional pharmacy, a nuclear pharmacy, a special pharmacy,
2257 or an Internet pharmacy that is licensed by the department under
2258 chapter 465 and that dispenses or delivers controlled substances
2259 to an individual or address in this state.
2260 (j) "Prescriber" means a prescribing physician,
2261 prescribing practitioner, or other prescribing health care
2262 practitioner authorized by the laws of this state to order
2263 controlled substances.
2264 (k) "Program manager" means an employee of or a person
2265 contracted by the department who is designated to ensure the
2266 integrity of the prescription drug monitoring program in
2267 accordance with the requirements established in this section.
2268 (2)(a) The department shall maintain an electronic system
2269 to collect and store controlled substance dispensing information
2270 and shall release the information as authorized in this section
2271 and s. 893.0551. The electronic system must:
2272 1. Not infringe upon the legitimate prescribing or
2273 dispensing of a controlled substance by a prescriber or
2274 dispenser acting in good faith and in the course of professional
2275 practice.

2276 2. Be consistent with standards of the American Society
2277 for Automation in Pharmacy.
2278 3. Comply with the Health Insurance Portability and
2279 Accountability Act as it pertains to protected health
2280 information, electronic protected health information, and all
2281 other relevant state and federal privacy and security laws and
2282 regulations.
2283 4. Purge or cause to be purged information in the database
2284 that is more than 4 years old.
2285 (b) The department may collaborate with professional
2286 health care regulatory boards, appropriate organizations, and
2287 other state agencies to identify indicators of controlled
2288 substance abuse.
2289 (3)(a) For each controlled substance dispensed to a
2290 patient in this state, the following information must be
2291 reported by the dispenser to the system as soon thereafter as
2292 possible but no later than the close of the next business day
2293 after the day the controlled substance is dispensed unless an
2294 extension or exemption is approved by the department:
2295 1. The name of the prescribing practitioner, the
2296 practitioner's federal Drug Enforcement Administration
2297 registration number, the practitioner's National Provider
2298 Identification or other appropriate identifier, and the date of
2299 the prescription.
2300 2. The date the prescription was filled and the method of

2301 payment, such as cash by an individual, insurance coverage
2302 through a third party, or Medicaid payment. This paragraph does
2303 not authorize the department to include individual credit card
2304 numbers or other account numbers in the system.
2305 3. The full name, address, telephone number, and date of
2306 birth of the person for whom the prescription was written.
2307 4. The name, national drug code, quantity, and strength of
2308 the controlled substance dispensed.
2309 5. The full name, federal Drug Enforcement Administration
2310 registration number, State of Florida Department of Health
2311 issued pharmacy permit number, and address of the pharmacy or
2312 other location from which the controlled substance was
2313 dispensed. If the controlled substance was dispensed by a
2314 practitioner other than a pharmacist, the practitioner's full
2315 name, address, federal Drug Enforcement Administration
2316 registration number, State of Florida Department of Health
2317 issued license number, and National Provider Identification.
2318 6. Whether the drug was dispensed as an initial
2319 prescription or a refill, and the number of refills ordered.
2320 7. The name of the individual picking up the controlled
2321 substance prescription and type and issuer of the identification
2322 provided.
2323 8. Other appropriate identifying information as determined
2324 by department rule.
2325 (b) The following acts of administration or dispensing are

2326 exempt from the reporting requirements of this subsection:
2327 1. All acts of administration of a controlled substance.
2328 2. The dispensing of a controlled substance in the health
2329 care system of the Department of Corrections.
2330 3. The dispensing of a controlled substance to a person
2331 under the age of 16.
2332 (4) The following persons must be provided direct access
2333 to information in the system:
2334 (a) A prescriber or dispenser or his or her designee.
2335 (b) An employee of the United States Department of
2336 Veterans Affairs, the United States Department of Defense, or
2337 the Indian Health Service who provides health care services
2338 pursuant to such employment and who has the authority to
2339 prescribe or dispense controlled substances shall have access to
2340 the information in the program's system upon verification of
2341 employment.
2342 (c) The program manager or designated program and support
2343 staff to administer the system.
2344 1. In order to calculate performance measures pursuant to
2345 subsection (14), the program manager or program and support
2346 staff members who have been directed by the program manager to
2347 calculate performance measures may have direct access to
2348 information that contains no identifying information of any
2349 patient, physician, health care practitioner, prescriber, or
2350 dispenser.

2351 2. The program manager or designated program and support
2352 staff must provide the department, upon request, data that does
2353 not contain patient, physician, health care practitioner,
2354 prescriber, or dispenser identifying information for public
2355 health care and safety initiatives purposes.
2356 3. The program manager, upon determining a pattern
2357 consistent with the department's rules established under
2358 subsection (16), may provide relevant information to the
2359 prescriber and dispenser.
2360 4. The program manager, upon determining a pattern
2361 consistent with the rules established under subsection (16) and
2362 having cause to believe a violation of s. 893.13(7)(a)8.,
2363 (8)(a), or (8)(b) has occurred, may provide relevant information
2364 to the applicable law enforcement agency.
2365
2366 The program manager and designated program and support staff
2367 must complete a level II background screening.
2368 (5) The following entities may not directly access
2369 information in the system, but may request information from the
2370 program manager or designated program and support staff:
2371 (a) The department and its health care regulatory boards,
2372 as appropriate, for investigations involving licensees
2373 authorized to prescribe or dispense controlled substances.
2374 (b) The Attorney General for Medicaid fraud cases
2375 involving prescribed controlled substances.

2376 (c) A law enforcement agency during active investigations
2377 of potential criminal activity, fraud, or theft regarding
2378 prescribed controlled substances.
2379 (d) A medical examiner when conducting an authorized
2380 investigation under s. 406.11, to determine the cause of death
2381 of an individual.
2382 (e) An impaired practitioner consultant who is retained by
2383 the department under s. 456.076 to review the system information
2384 of an impaired practitioner program participant or a referral
2385 who has agreed to be evaluated or monitored through the program
2386 and who has separately agreed in writing to the consultant's
2387 access to and review of such information.
2388 (f) A patient or the legal guardian or designated health
2389 care surrogate of an incapacitated patient who submits a written
2390 and notarized request that includes the patient's full name,
2391 address, phone number, date of birth, and a copy of a
2392 government-issued photo identification.
2393 (6) The department may enter into one or more reciprocal
2394 agreements or contracts to share prescription drug monitoring
2395 information with other states, districts, or territories if the
2396 prescription drug monitoring programs of such other states,
2397 districts, or territories are compatible with the Florida
2398 program.
2399 (a) In determining compatibility, the department shall
2400 consider:

2401 1. The safeguards for privacy of patient records and the
2402 success of the program in protecting patient privacy.
2403 2. The persons authorized to view the data collected by
2404 the program. Comparable entities and licensed health care
2405 practitioners in other states, districts, or territories of the
2406 United States, law enforcement agencies, the Attorney General's
2407 Medicaid Fraud Control Unit, medical regulatory boards, and, as
2408 needed, management staff that have similar duties as management
2409 staff who work with the prescription drug monitoring program as
2410 authorized in s. 893.0551 are authorized access upon approval by
2411 the department.
2412 3. The schedules of the controlled substances that are
2413 monitored by the program.
2414 4. The data reported to or included in the program's
2415 system.
2416 5. Any implementing criteria deemed essential for a
2417 thorough comparison.
2418 6. The costs and benefits to the state of sharing
2419 prescription information.
2420 (b) The department shall assess the prescription drug
2421 monitoring program's continued compatibility with other states',
2422 districts', or territories' programs every 4 years.
2423 (c) Any agreements or contracts for sharing of
2424 prescription drug monitoring information between the department
2425 and other states, districts, or territories shall contain the

2426 same restrictions and requirements as this section or s.
2427 893.0551, and the information must be provided according to the
2428 department's determination of compatibility.
2429 (7) The department may enter into agreements or contracts
2430 to establish secure connections between the system and a
2431 prescribing or dispensing health care practitioner's electronic
2432 health recordkeeping system. The electronic health recordkeeping
2433 system owner or license holder will be responsible for ensuring
2434 that only authorized individuals have access to prescription
2435 drug monitoring program information.
2436 (8) A prescriber or dispenser or a designee of a
2437 prescriber or dispenser must consult the system to review a
2438 patient's controlled substance dispensing history before
2439 prescribing or dispensing a controlled substance for a patient
2440 age 16 or older. This requirement does not apply when
2441 prescribing or dispensing a nonopioid controlled substance
2442 listed in Schedule V of s. 893.03 or 21 U.S.C. 812. For purposes
2443 of this subsection, a "nonopioid controlled substance" is a
2444 controlled substance that does not contain any amount of a
2445 substance listed as an opioid in s. 893.03 or 21 U.S.C. 812.
2446 (a) The duty to consult the system does not apply when the
2447 system:
2448 1. Is determined by the department to be nonoperational;
2449 or
2450 2. Cannot be accessed by the prescriber or dispenser or a

2451 designee of the prescriber or dispenser because of a temporary
2452 technological or electrical failure.
2453 (b) A prescriber or dispenser or designee of a prescriber
2454 or dispenser who does not consult the system under this
2455 subsection shall document the reason he or she did not consult
2456 the system in the patient's medical record or prescription
2457 record and shall not prescribe or dispense greater than a 3-day
2458 supply of a controlled substance to the patient.
2459 (c) The department shall issue a nondisciplinary citation
2460 to any prescriber or dispenser who fails to consult the system
2461 as required by this subsection for an initial offense. Each
2462 subsequent offense is subject to disciplinary action pursuant to
2463 s. 456.073.
2464 (9) A person who willfully and knowingly fails to report
2465 the dispensing of a controlled substance as required by this
2466 section commits a misdemeanor of the first degree, punishable as
2467 provided in s. 775.082 or s. 775.083.
2468 (10) Information in the prescription drug monitoring
2469 program's system may be released only as provided in this
2470 section and s. 893.0551. The content of the system is intended
2471 to be informational only. Information in the system is not
2472 subject to discovery or introduction into evidence in any civil
2473 or administrative action against a prescriber, dispenser,
2474 pharmacy, or patient arising out of matters that are the subject
2475 of information in the system. The program manager and authorized

2476 persons who participate in preparing, reviewing, issuing, or any
2477 other activity related to management of the system may not be
2478 permitted or required to testify in any such civil or
2479 administrative action as to any findings, recommendations,
2480 evaluations, opinions, or other actions taken in connection with
2481 management of the system.
2482 (11) A prescriber or dispenser, or his or her designee,
2483 may have access to the information under this section which
2484 relates to a patient of that prescriber or dispenser as needed
2485 for the purpose of reviewing the patient's controlled drug
2486 prescription history. A prescriber or dispenser acting in good
2487 faith is immune from any civil, criminal, or administrative
2488 liability that might otherwise be incurred or imposed for
2489 receiving or using information from the prescription drug
2490 monitoring program. This subsection does not create a private
2491 cause of action, and a person may not recover damages against a
2492 prescriber or dispenser authorized to access information under
2493 this subsection for accessing or failing to access such
2494 information.
2495 (12)(a) All costs incurred by the department in
2496 administering the prescription drug monitoring program shall be
2497 funded through federal grants, private funding applied for or
2498 received by the state, or state funds appropriated in the
2499 General Appropriations Act. The department may not:
2500 1. Commit funds for the monitoring program without

2501 ensuring funding is available; or
2502 2. Use funds provided, directly or indirectly, by
2503 prescription drug manufacturers to implement the program.
2504 (b) The department shall cooperate with the direct-support
2505 organization established under subsection (15) in seeking
2506 federal grant funds, other nonstate grant funds, gifts,
2507 donations, or other private moneys for the department if the
2508 costs of doing so are immaterial. Immaterial costs include, but
2509 are not limited to, the costs of mailing and personnel assigned
2510 to research or apply for a grant. The department may
2511 competitively procure and contract pursuant to s. 287.057 for
2512 any goods and services required by this section.
2513 (13) The department shall conduct or participate in
2514 studies to examine the feasibility of enhancing the prescription
2515 drug monitoring program for the purposes of public health
2516 initiatives and statistical reporting. Such studies shall
2517 respect the privacy of the patient, the prescriber, and the
2518 dispenser. Such studies may be conducted by the department or a
2519 contracted vendor in order to:
2520 (a) Improve the quality of health care services and safety
2521 by improving prescribing and dispensing practices for controlled
2522 substances;
2523 (b) Take advantage of advances in technology;
2524 (c) Reduce duplicative prescriptions and the
2525 overprescribing of controlled substances; and

2526 (d) Reduce drug abuse.
2527 (14) The department shall annually report on performance
2528 measures to the Governor, the President of the Senate, and the
2529 Speaker of the House of Representatives by December 1.
2530 Performance measures may include, but are not limited to, the
2531 following outcomes:
2532 (a) Reduction of the rate of inappropriate use of
2533 controlled substances through department education and safety
2534 efforts.
2535 (b) Reduction of the quantity of controlled substances
2536 obtained by individuals attempting to engage in fraud and
2537 deceit.
2538 (c) Increased coordination among partners participating in
2539 the prescription drug monitoring program.
2540 (d) Involvement of stakeholders in achieving improved
2541 patient health care and safety and reduction of controlled
2542 substance abuse and controlled substance diversion.
2543 (15) The department may establish a direct-support
2544 organization to provide assistance, funding, and promotional
2545 support for the activities authorized for the prescription drug
2546 monitoring program.
2547 (a) As used in this subsection, the term "direct-support
2548 organization" means an organization that is:
2549 1. A Florida corporation not for profit incorporated under
2550 chapter 617, exempted from filing fees, and approved by the

2551 Department of State.
2552 2. Organized and operated to conduct programs and
2553 activities; raise funds; request and receive grants, gifts, and
2554 bequests of money; acquire, receive, hold, and invest, in its
2555 own name, securities, funds, objects of value, or other
2556 property, either real or personal; and make expenditures or
2557 provide funding to or for the direct or indirect benefit of the
2558 department in the furtherance of the prescription drug
2559 monitoring program.
2560 (b) The State Surgeon General shall appoint a board of
2561 directors for the direct-support organization.
2562 1. The board of directors shall consist of no fewer than
2563 five members who shall serve at the pleasure of the State
2564 Surgeon General.
2565 2. The State Surgeon General shall provide guidance to
2566 members of the board to ensure that moneys received by the
2567 direct-support organization are not received from inappropriate
2568 sources. Inappropriate sources include, but are not limited to,
2569 donors, grantors, persons, prescription drug manufacturers, or
2570 organizations that may monetarily or substantively benefit from
2571 the purchase of goods or services by the department in
2572 furtherance of the prescription drug monitoring program.
2573 (c) The direct-support organization shall operate under
2574 written contract with the department. The contract must, at a
2575 minimum, provide for:

2576 1. Approval of the articles of incorporation and bylaws of
2577 the direct-support organization by the department.
2578 2. Submission of an annual budget for the approval of the
2579 department.
2580 3. The reversion, without penalty, to the department's
2581 grants and donations trust fund for the administration of the
2582 prescription drug monitoring program of all moneys and property
2583 held in trust by the direct-support organization for the benefit
2584 of the prescription drug monitoring program if the direct-
2585 support organization ceases to exist or if the contract is
2586 terminated.
2587 4. The fiscal year of the direct-support organization,
2588 which must begin July 1 of each year and end June 30 of the
2589 following year.
2590 5. The disclosure of the material provisions of the
2591 contract to donors of gifts, contributions, or bequests,
2592 including such disclosure on all promotional and fundraising
2593 publications, and an explanation to such donors of the
2594 distinction between the department and the direct-support
2595 organization.
2596 6. The direct-support organization's collecting,
2597 expending, and providing of funds to the department for the
2598 development, implementation, and operation of the prescription
2599 drug monitoring program as described in this section. The
2600 direct-support organization may collect and expend funds to be

2601 used for the functions of the direct-support organization's
2602 board of directors, as necessary and approved by the department.
2603 In addition, the direct-support organization may collect and
2604 provide funding to the department in furtherance of the
2605 prescription drug monitoring program by:
2606 a. Establishing and administering the prescription drug
2607 monitoring program's electronic system, including hardware and
2608 software.
2609 b. Conducting studies on the efficiency and effectiveness
2610 of the program to include feasibility studies as described in
2611 subsection (13).
2612 c. Providing funds for future enhancements of the program
2613 within the intent of this section.
2614 d. Providing user training of the prescription drug
2615 monitoring program, including distribution of materials to
2616 promote public awareness and education and conducting workshops
2617 or other meetings for health care practitioners, pharmacists,
2618 and others as appropriate.
2619 e. Providing funds for travel expenses.
2620 f. Providing funds for administrative costs, including
2621 personnel, audits, facilities, and equipment.
2622 g. Fulfilling all other requirements necessary to
2623 implement and operate the program as outlined in this section.
2624 7. Certification by the department that the direct-support
2625 organization is complying with the terms of the contract in a

2626 manner consistent with and in furtherance of the goals and
2627 purposes of the prescription drug monitoring program and in the
2628 best interests of the state. Such certification must be made
2629 annually and reported in the official minutes of a meeting of
2630 the direct-support organization.
2631 (d) The activities of the direct-support organization must
2632 be consistent with the goals and mission of the department, as
2633 determined by the department, and in the best interests of the
2634 state. The direct-support organization must obtain written
2635 approval from the department for any activities in support of
2636 the prescription drug monitoring program before undertaking
2637 those activities.
2638 (e) The direct-support organization shall provide for an
2639 independent annual financial audit in accordance with s.
2640 215.981. Copies of the audit shall be provided to the department
2641 and the Office of Policy and Budget in the Executive Office of
2642 the Governor.
2643 (f) The direct-support organization may not exercise any
2644 power under s. 617.0302(12) or (16).
2645 (g) The direct-support organization is not considered a
2646 lobbying firm within the meaning of s. 11.045.
2647 (h) The department may permit, without charge, appropriate
2648 use of administrative services, property, and facilities of the
2649 department by the direct-support organization, subject to this
2650 section. The use must be directly in keeping with the approved

2651 purposes of the direct-support organization and may not be made
2652 at times or places that would unreasonably interfere with
2653 opportunities for the public to use such facilities for
2654 established purposes. Any moneys received from rentals of
2655 facilities and properties managed by the department may be held
2656 in a separate depository account in the name of the direct-
2657 support organization and subject to the provisions of the letter
2658 of agreement with the department. The letter of agreement must
2659 provide that any funds held in the separate depository account
2660 in the name of the direct-support organization must revert to
2661 the department if the direct-support organization is no longer
2662 approved by the department to operate in the best interests of
2663 the state.
2664 (i) The department may adopt rules under s. 120.54 to
2665 govern the use of administrative services, property, or
2666 facilities of the department or office by the direct-support
2667 organization.
2668 (j) The department may not permit the use of any
2669 administrative services, property, or facilities of the state by
2670 a direct-support organization if that organization does not
2671 provide equal membership and employment opportunities to all
2672 persons regardless of race, color, religion, gender, age, or
2673 national origin.
2674 (k) This subsection is repealed October 1, 2027, unless
2675 reviewed and saved from repeal by the Legislature.

2676 (16) The department shall adopt rules necessary to
2677 implement this section.
2678 Section 11. Section 893.0551, Florida Statutes, is amended
2679 to read:
2680 893.0551 Public records exemption for the prescription
2681 drug monitoring program.—
2682 (1) For purposes of this section, the terms used in this
2683 section have the same meanings as provided in s. 893.055.
2684 (2) The following information of a patient or patient's
2685 agent, a health care practitioner, a dispenser, an employee of
2686 the practitioner who is acting on behalf of and at the direction
2687 of the practitioner, a pharmacist, or a pharmacy that is
2688 contained in records held by the department under s. 893.055 is
2689 confidential and exempt from s. 119.07(1) and s. 24(a), Art. I
2690 of the State Constitution:
2691 (a) Name.
2692 (b) Address.
2693 (c) Telephone number.
2694 (d) Insurance plan number.
2695 (e) Government-issued identification number.
2696 (f) Provider number.
2697 (g) Drug Enforcement Administration number.
2698 (h) Any other unique identifying information or number.
2699 (3) The department shall disclose such ~~confidential and~~
2700 ~~exempt~~ information to the following persons or entities upon

2701 request and after using a verification process to ensure the
2702 legitimacy of the request as provided in s. 893.055:
2703 (a) A health care practitioner, or his or her designee,
2704 who certifies that the information is necessary to provide
2705 medical treatment to a current patient in accordance with ss.
2706 893.04, 893.05, and 893.055.
2707 (b) An employee of the United States Department of
2708 Veterans Affairs, the United States Department of Defense, or
2709 the Indian Health Service who provides health care services
2710 pursuant to such employment and who has the authority to
2711 prescribe or dispense controlled substances shall have access to
2712 the information in the program's system upon verification of
2713 such employment.
2714 (c) The program manager and designated support staff for
2715 administration of the program, and to provide relevant
2716 information to the prescriber, dispenser, and appropriate law
2717 enforcement agencies, in accordance with s. 893.055.
2718 (d) The department and its relevant health care regulatory
2719 boards for investigations involving licensees authorized to
2720 prescribe or dispense controlled substances. The department or
2721 health care regulatory board may request information from the
2722 program but may not have direct access to its system. The
2723 department may provide to a law enforcement agency pursuant to
2724 ss. 456.066 and 456.073 only information that is relevant to the
2725 specific controlled substances investigation that prompted the

2726 request for the information.
2727 (e) ~~(a)~~ The Attorney General or his or her designee when
2728 working on Medicaid fraud cases involving prescribed controlled
2729 substances ~~prescription drugs~~ or when the Attorney General has
2730 initiated a review of specific identifiers of Medicaid fraud or
2731 specific identifiers that warrant a Medicaid investigation
2732 regarding prescribed controlled substances ~~prescription drugs~~.
2733 The Attorney General's Medicaid fraud investigators may not have
2734 direct access to the department's system ~~database~~. The Attorney
2735 General or his or her designee may disclose to a criminal
2736 justice agency, as defined in s. 119.011, only the ~~confidential~~
2737 ~~and exempt~~ information received from the department that is
2738 relevant to an identified active investigation that prompted the
2739 request for the information.
2740 ~~(b) The department's relevant health care regulatory~~
2741 ~~boards responsible for the licensure, regulation, or discipline~~
2742 ~~of a practitioner, pharmacist, or other person who is authorized~~
2743 ~~to prescribe, administer, or dispense controlled substances and~~
2744 ~~who is involved in a specific controlled substances~~
2745 ~~investigation for prescription drugs involving a designated~~
2746 ~~person. The health care regulatory boards may request~~
2747 ~~information from the department but may not have direct access~~
2748 ~~to its database. The health care regulatory boards may provide~~
2749 ~~to a law enforcement agency pursuant to ss. 456.066 and 456.073~~
2750 ~~only information that is relevant to the specific controlled~~

2751 ~~substances investigation that prompted the request for the~~
2752 ~~information.~~
2753 (f) ~~(e)~~ A law enforcement agency that has initiated an
2754 active investigation involving a specific violation of law
2755 regarding prescription drug abuse or diversion of prescribed
2756 controlled substances and that has entered into a user agreement
2757 with the department. A law enforcement agency may request
2758 information from the department but may not have direct access
2759 to its system ~~database~~. The law enforcement agency may disclose
2760 to a criminal justice agency, as defined in s. 119.011, only
2761 ~~confidential and exempt~~ information received from the department
2762 that is relevant to an identified active investigation that
2763 prompted the request for such information.
2764 (g) A district medical examiner or associate medical
2765 examiner, as described in s. 406.06, pursuant to his or her
2766 official duties, as required by s. 406.11, to determine the
2767 cause of death of an individual. Such medical examiners may
2768 request information from the department but may not have direct
2769 access to the system
2770 ~~(d) A health care practitioner, or his or her designee,~~
2771 ~~who certifies that the information is necessary to provide~~
2772 ~~medical treatment to a current patient in accordance with ss.~~
2773 ~~893.05 and 893.055.~~
2774 ~~(e) A pharmacist, or his or her designee, who certifies~~
2775 ~~that the requested information will be used to dispense~~

2776 ~~controlled substances to a current patient in accordance with~~
2777 ~~ss. 893.04 and 893.055.~~
2778 ~~(f) A patient or the legal guardian or designated health~~
2779 ~~care surrogate for an incapacitated patient, if applicable,~~
2780 ~~making a request as provided in s. 893.055(7)(c)4.~~
2781 ~~(g) The patient's pharmacy, prescriber, or dispenser, or~~
2782 ~~the designee of the pharmacy, prescriber, or dispenser, who~~
2783 ~~certifies that the information is necessary to provide medical~~
2784 ~~treatment to his or her current patient in accordance with s.~~
2785 ~~893.055~~.
2786 (h) An impaired practitioner consultant who has been
2787 authorized in writing by a participant in, or by a referral to,
2788 the impaired practitioner program to access and review
2789 information as provided in s. 893.055(5)(e) ~~893.055(7)(c)5~~.
2790 (i) A patient or the legal guardian or designated health
2791 care surrogate for an incapacitated patient, if applicable,
2792 making a request as provided in s. 893.055(5)(f).
2793 (4) If the department determines consistent with its rules
2794 that a pattern of controlled substance abuse exists, the
2795 department may disclose such confidential and exempt information
2796 to the applicable law enforcement agency in accordance with s.
2797 893.055. The law enforcement agency may disclose to a criminal
2798 justice agency, as defined in s. 119.011, only ~~confidential and~~
2799 ~~exempt~~ information received from the department that is relevant
2800 to an identified active investigation that is specific to a

2801 violation of s. 893.13(7)(a)8., s. 893.13(8)(a), or s.
2802 893.13(8)(b).
2803 (5) Before disclosing ~~confidential and exempt~~ information
2804 to a criminal justice agency or a law enforcement agency
2805 pursuant to this section, the disclosing person or entity must
2806 take steps to ensure the continued confidentiality of all
2807 ~~confidential and exempt~~ information. At a minimum, these steps
2808 must include redacting any nonrelevant information.
2809 (6) An agency or person who obtains any ~~confidential and~~
2810 ~~exempt~~ information pursuant to this section must maintain the
2811 confidential and exempt status of that information and may not
2812 disclose such information unless authorized by law. Information
2813 shared with a state attorney pursuant to paragraph (3)(f) ~~(3)(a)~~
2814 or paragraph (3)(h) ~~(3)(c)~~ may be released only in response to a
2815 discovery demand if such information is directly related to the
2816 criminal case for which the information was requested. Unrelated
2817 information may be released only upon an order of a court of
2818 competent jurisdiction.
2819 (7) A person who willfully and knowingly violates this
2820 section commits a felony of the third degree, punishable as
2821 provided in s. 775.082, s. 775.083, or s. 775.084.
2822 Section 12. Paragraphs (a), (c), (d), (e), (f), and (h) of
2823 subsection (1), subsection (2), paragraphs (a) and (b) of
2824 subsection (4), and subsections (5) and (7) of section 893.13,
2825 Florida Statutes, are amended to read:

2826 893.13 Prohibited acts; penalties.—
2827 (1)(a) Except as authorized by this chapter and chapter
2828 499, a person may not sell, manufacture, or deliver, or possess
2829 with intent to sell, manufacture, or deliver, a controlled
2830 substance. A person who violates this provision with respect to:
2831 1. A controlled substance named or described in s.
2832 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5.
2833 ~~(2)(c)4.~~ commits a felony of the second degree, punishable as
2834 provided in s. 775.082, s. 775.083, or s. 775.084.
2835 2. A controlled substance named or described in s.
2836 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6.,
2837 (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) commits a
2838 felony of the third degree, punishable as provided in s.
2839 775.082, s. 775.083, or s. 775.084.
2840 3. A controlled substance named or described in s.
2841 893.03(5) commits a misdemeanor of the first degree, punishable
2842 as provided in s. 775.082 or s. 775.083.
2843 (c) Except as authorized by this chapter, a person may not
2844 sell, manufacture, or deliver, or possess with intent to sell,
2845 manufacture, or deliver, a controlled substance in, on, or
2846 within 1,000 feet of the real property comprising a child care
2847 facility as defined in s. 402.302 or a public or private
2848 elementary, middle, or secondary school between the hours of 6
2849 a.m. and 12 midnight, or at any time in, on, or within 1,000
2850 feet of real property comprising a state, county, or municipal

2851 park, a community center, or a publicly owned recreational
2852 facility. As used in this paragraph, the term "community center"
2853 means a facility operated by a nonprofit community-based
2854 organization for the provision of recreational, social, or
2855 educational services to the public. A person who violates this
2856 paragraph with respect to:
2857 1. A controlled substance named or described in s.
2858 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5.
2859 ~~(2)(c)4.~~ commits a felony of the first degree, punishable as
2860 provided in s. 775.082, s. 775.083, or s. 775.084. The defendant
2861 must be sentenced to a minimum term of imprisonment of 3
2862 calendar years unless the offense was committed within 1,000
2863 feet of the real property comprising a child care facility as
2864 defined in s. 402.302.
2865 2. A controlled substance named or described in s.
2866 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6.,
2867 (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) commits a
2868 felony of the second degree, punishable as provided in s.
2869 775.082, s. 775.083, or s. 775.084.
2870 3. Any other controlled substance, except as lawfully
2871 sold, manufactured, or delivered, must be sentenced to pay a
2872 $500 fine and to serve 100 hours of public service in addition
2873 to any other penalty prescribed by law.
2874
2875 This paragraph does not apply to a child care facility unless

2876 the owner or operator of the facility posts a sign that is not
2877 less than 2 square feet in size with a word legend identifying
2878 the facility as a licensed child care facility and that is
2879 posted on the property of the child care facility in a
2880 conspicuous place where the sign is reasonably visible to the
2881 public.
2882 (d) Except as authorized by this chapter, a person may not
2883 sell, manufacture, or deliver, or possess with intent to sell,
2884 manufacture, or deliver, a controlled substance in, on, or
2885 within 1,000 feet of the real property comprising a public or
2886 private college, university, or other postsecondary educational
2887 institution. A person who violates this paragraph with respect
2888 to:
2889 1. A controlled substance named or described in s.
2890 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5.
2891 ~~(2)(c)4.~~ commits a felony of the first degree, punishable as
2892 provided in s. 775.082, s. 775.083, or s. 775.084.
2893 2. A controlled substance named or described in s.
2894 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6.,
2895 (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) commits a
2896 felony of the second degree, punishable as provided in s.
2897 775.082, s. 775.083, or s. 775.084.
2898 3. Any other controlled substance, except as lawfully
2899 sold, manufactured, or delivered, must be sentenced to pay a
2900 $500 fine and to serve 100 hours of public service in addition

2901 to any other penalty prescribed by law.
2902 (e) Except as authorized by this chapter, a person may not
2903 sell, manufacture, or deliver, or possess with intent to sell,
2904 manufacture, or deliver, a controlled substance not authorized
2905 by law in, on, or within 1,000 feet of a physical place for
2906 worship at which a church or religious organization regularly
2907 conducts religious services or within 1,000 feet of a
2908 convenience business as defined in s. 812.171. A person who
2909 violates this paragraph with respect to:
2910 1. A controlled substance named or described in s.
2911 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5.
2912 ~~(2)(c)4.~~ commits a felony of the first degree, punishable as
2913 provided in s. 775.082, s. 775.083, or s. 775.084.
2914 2. A controlled substance named or described in s.
2915 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6.,
2916 (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) commits a
2917 felony of the second degree, punishable as provided in s.
2918 775.082, s. 775.083, or s. 775.084.
2919 3. Any other controlled substance, except as lawfully
2920 sold, manufactured, or delivered, must be sentenced to pay a
2921 $500 fine and to serve 100 hours of public service in addition
2922 to any other penalty prescribed by law.
2923 (f) Except as authorized by this chapter, a person may not
2924 sell, manufacture, or deliver, or possess with intent to sell,
2925 manufacture, or deliver, a controlled substance in, on, or

2926 within 1,000 feet of the real property comprising a public
2927 housing facility at any time. As used in this section, the term
2928 "real property comprising a public housing facility" means real
2929 property, as defined in s. 421.03(12), of a public corporation
2930 created as a housing authority pursuant to part I of chapter
2931 421. A person who violates this paragraph with respect to:
2932 1. A controlled substance named or described in s.
2933 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5.
2934 ~~(2)(c)4.~~ commits a felony of the first degree, punishable as
2935 provided in s. 775.082, s. 775.083, or s. 775.084.
2936 2. A controlled substance named or described in s.
2937 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6.,
2938 (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) commits a
2939 felony of the second degree, punishable as provided in s.
2940 775.082, s. 775.083, or s. 775.084.
2941 3. Any other controlled substance, except as lawfully
2942 sold, manufactured, or delivered, must be sentenced to pay a
2943 $500 fine and to serve 100 hours of public service in addition
2944 to any other penalty prescribed by law.
2945 (h) Except as authorized by this chapter, a person may not
2946 sell, manufacture, or deliver, or possess with intent to sell,
2947 manufacture, or deliver, a controlled substance in, on, or
2948 within 1,000 feet of the real property comprising an assisted
2949 living facility, as that term is used in chapter 429. A person
2950 who violates this paragraph with respect to:

2951 1. A controlled substance named or described in s.
2952 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5.
2953 ~~(2)(c)4.~~ commits a felony of the first degree, punishable as
2954 provided in s. 775.082, s. 775.083, or s. 775.084.
2955 2. A controlled substance named or described in s.
2956 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6.,
2957 (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) commits a
2958 felony of the second degree, punishable as provided in s.
2959 775.082, s. 775.083, or s. 775.084.
2960 3. Any other controlled substance, except as lawfully
2961 sold, manufactured, or delivered, must be sentenced to pay a
2962 $500 fine and to serve 100 hours of public service in addition
2963 to any other penalty prescribed by law.
2964 (2)(a) Except as authorized by this chapter and chapter
2965 499, a person may not purchase, or possess with intent to
2966 purchase, a controlled substance. A person who violates this
2967 provision with respect to:
2968 1. A controlled substance named or described in s.
2969 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5.
2970 ~~(2)(c)4.~~ commits a felony of the second degree, punishable as
2971 provided in s. 775.082, s. 775.083, or s. 775.084.
2972 2. A controlled substance named or described in s.
2973 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6.,
2974 (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) commits a
2975 felony of the third degree, punishable as provided in s.

2976 775.082, s. 775.083, or s. 775.084.
2977 3. A controlled substance named or described in s.
2978 893.03(5) commits a misdemeanor of the first degree, punishable
2979 as provided in s. 775.082 or s. 775.083.
2980 (b) Except as provided in this chapter, a person may not
2981 purchase more than 10 grams of any substance named or described
2982 in s. 893.03(1)(a) or (1)(b), or any combination thereof, or any
2983 mixture containing any such substance. A person who violates
2984 this paragraph commits a felony of the first degree, punishable
2985 as provided in s. 775.082, s. 775.083, or s. 775.084.
2986 (4) Except as authorized by this chapter, a person 18
2987 years of age or older may not deliver any controlled substance
2988 to a person younger than 18 years of age, use or hire a person
2989 younger than 18 years of age as an agent or employee in the sale
2990 or delivery of such a substance, or use such person to assist in
2991 avoiding detection or apprehension for a violation of this
2992 chapter. A person who violates this subsection with respect to:
2993 (a) A controlled substance named or described in s.
2994 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5.
2995 ~~(2)(c)4.~~ commits a felony of the first degree, punishable as
2996 provided in s. 775.082, s. 775.083, or s. 775.084.
2997 (b) A controlled substance named or described in s.
2998 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6.,
2999 (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) commits a
3000 felony of the second degree, punishable as provided in s.

3001 775.082, s. 775.083, or s. 775.084.
3002
3003 Imposition of sentence may not be suspended or deferred, and the
3004 person so convicted may not be placed on probation.
3005 (5) A person may not bring into this state any controlled
3006 substance unless the possession of such controlled substance is
3007 authorized by this chapter or unless such person is licensed to
3008 do so by the appropriate federal agency. A person who violates
3009 this provision with respect to:
3010 (a) A controlled substance named or described in s.
3011 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5.
3012 ~~(2)(c)4.~~ commits a felony of the second degree, punishable as
3013 provided in s. 775.082, s. 775.083, or s. 775.084.
3014 (b) A controlled substance named or described in s.
3015 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6.,
3016 (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) commits a
3017 felony of the third degree, punishable as provided in s.
3018 775.082, s. 775.083, or s. 775.084.
3019 (c) A controlled substance named or described in s.
3020 893.03(5) commits a misdemeanor of the first degree, punishable
3021 as provided in s. 775.082 or s. 775.083.
3022 (7)
3023 (e) A person or health care practitioner who violates the
3024 provisions of subparagraph (a)13. or paragraph (b) commits a
3025 felony of the second ~~third~~ degree, punishable as provided in s.

3026 775.082, s. 775.083, or s. 775.084, if any controlled substance
3027 that is the subject of the offense is listed in Schedule II,
3028 Schedule III, or Schedule IV.
3029 Section 13. Section 893.147, Florida Statutes, is amended,
3030 to read:
3031 893.147 Use, possession, manufacture, delivery,
3032 transportation, advertisement, or retail sale of drug
3033 paraphernalia, specified machines, and materials.—
3034 (1) USE OR POSSESSION OF DRUG PARAPHERNALIA.—It is
3035 unlawful for any person to use, or to possess with intent to
3036 use, drug paraphernalia:
3037 (a) To plant, propagate, cultivate, grow, harvest,
3038 manufacture, compound, convert, produce, process, prepare, test,
3039 analyze, pack, repack, store, contain, or conceal a controlled
3040 substance in violation of this chapter; or
3041 (b) To inject, ingest, inhale, or otherwise introduce into
3042 the human body a controlled substance in violation of this
3043 chapter.
3044
3045 Any person who violates this subsection is guilty of a
3046 misdemeanor of the first degree, punishable as provided in s.
3047 775.082 or s. 775.083.
3048 (2) MANUFACTURE OR DELIVERY OF DRUG PARAPHERNALIA.—It is
3049 unlawful for any person to deliver, possess with intent to
3050 deliver, or manufacture with intent to deliver drug

3051 paraphernalia, knowing, or under circumstances where one
3052 reasonably should know, that it will be used:
3053 (a) To plant, propagate, cultivate, grow, harvest,
3054 manufacture, compound, convert, produce, process, prepare, test,
3055 analyze, pack, repack, store, contain, or conceal a controlled
3056 substance in violation of this act; or
3057 (b) To inject, ingest, inhale, or otherwise introduce into
3058 the human body a controlled substance in violation of this act.
3059
3060 Any person who violates this subsection is guilty of a felony of
3061 the third degree, punishable as provided in s. 775.082, s.
3062 775.083, or s. 775.084.
3063 (3) DELIVERY OF DRUG PARAPHERNALIA TO A MINOR.—
3064 (a) Any person 18 years of age or over who violates
3065 subsection (2) by delivering drug paraphernalia to a person
3066 under 18 years of age is guilty of a felony of the second
3067 degree, punishable as provided in s. 775.082, s. 775.083, or s.
3068 775.084.
3069 (b) It is unlawful for any person to sell or otherwise
3070 deliver hypodermic syringes, needles, or other objects which may
3071 be used, are intended for use, or are designed for use in
3072 parenterally injecting substances into the human body to any
3073 person under 18 years of age, except that hypodermic syringes,
3074 needles, or other such objects may be lawfully dispensed to a
3075 person under 18 years of age by a licensed practitioner, parent,

3076 or legal guardian or by a pharmacist pursuant to a valid
3077 prescription for same. Any person who violates the provisions of
3078 this paragraph is guilty of a misdemeanor of the first degree,
3079 punishable as provided in s. 775.082 or s. 775.083.
3080 (4) TRANSPORTATION OF DRUG PARAPHERNALIA.—It is unlawful
3081 to use, possess with the intent to use, or manufacture with the
3082 intent to use drug paraphernalia, knowing or under circumstances
3083 in which one reasonably should know that it will be used to
3084 transport:
3085 (a) A controlled substance in violation of this chapter;
3086 or
3087 (b) Contraband as defined in s. 932.701(2)(a)1.
3088
3089 Any person who violates this subsection commits a felony of the
3090 third degree, punishable as provided in s. 775.082, s. 775.083,
3091 or s. 775.084.
3092 (5) ADVERTISEMENT OF DRUG PARAPHERNALIA.—It is unlawful
3093 for any person to place in any newspaper, magazine, handbill, or
3094 other publication any advertisement, knowing, or under
3095 circumstances where one reasonably should know, that the purpose
3096 of the advertisement, in whole or in part, is to promote the
3097 sale of objects designed or intended for use as drug
3098 paraphernalia. Any person who violates this subsection is guilty
3099 of a misdemeanor of the first degree, punishable as provided in
3100 s. 775.082 or s. 775.083.

3101 (6) RETAIL SALE OF DRUG PARAPHERNALIA.—
3102 (a) It is unlawful for a person to knowingly and willfully
3103 sell or offer for sale at retail any drug paraphernalia
3104 described in s. 893.145(12)(a)-(c) or (g)-(m), other than a pipe
3105 that is primarily made of briar, meerschaum, clay, or corn cob.
3106 (b) A person who violates paragraph (a) commits a
3107 misdemeanor of the first degree, punishable as provided in s.
3108 775.082 or s. 775.083, and, upon a second or subsequent
3109 violation, commits a felony of the third degree, punishable as
3110 provided in s. 775.082, s. 775.083, or s. 775.084.
3111 (7) TABLETING MACHINES, ENCAPSULATING MACHINES, AND
3112 CONTROLLED SUBSTANCE COUNTERFEITING MATERIALS.—
3113 (a) Except as provided in paragraph (b), it is unlawful
3114 for any person to possess, purchase, deliver, sell, or possess
3115 with intent to sell or deliver a tableting machine, an
3116 encapsulating machine, or controlled substance counterfeiting
3117 materials knowing, intending, or having reasonable cause to
3118 believe that it will be used to manufacture a controlled
3119 substance or counterfeit controlled substance.
3120 (b)1. A regulated person may possess, purchase, deliver,
3121 sell, or possess with intent to deliver or sell a tableting
3122 machine or encapsulating machine as part of a regulated
3123 transaction with a regular customer or regular importer if he or
3124 she is in compliance with 21 U.S.C. s. 830. For purposes of this
3125 paragraph, the terms "regulated person," "regulated

3126 transaction," "regular customer," and "regular importer" have
3127 the same meanings as provided in 21 U.S.C. s. 802.
3128 2. A person registered under 21 U.S.C. s. 822 may possess,
3129 purchase, deliver, sell, or possess with intent to deliver or
3130 sell a tableting machine or encapsulating machine to manufacture
3131 a controlled substance pursuant to such registration.
3132 3. A person who holds an active, unencumbered license or a
3133 permit under s. 381.986 or chapter 465 may possess, purchase,
3134 deliver, sell, or possess with intent to sell or deliver a
3135 tableting machine or encapsulating machine to manufacture a
3136 controlled substance, if such person is performing functions in
3137 compliance with or under the authority of that license or
3138 permit.
3139 (c) For purposes of this subsection, the term:
3140 1. "Controlled substance" has the same meaning as provided
3141 in s. 893.02(4).
3142 2. "Controlled substance counterfeiting material" means a
3143 punch, die, plate, stone, or other item designed to print,
3144 imprint, or reproduce the trademark, trade name, or other
3145 identifying mark, imprint, or device of another or any likeness
3146 of any of the foregoing upon a drug or container or labeling
3147 thereof so as to render such drug a counterfeit controlled
3148 substance.
3149 3. "Counterfeit controlled substance" has the same meaning
3150 as provided in s. 831.31(2).

3151 4. "Encapsulating machine" means manual, semiautomatic, or
3152 fully automatic equipment that can be used to fill shells or
3153 capsules with powdered or granular solids or semisolid material
3154 to produce coherent solid tablets.
3155 5. "Tableting machine" means manual, semiautomatic, or
3156 fully automatic equipment that can be used to compact or mold
3157 powdered or granular solids or semisolid material to produce
3158 coherent solid tablets.
3159 (d)1. Except as provided in subparagraph 2., a person who
3160 violates this subsection commits a felony of the third degree,
3161 punishable as provided in s. 775.082, s. 775.083, or s. 775.084.
3162 2. Any person who violates this subsection knowing,
3163 intending, or having reasonable cause to believe that such
3164 action will result in the unlawful manufacture of a controlled
3165 substance or counterfeit controlled substance that contains:
3166 a. A substance controlled under s. 893.03(1);
3167 b. Cocaine, as described in s. 893.03(2)(a)4.;
3168 c. Opium or any synthetic or natural salt, compound,
3169 derivative, or preparation of opium;
3170 d. Methadone;
3171 e. Alfentanil, as described in s. 893.03(2)(b)1.;
3172 f. Carfentanil, as described in s. 893.03(2)(b)6.;
3173 g. Fentanyl, as described in s. 893.03(2)(b)9.;
3174 h. Sufentanil, as described in s. 893.03(2)(b)30.; or
3175 i. A controlled substance analog, as described in s.

3176 893.0356, of any substance specified in sub-subparagraphs a.-h.,
3177
3178 commits a felony of the second degree, punishable as provided in
3179 s. 775.082, s. 775.083, or s. 775.084.
3180 Section 14. Effective January 1, 2019, paragraphs (pp) and
3181 (qq) of subsection (1) of section 458.331, Florida Statutes, are
3182 amended to read:
3183 458.331 Grounds for disciplinary action; action by the
3184 board and department.—
3185 (1) The following acts constitute grounds for denial of a
3186 license or disciplinary action, as specified in s. 456.072(2):
3187 (pp) Applicable to a licensee who serves as the designated
3188 physician of a pain-management clinic as defined in s. 458.3265
3189 or s. 459.0137:
3190 1. Registering a pain-management clinic through
3191 misrepresentation or fraud;
3192 2. Procuring, or attempting to procure, the registration
3193 of a pain-management clinic for any other person by making or
3194 causing to be made, any false representation;
3195 3. Failing to comply with any requirement of chapter 499,
3196 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
3197 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
3198 the Drug Abuse Prevention and Control Act; or chapter 893, the
3199 Florida Comprehensive Drug Abuse Prevention and Control Act;
3200 4. Being convicted or found guilty of, regardless of

3201 adjudication to, a felony or any other crime involving moral
3202 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
3203 the courts of this state, of any other state, or of the United
3204 States;
3205 5. Being convicted of, or disciplined by a regulatory
3206 agency of the Federal Government or a regulatory agency of
3207 another state for, any offense that would constitute a violation
3208 of this chapter;
3209 6. Being convicted of, or entering a plea of guilty or
3210 nolo contendere to, regardless of adjudication, a crime in any
3211 jurisdiction of the courts of this state, of any other state, or
3212 of the United States which relates to the practice of, or the
3213 ability to practice, a licensed health care profession;
3214 7. Being convicted of, or entering a plea of guilty or
3215 nolo contendere to, regardless of adjudication, a crime in any
3216 jurisdiction of the courts of this state, of any other state, or
3217 of the United States which relates to health care fraud;
3218 8. Dispensing any medicinal drug based upon a
3219 communication that purports to be a prescription as defined in
3220 s. 465.003(14) or s. 893.02 if the dispensing practitioner knows
3221 or has reason to believe that the purported prescription is not
3222 based upon a valid practitioner-patient relationship; or
3223 9. Failing to timely notify the board of the date of his
3224 or her termination from a pain-management clinic as required by
3225 s. 458.3265(3) ~~458.3265(2)~~.

3226 (qq) Failing to timely notify the department of the theft
3227 of prescription blanks from a pain-management clinic or a breach
3228 of other methods for prescribing within 24 hours as required by
3229 s. 458.3265(3) ~~458.3265(2)~~.
3230 Section 15. Effective January 1, 2019, paragraphs (rr)
3231 and (ss) of subsection (1) of section 459.015, Florida Statutes,
3232 are amended to read:
3233 459.015 Grounds for disciplinary action; action by the
3234 board and department.—
3235 (1) The following acts constitute grounds for denial of a
3236 license or disciplinary action, as specified in s. 456.072(2):
3237 (rr) Applicable to a licensee who serves as the designated
3238 physician of a pain-management clinic as defined in s. 458.3265
3239 or s. 459.0137:
3240 1. Registering a pain-management clinic through
3241 misrepresentation or fraud;
3242 2. Procuring, or attempting to procure, the registration
3243 of a pain-management clinic for any other person by making or
3244 causing to be made, any false representation;
3245 3. Failing to comply with any requirement of chapter 499,
3246 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
3247 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
3248 the Drug Abuse Prevention and Control Act; or chapter 893, the
3249 Florida Comprehensive Drug Abuse Prevention and Control Act;
3250 4. Being convicted or found guilty of, regardless of

3251 adjudication to, a felony or any other crime involving moral
3252 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
3253 the courts of this state, of any other state, or of the United
3254 States;
3255 5. Being convicted of, or disciplined by a regulatory
3256 agency of the Federal Government or a regulatory agency of
3257 another state for, any offense that would constitute a violation
3258 of this chapter;
3259 6. Being convicted of, or entering a plea of guilty or
3260 nolo contendere to, regardless of adjudication, a crime in any
3261 jurisdiction of the courts of this state, of any other state, or
3262 of the United States which relates to the practice of, or the
3263 ability to practice, a licensed health care profession;
3264 7. Being convicted of, or entering a plea of guilty or
3265 nolo contendere to, regardless of adjudication, a crime in any
3266 jurisdiction of the courts of this state, of any other state, or
3267 of the United States which relates to health care fraud;
3268 8. Dispensing any medicinal drug based upon a
3269 communication that purports to be a prescription as defined in
3270 s. 465.003(14) or s. 893.02 if the dispensing practitioner knows
3271 or has reason to believe that the purported prescription is not
3272 based upon a valid practitioner-patient relationship; or
3273 9. Failing to timely notify the board of the date of his
3274 or her termination from a pain-management clinic as required by
3275 s. 459.0137(3) ~~459.0137(2)~~.

3276 (ss) Failing to timely notify the department of the theft
3277 of prescription blanks from a pain-management clinic or a breach
3278 of other methods for prescribing within 24 hours as required by
3279 s. 459.0137(3) ~~459.0137(2)~~.
3280 Section 16. Paragraph (b) of subsection (4) of section
3281 463.0055, Florida Statutes, is amended to read:
3282 463.0055 Administration and prescription of ocular
3283 pharmaceutical agents.—
3284 (4) A certified optometrist shall be issued a prescriber
3285 number by the board. Any prescription written by a certified
3286 optometrist for an ocular pharmaceutical agent pursuant to this
3287 section shall have the prescriber number printed thereon. A
3288 certified optometrist may not administer or prescribe:
3289 (b) A controlled substance for the treatment of chronic
3290 nonmalignant pain as defined in s. 456.44(1)(f) ~~456.44(1)(e)~~.
3291 Section 17. Paragraph (a) of subsection (1) of section
3292 782.04, Florida Statutes, is amended to read:
3293 782.04 Murder.—
3294 (1)(a) The unlawful killing of a human being:
3295 1. When perpetrated from a premeditated design to effect
3296 the death of the person killed or any human being;
3297 2. When committed by a person engaged in the perpetration
3298 of, or in the attempt to perpetrate, any:
3299 a. Trafficking offense prohibited by s. 893.135(1),
3300 b. Arson,

3301 c. Sexual battery,
3302 d. Robbery,
3303 e. Burglary,
3304 f. Kidnapping,
3305 g. Escape,
3306 h. Aggravated child abuse,
3307 i. Aggravated abuse of an elderly person or disabled
3308 adult,
3309 j. Aircraft piracy,
3310 k. Unlawful throwing, placing, or discharging of a
3311 destructive device or bomb,
3312 l. Carjacking,
3313 m. Home-invasion robbery,
3314 n. Aggravated stalking,
3315 o. Murder of another human being,
3316 p. Resisting an officer with violence to his or her
3317 person,
3318 q. Aggravated fleeing or eluding with serious bodily
3319 injury or death,
3320 r. Felony that is an act of terrorism or is in furtherance
3321 of an act of terrorism, including a felony under s. 775.30, s.
3322 775.32, s. 775.33, s. 775.34, or s. 775.35, or
3323 s. Human trafficking; or
3324 3. Which resulted from the unlawful distribution by a
3325 person 18 years of age or older of any of the following

3326 substances, or mixture containing any of the following
3327 substances, when such substance or mixture is proven to be the
3328 proximate cause of the death of the user:
3329 a. A substance controlled under s. 893.03(1);
3330 b. Cocaine, as described in s. 893.03(2)(a)4.;
3331 c. Opium or any synthetic or natural salt, compound,
3332 derivative, or preparation of opium;
3333 d. Methadone;
3334 e. Alfentanil, as described in s. 893.03(2)(b)1.;
3335 f. Carfentanil, as described in s. 893.03(2)(b)6.;
3336 g. Fentanyl, as described in s. 893.03(2)(b)9.;
3337 h. Sufentanil, as described in s. 893.03(2)(b)30.
3338 ~~893.03(2)(b)29.~~; or
3339 i. A controlled substance analog, as described in s.
3340 893.0356, of any substance specified in sub-subparagraphs a.-h.,
3341
3342 is murder in the first degree and constitutes a capital felony,
3343 punishable as provided in s. 775.082.
3344 Section 18. Paragraphs (c) and (f) of subsection (1) of
3345 section 893.135, Florida Statutes, are amended to read:
3346 893.135 Trafficking; mandatory sentences; suspension or
3347 reduction of sentences; conspiracy to engage in trafficking.—
3348 (1) Except as authorized in this chapter or in chapter 499
3349 and notwithstanding the provisions of s. 893.13:
3350 (c)1. A person who knowingly sells, purchases,

3351 manufactures, delivers, or brings into this state, or who is
3352 knowingly in actual or constructive possession of, 4 grams or
3353 more of any morphine, opium, hydromorphone, or any salt,
3354 derivative, isomer, or salt of an isomer thereof, including
3355 heroin, as described in s. 893.03(1)(b), (2)(a), (3)(c)3., or
3356 (3)(c)4., or 4 grams or more of any mixture containing any such
3357 substance, but less than 30 kilograms of such substance or
3358 mixture, commits a felony of the first degree, which felony
3359 shall be known as "trafficking in illegal drugs," punishable as
3360 provided in s. 775.082, s. 775.083, or s. 775.084. If the
3361 quantity involved:
3362 a. Is 4 grams or more, but less than 14 grams, such person
3363 shall be sentenced to a mandatory minimum term of imprisonment
3364 of 3 years and shall be ordered to pay a fine of $50,000.
3365 b. Is 14 grams or more, but less than 28 grams, such
3366 person shall be sentenced to a mandatory minimum term of
3367 imprisonment of 15 years and shall be ordered to pay a fine of
3368 $100,000.
3369 c. Is 28 grams or more, but less than 30 kilograms, such
3370 person shall be sentenced to a mandatory minimum term of
3371 imprisonment of 25 years and shall be ordered to pay a fine of
3372 $500,000.
3373 2. A person who knowingly sells, purchases, manufactures,
3374 delivers, or brings into this state, or who is knowingly in
3375 actual or constructive possession of, 14 grams or more of

3376 hydrocodone, as described in s. 893.03(2)(a)1.k.
3377 ~~893.03(2)(a)1.j.~~, codeine, as described in s. 893.03(2)(a)1.g.,
3378 or any salt thereof, or 14 grams or more of any mixture
3379 containing any such substance, commits a felony of the first
3380 degree, which felony shall be known as "trafficking in
3381 hydrocodone," punishable as provided in s. 775.082, s. 775.083,
3382 or s. 775.084. If the quantity involved:
3383 a. Is 14 grams or more, but less than 28 grams, such
3384 person shall be sentenced to a mandatory minimum term of
3385 imprisonment of 3 years and shall be ordered to pay a fine of
3386 $50,000.
3387 b. Is 28 grams or more, but less than 50 grams, such
3388 person shall be sentenced to a mandatory minimum term of
3389 imprisonment of 7 years and shall be ordered to pay a fine of
3390 $100,000.
3391 c. Is 50 grams or more, but less than 200 grams, such
3392 person shall be sentenced to a mandatory minimum term of
3393 imprisonment of 15 years and shall be ordered to pay a fine of
3394 $500,000.
3395 d. Is 200 grams or more, but less than 30 kilograms, such
3396 person shall be sentenced to a mandatory minimum term of
3397 imprisonment of 25 years and shall be ordered to pay a fine of
3398 $750,000.
3399 3. A person who knowingly sells, purchases, manufactures,
3400 delivers, or brings into this state, or who is knowingly in

3401 actual or constructive possession of, 7 grams or more of
3402 oxycodone, as described in s. 893.03(2)(a)1.q. ~~893.03(2)(a)1.o.~~,
3403 or any salt thereof, or 7 grams or more of any mixture
3404 containing any such substance, commits a felony of the first
3405 degree, which felony shall be known as "trafficking in
3406 oxycodone," punishable as provided in s. 775.082, s. 775.083, or
3407 s. 775.084. If the quantity involved:
3408 a. Is 7 grams or more, but less than 14 grams, such person
3409 shall be sentenced to a mandatory minimum term of imprisonment
3410 of 3 years and shall be ordered to pay a fine of $50,000.
3411 b. Is 14 grams or more, but less than 25 grams, such
3412 person shall be sentenced to a mandatory minimum term of
3413 imprisonment of 7 years and shall be ordered to pay a fine of
3414 $100,000.
3415 c. Is 25 grams or more, but less than 100 grams, such
3416 person shall be sentenced to a mandatory minimum term of
3417 imprisonment of 15 years and shall be ordered to pay a fine of
3418 $500,000.
3419 d. Is 100 grams or more, but less than 30 kilograms, such
3420 person shall be sentenced to a mandatory minimum term of
3421 imprisonment of 25 years and shall be ordered to pay a fine of
3422 $750,000.
3423 4.a. A person who knowingly sells, purchases,
3424 manufactures, delivers, or brings into this state, or who is
3425 knowingly in actual or constructive possession of, 4 grams or

3426 more of:
3427 (I) Alfentanil, as described in s. 893.03(2)(b)1.;
3428 (II) Carfentanil, as described in s. 893.03(2)(b)6.;
3429 (III) Fentanyl, as described in s. 893.03(2)(b)9.;
3430 (IV) Sufentanil, as described in s. 893.03(2)(b)30.
3431 ~~893.03(2)(b)29.~~;
3432 (V) A fentanyl derivative, as described in s.
3433 893.03(1)(a)62.;
3434 (VI) A controlled substance analog, as described in s.
3435 893.0356, of any substance described in sub-sub-subparagraphs
3436 (I)-(V); or
3437 (VII) A mixture containing any substance described in sub-
3438 sub-subparagraphs (I)-(VI),
3439
3440 commits a felony of the first degree, which felony shall be
3441 known as "trafficking in fentanyl," punishable as provided in s.
3442 775.082, s. 775.083, or s. 775.084.
3443 b. If the quantity involved under sub-subparagraph a.:
3444 (I) Is 4 grams or more, but less than 14 grams, such
3445 person shall be sentenced to a mandatory minimum term of
3446 imprisonment of 3 years, and shall be ordered to pay a fine of
3447 $50,000.
3448 (II) Is 14 grams or more, but less than 28 grams, such
3449 person shall be sentenced to a mandatory minimum term of
3450 imprisonment of 15 years, and shall be ordered to pay a fine of

3451 $100,000.
3452 (III) Is 28 grams or more, such person shall be sentenced
3453 to a mandatory minimum term of imprisonment of 25 years, and
3454 shall be ordered to pay a fine of $500,000.
3455 5. A person who knowingly sells, purchases, manufactures,
3456 delivers, or brings into this state, or who is knowingly in
3457 actual or constructive possession of, 30 kilograms or more of
3458 any morphine, opium, oxycodone, hydrocodone, codeine,
3459 hydromorphone, or any salt, derivative, isomer, or salt of an
3460 isomer thereof, including heroin, as described in s.
3461 893.03(1)(b), (2)(a), (3)(c)3., or (3)(c)4., or 30 kilograms or
3462 more of any mixture containing any such substance, commits the
3463 first degree felony of trafficking in illegal drugs. A person
3464 who has been convicted of the first degree felony of trafficking
3465 in illegal drugs under this subparagraph shall be punished by
3466 life imprisonment and is ineligible for any form of
3467 discretionary early release except pardon or executive clemency
3468 or conditional medical release under s. 947.149. However, if the
3469 court determines that, in addition to committing any act
3470 specified in this paragraph:
3471 a. The person intentionally killed an individual or
3472 counseled, commanded, induced, procured, or caused the
3473 intentional killing of an individual and such killing was the
3474 result; or
3475 b. The person's conduct in committing that act led to a

3476 natural, though not inevitable, lethal result,
3477
3478 such person commits the capital felony of trafficking in illegal
3479 drugs, punishable as provided in ss. 775.082 and 921.142. A
3480 person sentenced for a capital felony under this paragraph shall
3481 also be sentenced to pay the maximum fine provided under
3482 subparagraph 1.
3483 6. A person who knowingly brings into this state 60
3484 kilograms or more of any morphine, opium, oxycodone,
3485 hydrocodone, codeine, hydromorphone, or any salt, derivative,
3486 isomer, or salt of an isomer thereof, including heroin, as
3487 described in s. 893.03(1)(b), (2)(a), (3)(c)3., or (3)(c)4., or
3488 60 kilograms or more of any mixture containing any such
3489 substance, and who knows that the probable result of such
3490 importation would be the death of a person, commits capital
3491 importation of illegal drugs, a capital felony punishable as
3492 provided in ss. 775.082 and 921.142. A person sentenced for a
3493 capital felony under this paragraph shall also be sentenced to
3494 pay the maximum fine provided under subparagraph 1.
3495 (f)1. Any person who knowingly sells, purchases,
3496 manufactures, delivers, or brings into this state, or who is
3497 knowingly in actual or constructive possession of, 14 grams or
3498 more of amphetamine, as described in s. 893.03(2)(c)2., or
3499 methamphetamine, as described in s. 893.03(2)(c)5.
3500 ~~893.03(2)(c)4.~~, or of any mixture containing amphetamine or

3501 methamphetamine, or phenylacetone, phenylacetic acid,
3502 pseudoephedrine, or ephedrine in conjunction with other
3503 chemicals and equipment utilized in the manufacture of
3504 amphetamine or methamphetamine, commits a felony of the first
3505 degree, which felony shall be known as "trafficking in
3506 amphetamine," punishable as provided in s. 775.082, s. 775.083,
3507 or s. 775.084. If the quantity involved:
3508 a. Is 14 grams or more, but less than 28 grams, such
3509 person shall be sentenced to a mandatory minimum term of
3510 imprisonment of 3 years, and the defendant shall be ordered to
3511 pay a fine of $50,000.
3512 b. Is 28 grams or more, but less than 200 grams, such
3513 person shall be sentenced to a mandatory minimum term of
3514 imprisonment of 7 years, and the defendant shall be ordered to
3515 pay a fine of $100,000.
3516 c. Is 200 grams or more, such person shall be sentenced to
3517 a mandatory minimum term of imprisonment of 15 calendar years
3518 and pay a fine of $250,000.
3519 2. Any person who knowingly manufactures or brings into
3520 this state 400 grams or more of amphetamine, as described in s.
3521 893.03(2)(c)2., or methamphetamine, as described in s.
3522 893.03(2)(c)5. ~~893.03(2)(c)4.~~, or of any mixture containing
3523 amphetamine or methamphetamine, or phenylacetone, phenylacetic
3524 acid, pseudoephedrine, or ephedrine in conjunction with other
3525 chemicals and equipment used in the manufacture of amphetamine

3526 or methamphetamine, and who knows that the probable result of
3527 such manufacture or importation would be the death of any person
3528 commits capital manufacture or importation of amphetamine, a
3529 capital felony punishable as provided in ss. 775.082 and
3530 921.142. Any person sentenced for a capital felony under this
3531 paragraph shall also be sentenced to pay the maximum fine
3532 provided under subparagraph 1.
3533 Section 19. Paragraphs (b) through (e) and (g) of
3534 subsection (3) of section 921.0022, Florida Statutes, are
3535 amended to read:
3536 921.0022 Criminal Punishment Code; offense severity
3537 ranking chart.—
3538 (3) OFFENSE SEVERITY RANKING CHART
3539 (b) LEVEL 2
3540
3541

Florida Statute	Felony Degree	Description
379.2431 (1)(e)3.	3rd	Possession of 11 or fewer marine turtle eggs in violation of the Marine Turtle Protection Act.
379.2431 (1)(e)4.	3rd	Possession of more than 11 marine turtle eggs in violation

		of the Marine Turtle Protection Act.
403.413(6)(c)	3rd	Dumps waste litter exceeding 500 lbs. in weight or 100 cubic feet in volume or any quantity for commercial purposes, or hazardous waste.
517.07(2)	3rd	Failure to furnish a prospectus meeting requirements.
590.28(1)	3rd	Intentional burning of lands.
784.05(3)	3rd	Storing or leaving a loaded firearm within reach of minor who uses it to inflict injury or death.
787.04(1)	3rd	In violation of court order, take, entice, etc., minor beyond state limits.
806.13(1)(b)3.	3rd	Criminal mischief; damage $1,000 or more to public communication

		or any other public service.
810.061(2)	3rd	Impairing or impeding telephone or power to a dwelling; facilitating or furthering burglary.
810.09(2)(e)	3rd	Trespassing on posted commercial horticulture property.
812.014(2)(c)1.	3rd	Grand theft, 3rd degree; $300 or more but less than $5,000.
812.014(2)(d)	3rd	Grand theft, 3rd degree; $100 or more but less than $300, taken from unenclosed curtilage of dwelling.
812.015(7)	3rd	Possession, use, or attempted use of an antishoplifting or inventory control device countermeasure.
817.234(1)(a)2.	3rd	False statement in support of insurance claim.

3556

817.481(3)(a)	3rd	Obtain credit or purchase with false, expired, counterfeit, etc., credit card, value over $300.

3557

817.52(3)	3rd	Failure to redeliver hired vehicle.

3558

817.54	3rd	With intent to defraud, obtain mortgage note, etc., by false representation.

3559

817.60(5)	3rd	Dealing in credit cards of another.

3560

817.60(6)(a)	3rd	Forgery; purchase goods, services with false card.

3561

817.61	3rd	Fraudulent use of credit cards over $100 or more within 6 months.

3562

826.04	3rd	Knowingly marries or has sexual intercourse with person to whom

		related.
831.01	3rd	Forgery.
831.02	3rd	Uttering forged instrument; utters or publishes alteration with intent to defraud.
831.07	3rd	Forging bank bills, checks, drafts, or promissory notes.
831.08	3rd	Possessing 10 or more forged notes, bills, checks, or drafts.
831.09	3rd	Uttering forged notes, bills, checks, drafts, or promissory notes.
831.11	3rd	Bringing into the state forged bank bills, checks, drafts, or notes.
832.05(3)(a)	3rd	Cashing or depositing item with intent to defraud.

843.08	3rd	False personation.
893.13(2)(a)2.	3rd	Purchase of any s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) drugs other than cannabis.
893.147(2)	3rd	Manufacture or delivery of drug paraphernalia.

(c) LEVEL 3

Florida Statute	Felony Degree	Description
119.10(2)(b)	3rd	Unlawful use of confidential information from police reports.
316.066	3rd	Unlawfully obtaining or using

(3)(b)-(d)		confidential crash reports.
316.193(2)(b)	3rd	Felony DUI, 3rd conviction.
316.1935(2)	3rd	Fleeing or attempting to elude law enforcement officer in patrol vehicle with siren and lights activated.
319.30(4)	3rd	Possession by junkyard of motor vehicle with identification number plate removed.
319.33(1)(a)	3rd	Alter or forge any certificate of title to a motor vehicle or mobile home.
319.33(1)(c)	3rd	Procure or pass title on stolen vehicle.
319.33(4)	3rd	With intent to defraud, possess, sell, etc., a blank, forged, or unlawfully obtained title or registration.

327.35(2)(b)	3rd	Felony BUI.
328.05(2)	3rd	Possess, sell, or counterfeit fictitious, stolen, or fraudulent titles or bills of sale of vessels.
328.07(4)	3rd	Manufacture, exchange, or possess vessel with counterfeit or wrong ID number.
376.302(5)	3rd	Fraud related to reimbursement for cleanup expenses under the Inland Protection Trust Fund.
379.2431 (1)(e)5.	3rd	Taking, disturbing, mutilating, destroying, causing to be destroyed, transferring, selling, offering to sell, molesting, or harassing marine turtles, marine turtle eggs, or marine turtle nests in violation of the Marine Turtle Protection Act.

379.2431 (1)(e)6.	3rd	Possessing any marine turtle species or hatchling, or parts thereof, or the nest of any marine turtle species described in the Marine Turtle Protection Act.
379.2431 (1)(e)7.	3rd	Soliciting to commit or conspiring to commit a violation of the Marine Turtle Protection Act.
400.9935(4)(a) or (b)	3rd	Operating a clinic, or offering services requiring licensure, without a license.
400.9935(4)(e)	3rd	Filing a false license application or other required information or failing to report information.
440.1051(3)	3rd	False report of workers' compensation fraud or retaliation for making such a report.

3598

501.001(2)(b)	2nd	Tampers with a consumer product or the container using materially false/misleading information.

3599

624.401(4)(a)	3rd	Transacting insurance without a certificate of authority.

3600

624.401(4)(b)1.	3rd	Transacting insurance without a certificate of authority; premium collected less than $20,000.

3601

626.902(1)(a) & (b)	3rd	Representing an unauthorized insurer.

3602

697.08	3rd	Equity skimming.

3603

790.15(3)	3rd	Person directs another to discharge firearm from a vehicle.

3604

806.10(1)	3rd	Maliciously injure, destroy, or interfere with vehicles or

		equipment used in firefighting.
806.10(2)	3rd	Interferes with or assaults firefighter in performance of duty.
810.09(2)(c)	3rd	Trespass on property other than structure or conveyance armed with firearm or dangerous weapon.
812.014(2)(c)2.	3rd	Grand theft; $5,000 or more but less than $10,000.
812.0145(2)(c)	3rd	Theft from person 65 years of age or older; $300 or more but less than $10,000.
815.04(5)(b)	2nd	Computer offense devised to defraud or obtain property.
817.034(4)(a)3.	3rd	Engages in scheme to defraud (Florida Communications Fraud Act), property valued at less than $20,000.

3611

817.233	3rd	Burning to defraud insurer.

3612

817.234 (8)(b) & (c)	3rd	Unlawful solicitation of persons involved in motor vehicle accidents.

3613

817.234(11)(a)	3rd	Insurance fraud; property value less than $20,000.

3614

817.236	3rd	Filing a false motor vehicle insurance application.

3615

817.2361	3rd	Creating, marketing, or presenting a false or fraudulent motor vehicle insurance card.

3616

817.413(2)	3rd	Sale of used goods as new.

3617

828.12(2)	3rd	Tortures any animal with intent to inflict intense pain, serious physical injury, or death.

3618

831.28(2)(a)	3rd	Counterfeiting a payment instrument with intent to

			defraud or possessing a counterfeit payment instrument.
3619			
	831.29	2nd	Possession of instruments for counterfeiting driver licenses or identification cards.
3620			
	838.021(3)(b)	3rd	Threatens unlawful harm to public servant.
3621			
	843.19	3rd	Injure, disable, or kill police dog or horse.
3622			
	860.15(3)	3rd	Overcharging for repairs and parts.
3623			
	870.01(2)	3rd	Riot; inciting or encouraging.
3624			
	893.13(1)(a)2.	3rd	Sell, manufacture, or deliver cannabis (or other s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) drugs).

3625

893.13(1)(d)2.	2nd	Sell, manufacture, or deliver s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) drugs within 1,000 feet of university.

3626

893.13(1)(f)2.	2nd	Sell, manufacture, or deliver s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) drugs within 1,000 feet of public housing facility.

3627

893.13(4)(c)	3rd	Use or hire of minor; deliver to minor other controlled substances.

3628

893.13(6)(a)	3rd	Possession of any controlled substance other than felony possession of cannabis.

3629

893.13(7)(a)8.	3rd	Withhold information from practitioner regarding previous receipt of or prescription for a controlled substance.
893.13(7)(a)9.	3rd	Obtain or attempt to obtain controlled substance by fraud, forgery, misrepresentation, etc.
893.13(7)(a)10.	3rd	Affix false or forged label to package of controlled substance.
893.13(7)(a)11.	3rd	Furnish false or fraudulent material information on any document or record required by chapter 893.
893.13(8)(a)1.	3rd	Knowingly assist a patient, other person, or owner of an animal in obtaining a controlled substance through deceptive, untrue, or fraudulent representations in or related to the practitioner's practice.

893.13(8)(a)2.	3rd	Employ a trick or scheme in the practitioner's practice to assist a patient, other person, or owner of an animal in obtaining a controlled substance.
893.13(8)(a)3.	3rd	Knowingly write a prescription for a controlled substance for a fictitious person.
893.13(8)(a)4.	3rd	Write a prescription for a controlled substance for a patient, other person, or an animal if the sole purpose of writing the prescription is a monetary benefit for the practitioner.
918.13(1)(a)	3rd	Alter, destroy, or conceal investigation evidence.
944.47 (1)(a)1. & 2.	3rd	Introduce contraband to correctional facility.

944.47(1)(c)	2nd	Possess contraband while upon the grounds of a correctional institution.
985.721	3rd	Escapes from a juvenile facility (secure detention or residential commitment facility).

(d) LEVEL 4

Florida Statute	Felony Degree	Description
316.1935(3)(a)	2nd	Driving at high speed or with wanton disregard for safety while fleeing or attempting to elude law enforcement officer who is in a patrol vehicle with siren and lights activated.

499.0051(1)	3rd	Failure to maintain or deliver transaction history, transaction information, or transaction statements.
499.0051(5)	2nd	Knowing sale or delivery, or possession with intent to sell, contraband prescription drugs.
517.07(1)	3rd	Failure to register securities.
517.12(1)	3rd	Failure of dealer, associated person, or issuer of securities to register.
784.07(2)(b)	3rd	Battery of law enforcement officer, firefighter, etc.
784.074(1)(c)	3rd	Battery of sexually violent predators facility staff.

3654 784.075 3rd Battery on detention or commitment facility staff.

3655 784.078 3rd Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.

3656 784.08(2)(c) 3rd Battery on a person 65 years of age or older.

3657 784.081(3) 3rd Battery on specified official or employee.

3658 784.082(3) 3rd Battery by detained person on visitor or other detainee.

3659 784.083(3) 3rd Battery on code inspector.

3660 784.085 3rd Battery of child by throwing, tossing, projecting, or expelling certain fluids or

materials.

3661

787.03(1) 3rd Interference with custody; wrongly takes minor from appointed guardian.

3662

787.04(2) 3rd Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.

3663

787.04(3) 3rd Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.

3664

787.07 3rd Human smuggling.

3665

790.115(1) 3rd Exhibiting firearm or weapon within 1,000 feet of a school.

3666

790.115(2)(b) 3rd Possessing electric

			weapon or device, destructive device, or other weapon on school property.
790.115(2)(c)	3rd	Possessing firearm on school property.	
800.04(7)(c)	3rd	Lewd or lascivious exhibition; offender less than 18 years.	
810.02(4)(a)	3rd	Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.	
810.02(4)(b)	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.	
810.06	3rd	Burglary; possession of tools.	

3672

810.08(2)(c)	3rd	Trespass on property, armed with firearm or dangerous weapon.

3673

812.014(2)(c)3.	3rd	Grand theft, 3rd degree $10,000 or more but less than $20,000.

3674

812.014 (2)(c)4.-10.	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.

3675

812.0195(2)	3rd	Dealing in stolen property by use of the Internet; property stolen $300 or more.

3676

817.505(4)(a)	3rd	Patient brokering.

3677

817.563(1)	3rd	Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03(5)

			drugs.
3678			
	817.568(2)(a)	3rd	Fraudulent use of personal identification information.
3679			
	817.625(2)(a)	3rd	Fraudulent use of scanning device, skimming device, or reencoder.
3680			
	817.625(2)(c)	3rd	Possess, sell, or deliver skimming device.
3681			
	828.125(1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.
3682			
	837.02(1)	3rd	Perjury in official proceedings.
3683			
	837.021(1)	3rd	Make contradictory statements in official proceedings.

3684 838.022 3rd Official misconduct.

3685 839.13(2)(a) 3rd Falsifying records of an individual in the care and custody of a state agency.

3686 839.13(2)(c) 3rd Falsifying records of the Department of Children and Families.

3687 843.021 3rd Possession of a concealed handcuff key by a person in custody.

3688 843.025 3rd Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.

3689 843.15(1)(a) 3rd Failure to appear while on bail for felony (bond estreature or bond jumping).

3690

847.0135(5)(c)	3rd	Lewd or lascivious exhibition using computer; offender less than 18 years.

3691

874.05(1)(a)	3rd	Encouraging or recruiting another to join a criminal gang.

3692

893.13(2)(a)1.	2nd	Purchase of cocaine (or other s. 893.03(1)(a), (b), or (d), (2)(a), (2)(b), or (2)(c)5. ~~(2)(c)4.~~ drugs).

3693

914.14(2)	3rd	Witnesses accepting bribes.

3694

914.22(1)	3rd	Force, threaten, etc., witness, victim, or informant.

3695

914.23(2)	3rd	Retaliation against a witness, victim, or

			informant, no bodily injury.
918.12	3rd	Tampering with jurors.	
934.215	3rd	Use of two-way communications device to facilitate commission of a crime.	

(e) LEVEL 5

Florida Statute	Felony Degree	Description
316.027(2)(a)	3rd	Accidents involving personal injuries other than serious bodily injury, failure to stop; leaving scene.
316.1935(4)(a)	2nd	Aggravated fleeing or eluding.

316.80(2)	2nd	Unlawful conveyance of fuel; obtaining fuel fraudulently.
322.34(6)	3rd	Careless operation of motor vehicle with suspended license, resulting in death or serious bodily injury.
327.30(5)	3rd	Vessel accidents involving personal injury; leaving scene.
379.365(2)(c)1.	3rd	Violation of rules relating to: willful molestation of stone crab traps, lines, or buoys; illegal bartering, trading, or sale, conspiring or aiding in such barter, trade, or sale, or supplying, agreeing to supply, aiding in supplying, or giving away stone crab trap tags or certificates; making, altering, forging, counterfeiting, or reproducing stone crab trap tags; possession of forged, counterfeit, or imitation stone

			crab trap tags; and engaging in the commercial harvest of stone crabs while license is suspended or revoked.
3712			
	379.367(4)	3rd	Willful molestation of a commercial harvester's spiny lobster trap, line, or buoy.
3713			
	379.407(5)(b)3.	3rd	Possession of 100 or more undersized spiny lobsters.
3714			
	381.0041(11)(b)	3rd	Donate blood, plasma, or organs knowing HIV positive.
3715			
	440.10(1)(g)	2nd	Failure to obtain workers' compensation coverage.
3716			
	440.105(5)	2nd	Unlawful solicitation for the purpose of making workers' compensation claims.
3717			
	440.381(2)	2nd	Submission of false, misleading, or incomplete information with the purpose of avoiding or

		reducing workers' compensation premiums.
624.401(4)(b)2.	2nd	Transacting insurance without a certificate or authority; premium collected $20,000 or more but less than $100,000.
626.902(1)(c)	2nd	Representing an unauthorized insurer; repeat offender.
790.01(2)	3rd	Carrying a concealed firearm.
790.162	2nd	Threat to throw or discharge destructive device.
790.163(1)	2nd	False report of bomb, explosive, weapon of mass destruction, or use of firearms in violent manner.
790.221(1)	2nd	Possession of short-barreled shotgun or machine gun.
790.23	2nd	Felons in possession of

			firearms, ammunition, or electronic weapons or devices.
3725			
	796.05(1)	2nd	Live on earnings of a prostitute; 1st offense.
3726			
	800.04(6)(c)	3rd	Lewd or lascivious conduct; offender less than 18 years of age.
3727			
	800.04(7)(b)	2nd	Lewd or lascivious exhibition; offender 18 years of age or older.
3728			
	806.111(1)	3rd	Possess, manufacture, or dispense fire bomb with intent to damage any structure or property.
3729			
	812.0145(2)(b)	2nd	Theft from person 65 years of age or older; $10,000 or more but less than $50,000.
3730			
	812.015(8)	3rd	Retail theft; property stolen is valued at $300 or more and one

		or more specified acts.
812.019(1)	2nd	Stolen property; dealing in or trafficking in.
812.131(2)(b)	3rd	Robbery by sudden snatching.
812.16(2)	3rd	Owning, operating, or conducting a chop shop.
817.034(4)(a)2.	2nd	Communications fraud, value $20,000 to $50,000.
817.234(11)(b)	2nd	Insurance fraud; property value $20,000 or more but less than $100,000.
817.2341(1), (2)(a) & (3)(a)	3rd	Filing false financial statements, making false entries of material fact or false statements regarding property values relating to the solvency of an insuring entity.
817.568(2)(b)	2nd	Fraudulent use of personal

			identification information; value of benefit, services received, payment avoided, or amount of injury or fraud, $5,000 or more or use of personal identification information of 10 or more persons.
3738	817.611(2)(a)	2nd	Traffic in or possess 5 to 14 counterfeit credit cards or related documents.
3739	817.625(2)(b)	2nd	Second or subsequent fraudulent use of scanning device, skimming device, or reencoder.
3740	825.1025(4)	3rd	Lewd or lascivious exhibition in the presence of an elderly person or disabled adult.
3741	827.071(4)	2nd	Possess with intent to promote any photographic material, motion picture, etc., which includes sexual conduct by a

		child.
827.071(5)	3rd	Possess, control, or intentionally view any photographic material, motion picture, etc., which includes sexual conduct by a child.
839.13(2)(b)	2nd	Falsifying records of an individual in the care and custody of a state agency involving great bodily harm or death.
843.01	3rd	Resist officer with violence to person; resist arrest with violence.
847.0135(5)(b)	2nd	Lewd or lascivious exhibition using computer; offender 18 years or older.
847.0137 (2) & (3)	3rd	Transmission of pornography by electronic device or equipment.

847.0138 (2) & (3)	3rd	Transmission of material harmful to minors to a minor by electronic device or equipment.
874.05(1)(b)	2nd	Encouraging or recruiting another to join a criminal gang; second or subsequent offense.
874.05(2)(a)	2nd	Encouraging or recruiting person under 13 years of age to join a criminal gang.
893.13(1)(a)1.	2nd	Sell, manufacture, or deliver cocaine (or other s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5. ~~(2)(c)4.~~ drugs).
893.13(1)(c)2.	2nd	Sell, manufacture, or deliver cannabis (or other s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) drugs) within 1,000 feet of a

			child care facility, school, or state, county, or municipal park or publicly owned recreational facility or community center.
3752			
	893.13(1)(d)1.	1st	Sell, manufacture, or deliver cocaine (or other s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5. ~~(2)(c)4.~~ drugs) within 1,000 feet of university.
3753			
	893.13(1)(e)2.	2nd	Sell, manufacture, or deliver cannabis or other drug prohibited under s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) within 1,000 feet of property used for religious services or a specified business site.
3754			
	893.13(1)(f)1.	1st	Sell, manufacture, or deliver cocaine (or other s.

		893.03(1)(a), (1)(b), (1)(d), or (2)(a), (2)(b), or (2)(c)5. ~~(2)(c)4.~~ drugs) within 1,000 feet of public housing facility.
893.13(4)(b)	2nd	Use or hire of minor; deliver to minor other controlled substance.
893.1351(1)	3rd	Ownership, lease, or rental for trafficking in or manufacturing of controlled substance.

(g) LEVEL 7

Florida Statute	Felony Degree	Description
316.027(2)(c)	1st	Accident involving death, failure to stop; leaving scene.

316.193(3)(c)2.	3rd	DUI resulting in serious bodily injury.
316.1935(3)(b)	1st	Causing serious bodily injury or death to another person; driving at high speed or with wanton disregard for safety while fleeing or attempting to elude law enforcement officer who is in a patrol vehicle with siren and lights activated.
327.35(3)(c)2.	3rd	Vessel BUI resulting in serious bodily injury.
402.319(2)	2nd	Misrepresentation and negligence or intentional act resulting in great bodily harm, permanent disfiguration, permanent disability, or death.

3768

409.920 (2)(b)1.a.	3rd	Medicaid provider fraud; $10,000 or less.

3769

409.920 (2)(b)1.b.	2nd	Medicaid provider fraud; more than $10,000, but less than $50,000.

3770

456.065(2)	3rd	Practicing a health care profession without a license.

3771

456.065(2)	2nd	Practicing a health care profession without a license which results in serious bodily injury.

3772

458.327(1)	3rd	Practicing medicine without a license.

3773

459.013(1)	3rd	Practicing osteopathic medicine without a license.

3774

460.411(1)	3rd	Practicing chiropractic

			medicine without a license.
461.012(1)	3rd	Practicing podiatric medicine without a license.	
462.17	3rd	Practicing naturopathy without a license.	
463.015(1)	3rd	Practicing optometry without a license.	
464.016(1)	3rd	Practicing nursing without a license.	
465.015(2)	3rd	Practicing pharmacy without a license.	
466.026(1)	3rd	Practicing dentistry or dental hygiene without a license.	
467.201	3rd	Practicing midwifery without a license.	

468.366	3rd	Delivering respiratory care services without a license.
483.828(1)	3rd	Practicing as clinical laboratory personnel without a license.
483.901(7)	3rd	Practicing medical physics without a license.
484.013(1)(c)	3rd	Preparing or dispensing optical devices without a prescription.
484.053	3rd	Dispensing hearing aids without a license.
494.0018(2)	1st	Conviction of any violation of chapter 494 in which the total money and property unlawfully obtained exceeded $50,000 and there were five or more victims.

560.123(8)(b)1.	3rd	Failure to report currency or payment instruments exceeding $300 but less than $20,000 by a money services business.
560.125(5)(a)	3rd	Money services business by unauthorized person, currency or payment instruments exceeding $300 but less than $20,000.
655.50(10)(b)1.	3rd	Failure to report financial transactions exceeding $300 but less than $20,000 by financial institution.
775.21(10)(a)	3rd	Sexual predator; failure to register; failure to renew driver license or identification card; other registration violations.

775.21(10)(b)	3rd	Sexual predator working where children regularly congregate.
775.21(10)(g)	3rd	Failure to report or providing false information about a sexual predator; harbor or conceal a sexual predator.
782.051(3)	2nd	Attempted felony murder of a person by a person other than the perpetrator or the perpetrator of an attempted felony.
782.07(1)	2nd	Killing of a human being by the act, procurement, or culpable negligence of another (manslaughter).
782.071	2nd	Killing of a human being or unborn child by the operation of a motor vehicle in a

			reckless manner (vehicular homicide).
3797			
	782.072	2nd	Killing of a human being by the operation of a vessel in a reckless manner (vessel homicide).
3798			
	784.045(1)(a)1.	2nd	Aggravated battery; intentionally causing great bodily harm or disfigurement.
3799			
	784.045(1)(a)2.	2nd	Aggravated battery; using deadly weapon.
3800			
	784.045(1)(b)	2nd	Aggravated battery; perpetrator aware victim pregnant.
3801			
	784.048(4)	3rd	Aggravated stalking; violation of injunction or court order.
3802			
	784.048(7)	3rd	Aggravated stalking;

			violation of court order.
3803			
	784.07(2)(d)	1st	Aggravated battery on law enforcement officer.
3804			
	784.074(1)(a)	1st	Aggravated battery on sexually violent predators facility staff.
3805			
	784.08(2)(a)	1st	Aggravated battery on a person 65 years of age or older.
3806			
	784.081(1)	1st	Aggravated battery on specified official or employee.
3807			
	784.082(1)	1st	Aggravated battery by detained person on visitor or other detainee.
3808			
	784.083(1)	1st	Aggravated battery on code inspector.
3809			

787.06(3)(a)2.	1st	Human trafficking using coercion for labor and services of an adult.
787.06(3)(e)2.	1st	Human trafficking using coercion for labor and services by the transfer or transport of an adult from outside Florida to within the state.
790.07(4)	1st	Specified weapons violation subsequent to previous conviction of s. 790.07(1) or (2).
790.16(1)	1st	Discharge of a machine gun under specified circumstances.
790.165(2)	2nd	Manufacture, sell, possess, or deliver hoax bomb.
790.165(3)	2nd	Possessing, displaying, or threatening to use any hoax bomb while committing or

			attempting to commit a felony.
3815			
	790.166(3)	2nd	Possessing, selling, using, or attempting to use a hoax weapon of mass destruction.
3816			
	790.166(4)	2nd	Possessing, displaying, or threatening to use a hoax weapon of mass destruction while committing or attempting to commit a felony.
3817			
	790.23	1st,PBL	Possession of a firearm by a person who qualifies for the penalty enhancements provided for in s. 874.04.
3818			
	794.08(4)	3rd	Female genital mutilation; consent by a parent, guardian, or a person in custodial authority to a victim younger than 18 years of age.

3819

796.05(1)	1st	Live on earnings of a prostitute; 2nd offense.

3820

796.05(1)	1st	Live on earnings of a prostitute; 3rd and subsequent offense.

3821

800.04(5)(c)1.	2nd	Lewd or lascivious molestation; victim younger than 12 years of age; offender younger than 18 years of age.

3822

800.04(5)(c)2.	2nd	Lewd or lascivious molestation; victim 12 years of age or older but younger than 16 years of age; offender 18 years of age or older.

3823

800.04(5)(e)	1st	Lewd or lascivious molestation; victim 12 years of age or older but younger than 16 years;

			offender 18 years or older; prior conviction for specified sex offense.
3824			
	806.01(2)	2nd	Maliciously damage structure by fire or explosive.
3825			
	810.02(3)(a)	2nd	Burglary of occupied dwelling; unarmed; no assault or battery.
3826			
	810.02(3)(b)	2nd	Burglary of unoccupied dwelling; unarmed; no assault or battery.
3827			
	810.02(3)(d)	2nd	Burglary of occupied conveyance; unarmed; no assault or battery.
3828			
	810.02(3)(e)	2nd	Burglary of authorized emergency vehicle.
3829			
	812.014(2)(a)1.	1st	Property stolen, valued at $100,000 or more or a semitrailer deployed

			by a law enforcement officer; property stolen while causing other property damage; 1st degree grand theft.
3830			
	812.014(2)(b)2.	2nd	Property stolen, cargo valued at less than $50,000, grand theft in 2nd degree.
3831			
	812.014(2)(b)3.	2nd	Property stolen, emergency medical equipment; 2nd degree grand theft.
3832			
	812.014(2)(b)4.	2nd	Property stolen, law enforcement equipment from authorized emergency vehicle.
3833			
	812.0145(2)(a)	1st	Theft from person 65 years of age or older; $50,000 or

			more.
3834			
	812.019(2)	1st	Stolen property; initiates, organizes, plans, etc., the theft of property and traffics in stolen property.
3835			
	812.131(2)(a)	2nd	Robbery by sudden snatching.
3836			
	812.133(2)(b)	1st	Carjacking; no firearm, deadly weapon, or other weapon.
3837			
	817.034(4)(a)1.	1st	Communications fraud, value greater than $50,000.
3838			
	817.234(8)(a)	2nd	Solicitation of motor vehicle accident victims with intent to defraud.
3839			
	817.234(9)	2nd	Organizing, planning, or participating in an

			intentional motor vehicle collision.
817.234(11)(c)	1st	Insurance fraud; property value $100,000 or more.	
817.2341 (2)(b) & (3)(b)	1st	Making false entries of material fact or false statements regarding property values relating to the solvency of an insuring entity which are a significant cause of the insolvency of that entity.	
817.535(2)(a)	3rd	Filing false lien or other unauthorized document.	
817.611(2)(b)	2nd	Traffic in or possess 15 to 49 counterfeit credit cards or related documents.	
825.102(3)(b)	2nd	Neglecting an elderly person	

			or disabled adult causing great bodily harm, disability, or disfigurement.
825.103(3)(b)	2nd		Exploiting an elderly person or disabled adult and property is valued at $10,000 or more, but less than $50,000.
827.03(2)(b)	2nd		Neglect of a child causing great bodily harm, disability, or disfigurement.
827.04(3)	3rd		Impregnation of a child under 16 years of age by person 21 years of age or older.
837.05(2)	3rd		Giving false information about alleged capital felony to a law enforcement officer.

838.015	2nd	Bribery.	
838.016	2nd	Unlawful compensation or reward for official behavior.	
838.021(3)(a)	2nd	Unlawful harm to a public servant.	
838.22	2nd	Bid tampering.	
843.0855(2)	3rd	Impersonation of a public officer or employee.	
843.0855(3)	3rd	Unlawful simulation of legal process.	
843.0855(4)	3rd	Intimidation of a public officer or employee.	
847.0135(3)	3rd	Solicitation of a child, via a computer service, to commit an unlawful sex act.	
847.0135(4)	2nd	Traveling to meet a minor to commit an	

			unlawful sex act.
872.06	2nd		Abuse of a dead human body.
874.05(2)(b)	1st		Encouraging or recruiting person under 13 to join a criminal gang; second or subsequent offense.
874.10	1st,PBL		Knowingly initiates, organizes, plans, finances, directs, manages, or supervises criminal gang-related activity.
893.13(1)(c)1.	1st		Sell, manufacture, or deliver cocaine (or other drug prohibited under s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5. ~~(2)(c)4.~~) within 1,000 feet of a child care facility, school, or

			state, county, or municipal park or publicly owned recreational facility or community center.
3862			
	893.13(1)(e)1.	1st	Sell, manufacture, or deliver cocaine or other drug prohibited under s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5. ~~(2)(c)4.~~, within 1,000 feet of property used for religious services or a specified business site.
3863			
	893.13(4)(a)	1st	Use or hire of minor; deliver to minor other controlled substance.
3864			
	893.135(1)(a)1.	1st	Trafficking in cannabis, more than 25 lbs., less than 2,000 lbs.

3865

893.135 (1)(b)1.a.	1st	Trafficking in cocaine, more than 28 grams, less than 200 grams.

3866

893.135 (1)(c)1.a.	1st	Trafficking in illegal drugs, more than 4 grams, less than 14 grams.

3867

893.135 (1)(c)2.a.	1st	Trafficking in hydrocodone, 14 grams or more, less than 28 grams.

3868

893.135 (1)(c)2.b.	1st	Trafficking in hydrocodone, 28 grams or more, less than 50 grams.

3869

893.135 (1)(c)3.a.	1st	Trafficking in oxycodone, 7 grams or more, less than 14 grams.

3870

893.135 (1)(c)3.b.	1st	Trafficking in oxycodone, 14 grams or more, less than 25 grams.

3871

893.135 (1)(c)4.b.(I)	1st	Trafficking in fentanyl, 4 grams or more, less than 14 grams.
893.135 (1)(d)1.a.	1st	Trafficking in phencyclidine, 28 grams or more, less than 200 grams.
893.135(1)(e)1.	1st	Trafficking in methaqualone, 200 grams or more, less than 5 kilograms.
893.135(1)(f)1.	1st	Trafficking in amphetamine, 14 grams or more, less than 28 grams.
893.135 (1)(g)1.a.	1st	Trafficking in flunitrazepam, 4 grams or more, less than 14 grams.
893.135 (1)(h)1.a.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 1 kilogram or more, less than 5

			kilograms.
3877			
893.135 (1)(j)1.a.	1st	Trafficking in 1,4-Butanediol, 1 kilogram or more, less than 5 kilograms.	
3878			
893.135 (1)(k)2.a.	1st	Trafficking in Phenethylamines, 10 grams or more, less than 200 grams.	
3879			
893.135 (1)(m)2.a.	1st	Trafficking in synthetic cannabinoids, 280 grams or more, less than 500 grams.	
3880			
893.135 (1)(m)2.b.	1st	Trafficking in synthetic cannabinoids, 500 grams or more, less than 1,000 grams.	
3881			
893.135 (1)(n)2.a.	1st	Trafficking in n-benzyl phenethylamines, 14 grams or more, less than 100 grams.	
3882			
893.1351(2)	2nd	Possession of place for trafficking in or	

			manufacturing of controlled substance.
3883			
	896.101(5)(a)	3rd	Money laundering, financial transactions exceeding $300 but less than $20,000.
3884			
	896.104(4)(a)1.	3rd	Structuring transactions to evade reporting or registration requirements, financial transactions exceeding $300 but less than $20,000.
3885			
	943.0435(4)(c)	2nd	Sexual offender vacating permanent residence; failure to comply with reporting requirements.
3886			
	943.0435(8)	2nd	Sexual offender; remains in state after indicating intent to leave; failure to comply with reporting requirements.

3887

943.0435(9)(a)	3rd	Sexual offender; failure to comply with reporting requirements.

3888

943.0435(13)	3rd	Failure to report or providing false information about a sexual offender; harbor or conceal a sexual offender.

3889

943.0435(14)	3rd	Sexual offender; failure to report and reregister; failure to respond to address verification; providing false registration information.

3890

944.607(9)	3rd	Sexual offender; failure to comply with reporting requirements.

3891

944.607(10)(a)	3rd	Sexual offender; failure to submit to the taking

			of a digitized photograph.
944.607(12)	3rd		Failure to report or providing false information about a sexual offender; harbor or conceal a sexual offender.
944.607(13)	3rd		Sexual offender; failure to report and reregister; failure to respond to address verification; providing false registration information.
985.4815(10)	3rd		Sexual offender; failure to submit to the taking of a digitized photograph.
985.4815(12)	3rd		Failure to report or providing false information about a sexual offender; harbor or conceal a sexual

		offender.
985.4815(13)	3rd	Sexual offender; failure to report and reregister; failure to respond to address verification; providing false registration information.

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3900 Section 20. For the 2018-2019 fiscal year:
3901 (1) The nonrecurring sum of $27,035,532 is appropriated
3902 from the Federal Grants Trust Fund to the Department of Children
3903 and Families for expenditure of funds related to the second year
3904 of the State Targeted Response to the Opioid Crisis grant, to
3905 increase access to treatment, reduce unmet treatment needs, and
3906 reduce opioid overdose-related deaths through prevention,
3907 treatment, and recovery activities.
3908 (2) To enhance the entire substance abuse continuum of
3909 care, the sum of $14,626,911 in recurring funds is appropriated
3910 from the General Revenue Fund to the Department of Children and
3911 Families for community-based services to address the opioid
3912 crisis, including, but not limited to, outreach, addiction
3913 treatment, and recovery support services. Funding under this

3914 subsection shall be used to expand capacity to increase access
3915 to and reduce waitlists for treatment; increase efforts to
3916 effectively engage and retain in treatment youth, pregnant
3917 women, high-risk populations, and high utilizers of acute care
3918 services; and further develop a recovery-based model of care.
3919 Funding for specific services may include, but are not limited
3920 to, case management, residential services, outpatient services,
3921 aftercare services, and medication-assisted treatment.
3922 Medication-assisted treatment may include, but is not limited
3923 to, methadone, buprenorphine, and naltrexone extended release
3924 injectable.
3925 (3) The recurring sum of $5,000,000 from the General
3926 Revenue Fund is appropriated to the Department of Health for the
3927 purchase of emergency opioid antagonists to be made available to
3928 emergency responders.
3929 (4) The recurring sum of $6 million from the General
3930 Revenue Fund is appropriated to the Office of State Court
3931 Administrator for medication-assisted treatment of substance
3932 abuse disorders in individuals involved in the criminal justice
3933 system, individuals who have a high likelihood of becoming
3934 involved in the criminal justice system, or individuals who are
3935 in court-ordered, community-based drug treatment. Such
3936 medication-assisted treatment may include, but is not limited
3937 to, methadone, buprenorphine, and naltrexone extended release
3938 injectable.

3939 (5) The sums of $873,089 in recurring funds and $117,700
3940 in nonrecurring funds are appropriated from the General Revenue
3941 Fund to the Department of Health for improvements to the
3942 Prescription Drug Monitoring Program system pursuant to s.
3943 893.055, Florida Statutes.
3944 Section 21. Except as otherwise expressly provided in this
3945 act, this act shall take effect July 1, 2018.

An act relating to pharmacies; amending s. 465.003, F.S.; revising and providing definitions; amending s. 465.004, F.S.; revising the membership of the Board of Pharmacy; amending s. 465.019, F.S.; establishing Class III institutional pharmacies; providing requirements for such pharmacies; conforming provisions to changes made by the act; amending s. 465.0252, F.S.; revising notice requirements to conform to changes made by the act; amending s. 499.003, F.S.; providing and revising definitions; amending s. 499.01, F.S.; authorizing the distribution of medicinal drugs and prepackaged drug products without a specified permit under certain conditions; deleting a provision exempting certain drug repackagers from specified permit requirements; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsections (7) and (13) of section 465.003, Florida Statutes, are amended, and subsections (21) and (22) are added to that section, to read:

465.003 Definitions.—As used in this chapter, the term:

(7) "Institutional formulary system" means a method

26 whereby the medical staff evaluates, appraises, and selects
27 those medicinal drugs or proprietary preparations which in the
28 medical staff's clinical judgment are most useful in patient
29 care, and which are available for dispensing by a practicing
30 pharmacist in a Class II or Class III institutional pharmacy.
31 (13) "Practice of the profession of pharmacy" includes
32 compounding, dispensing, and consulting concerning contents,
33 therapeutic values, and uses of any medicinal drug; consulting
34 concerning therapeutic values and interactions of patent or
35 proprietary preparations, whether pursuant to prescriptions or
36 in the absence and entirely independent of such prescriptions or
37 orders; and conducting other pharmaceutical services. For
38 purposes of this subsection, "other pharmaceutical services"
39 means the monitoring of the patient's drug therapy and assisting
40 the patient in the management of his or her drug therapy, and
41 includes review of the patient's drug therapy and communication
42 with the patient's prescribing health care provider as licensed
43 under chapter 458, chapter 459, chapter 461, or chapter 466, or
44 similar statutory provision in another jurisdiction, or such
45 provider's agent or such other persons as specifically
46 authorized by the patient, regarding the drug therapy. However,
47 nothing in this subsection may be interpreted to permit an
48 alteration of a prescriber's directions, the diagnosis or
49 treatment of any disease, the initiation of any drug therapy,
50 the practice of medicine, or the practice of osteopathic

51 medicine, unless otherwise permitted by law. "Practice of the
52 profession of pharmacy" also includes any other act, service,
53 operation, research, or transaction incidental to, or forming a
54 part of, any of the foregoing acts, requiring, involving, or
55 employing the science or art of any branch of the pharmaceutical
56 profession, study, or training, and shall expressly permit a
57 pharmacist to transmit information from persons authorized to
58 prescribe medicinal drugs to their patients. The practice of the
59 profession of pharmacy also includes the administration of
60 vaccines to adults pursuant to s. 465.189 and the preparation of
61 prepackaged drug products in facilities holding Class III
62 institutional pharmacy permits.
63 (21) "Central distribution facility" means a facility
64 under common control with a hospital holding a Class III
65 institutional pharmacy permit that may dispense, distribute,
66 compound, or fill prescriptions for medicinal drugs; prepare
67 prepackaged drug products; and conduct other pharmaceutical
68 services.
69 (22) "Common control" means the power to direct or cause
70 the direction of the management and policies of a person or an
71 organization, whether by ownership of stock, voting rights,
72 contract, or otherwise.
73 Section 2. Subsection (2) of section 465.004, Florida
74 Statutes, is amended to read:
75 465.004 Board of Pharmacy.—

76 (2) Seven members of the board must be licensed
77 pharmacists who are residents of this state and who have been
78 engaged in the practice of the profession of pharmacy in this
79 state for at least 4 years and, to the extent practicable,
80 represent the various pharmacy practice settings. Of the
81 pharmacist members, two must be currently engaged in the
82 practice of pharmacy in a community pharmacy, two must be
83 currently engaged in the practice of pharmacy in a Class II,
84 ~~institutional pharmacy or a~~ Modified Class II, or Class III
85 institutional pharmacy, and three must be pharmacists licensed
86 in this state irrespective of practice setting. The remaining
87 two members must be residents of the state who have never been
88 licensed as pharmacists and who are in no way connected with the
89 practice of the profession of pharmacy. No person may be
90 appointed as a consumer member who is in any way connected with
91 a drug manufacturer or wholesaler. At least one member of the
92 board must be 60 years of age or older. The Governor shall
93 appoint members to the board in accordance with this subsection
94 as members' terms expire or as a vacancy occurs until the
95 composition of the board complies with the requirements of this
96 subsection.
97 Section 3. Subsections (4) and (6) of section 465.019,
98 Florida Statutes, are amended, and paragraph (d) is added to
99 subsection (2) of that section, to read:
100 465.019 Institutional pharmacies; permits.—

101 (2) The following classes of institutional pharmacies are
102 established:
103 (d)1. "Class III institutional pharmacies" are those
104 institutional pharmacies, including central distribution
105 facilities, affiliated with a hospital that provide the same
106 services that are authorized by a Class II institutional
107 pharmacy permit. Class III institutional pharmacies may also:
108 a. Dispense, distribute, compound, and fill prescriptions
109 for medicinal drugs.
110 b. Prepare prepackaged drug products.
111 c. Conduct other pharmaceutical services for the
112 affiliated hospital and for entities under common control that
113 are each permitted under this chapter to possess medicinal
114 drugs.
115 d. Provide the services in sub-subparagraphs a.-c. to an
116 entity under common control which holds an active health care
117 clinic establishment permit as required under s. 499.01(2)(r).
118 2. A Class III institutional pharmacy shall maintain
119 policies and procedures addressing:
120 a. The consultant pharmacist responsible for
121 pharmaceutical services.
122 b. Safe practices for the preparation, dispensing,
123 prepackaging, distribution, and transportation of medicinal
124 drugs and prepackaged drug products.
125 c. Recordkeeping to monitor the movement, distribution,

126 and transportation of medicinal drugs and prepackaged drug
127 products.
128 d. Recordkeeping of pharmacy staff responsible for each
129 step in the preparation, dispensing, prepackaging,
130 transportation, and distribution of medicinal drugs and
131 prepackaged drug products.
132 e. Medicinal drugs and prepackaged drug products that may
133 not be safely distributed among Class III institutional
134 pharmacies.
135 (4) Medicinal drugs shall be dispensed in an institutional
136 pharmacy to outpatients only when that institution has secured a
137 community pharmacy permit from the department. However, an
138 individual licensed to prescribe medicinal drugs in this state
139 may dispense up to a 24-hour supply of a medicinal drug to any
140 patient of an emergency department of a hospital that operates a
141 Class II or Class III institutional pharmacy, provided that the
142 physician treating the patient in such hospital's emergency
143 department determines that the medicinal drug is warranted and
144 that community pharmacy services are not readily accessible,
145 geographically or otherwise, to the patient. Such dispensing
146 from the emergency department must be in accordance with the
147 procedures of the hospital. For any such patient for whom a
148 medicinal drug is warranted for a period to exceed 24 hours, an
149 individual licensed to prescribe such drug must dispense a 24-
150 hour supply of such drug to the patient and must provide the

151 patient with a prescription for such drug for use after the
152 initial 24-hour period. The board may adopt rules necessary to
153 carry out the provisions of this subsection.
154 (6) In a Class II or Class III institutional pharmacy, an
155 institutional formulary system may be adopted with approval of
156 the medical staff for the purpose of identifying those medicinal
157 drugs, proprietary preparations, biologics, biosimilars, and
158 biosimilar interchangeables that may be dispensed by the
159 pharmacists employed in such institution. A facility with a
160 Class II or Class III institutional pharmacy permit which is
161 operating under the formulary system shall establish policies
162 and procedures for the development of the system in accordance
163 with the joint standards of the American Hospital Association
164 and American Society of Hospital Pharmacists for the utilization
165 of a hospital formulary system, which formulary shall be
166 approved by the medical staff.
167 Section 4. Subsection (3) of section 465.0252, Florida
168 Statutes, is amended to read:
169 465.0252 Substitution of interchangeable biosimilar
170 products.—
171 (3) A pharmacist who practices in a Class II, ~~or~~ Modified
172 Class II, or Class III institutional pharmacy shall comply with
173 the notification provisions of paragraph (2)(c) by entering the
174 substitution in the institution's written medical record system
175 or electronic medical record system.

176 Section 5. Subsection (39) of section 499.003, Florida
177 Statutes, is amended, and paragraphs (w) and (x) are added to
178 subsection (48) of that section, to read:
179 499.003 Definitions of terms used in this part.—As used in
180 this part, the term:
181 (39) "Prepackaged drug product" means a drug that
182 originally was in finished packaged form sealed by a
183 manufacturer and that is placed in a properly labeled container
184 by a pharmacy or practitioner authorized to dispense pursuant to
185 chapter 465 for the purpose of dispensing or by a facility
186 holding a Class III institutional pharmacy permit ~~in the~~
187 ~~establishment in which the prepackaging occurred~~.
188 (48) "Wholesale distribution" means the distribution of a
189 prescription drug to a person other than a consumer or patient,
190 or the receipt of a prescription drug by a person other than the
191 consumer or patient, but does not include:
192 (w) A hospital covered by s. 340B of the Public Health
193 Service Act, 42 U.S.C. s. 256b, that arranges for a prescription
194 drug wholesale distributor to distribute prescription drugs
195 covered under that act directly to a contract pharmacy. Such
196 hospital is exempt from obtaining a restricted prescription drug
197 distributor permit under s. 499.01(2)(h).
198 (x) The dispensing or distribution of a medicinal drug by
199 a Class III institutional pharmacy pursuant to s. 465.019.
200 Section 6. Paragraphs (b) and (h) of subsection (2) and

201 subsection (5) of section 499.01, Florida Statutes, are amended
202 to read:
203 499.01 Permits.—
204 (2) The following permits are established:
205 (b) Prescription drug repackager permit.—A prescription
206 drug repackager permit is required for any person that
207 repackages a prescription drug in this state.
208 1. A person that operates an establishment permitted as a
209 prescription drug repackager may engage in distribution of
210 prescription drugs repackaged at that establishment and must
211 comply with all of the provisions of this part and the rules
212 adopted under this part that apply to a prescription drug
213 manufacturer.
214 2. A prescription drug repackager must comply with all
215 appropriate state and federal good manufacturing practices.
216 3. A prescription drug repackager permit is not required
217 for distributing medicinal drugs or prepackaged drug products
218 between entities under common control which each hold either an
219 active Class III institutional pharmacy permit under chapter 465
220 or an active health care clinic establishment permit under
221 paragraph (2)(r). For purposes of this subparagraph, the term
222 "common control" has the same meaning as in s. 499.003(48)(a)3.
223 (h) Restricted prescription drug distributor permit.—
224 1. A restricted prescription drug distributor permit is
225 required for:

226 a. Any person located in this state who engages in the
227 distribution of a prescription drug, which distribution is not
228 considered "wholesale distribution" under s. 499.003(48)(a).
229 b. Any person located in this state who engages in the
230 receipt or distribution of a prescription drug in this state for
231 the purpose of processing its return or its destruction if such
232 person is not the person initiating the return, the prescription
233 drug wholesale supplier of the person initiating the return, or
234 the manufacturer of the drug.
235 c. A blood establishment located in this state which
236 collects blood and blood components only from volunteer donors
237 as defined in s. 381.06014 or pursuant to an authorized
238 practitioner's order for medical treatment or therapy and
239 engages in the wholesale distribution of a prescription drug not
240 described in s. 499.003(48)(j) to a health care entity. A mobile
241 blood unit operated by a blood establishment permitted under
242 this sub-subparagraph is not required to be separately
243 permitted. The health care entity receiving a prescription drug
244 distributed under this sub-subparagraph must be licensed as a
245 closed pharmacy or provide health care services at that
246 establishment. The blood establishment must operate in
247 accordance with s. 381.06014 and may distribute only:
248 (I) Prescription drugs indicated for a bleeding or
249 clotting disorder or anemia;
250 (II) Blood-collection containers approved under s. 505 of

251 the federal act;
252 (III) Drugs that are blood derivatives, or a recombinant
253 or synthetic form of a blood derivative;
254 (IV) Prescription drugs that are identified in rules
255 adopted by the department and that are essential to services
256 performed or provided by blood establishments and authorized for
257 distribution by blood establishments under federal law; or
258 (V) To the extent authorized by federal law, drugs
259 necessary to collect blood or blood components from volunteer
260 blood donors; for blood establishment personnel to perform
261 therapeutic procedures under the direction and supervision of a
262 licensed physician; and to diagnose, treat, manage, and prevent
263 any reaction of a volunteer blood donor or a patient undergoing
264 a therapeutic procedure performed under the direction and
265 supervision of a licensed physician,
266
267 as long as all of the health care services provided by the blood
268 establishment are related to its activities as a registered
269 blood establishment or the health care services consist of
270 collecting, processing, storing, or administering human
271 hematopoietic stem cells or progenitor cells or performing
272 diagnostic testing of specimens if such specimens are tested
273 together with specimens undergoing routine donor testing. The
274 blood establishment may purchase and possess the drugs described
275 in this sub-subparagraph without a health care clinic

276 establishment permit.
277 2. Storage, handling, and recordkeeping of these
278 distributions by a person required to be permitted as a
279 restricted prescription drug distributor must be in accordance
280 with the requirements for wholesale distributors under s.
281 499.0121.
282 3. A person who applies for a permit as a restricted
283 prescription drug distributor, or for the renewal of such a
284 permit, must provide to the department the information required
285 under s. 499.012.
286 4. The department may adopt rules regarding the
287 distribution of prescription drugs by hospitals, health care
288 entities, charitable organizations, other persons not involved
289 in wholesale distribution, and blood establishments, which rules
290 are necessary for the protection of the public health, safety,
291 and welfare.
292 5. A restricted prescription drug distributor permit is
293 not required for distributions between pharmacies that each hold
294 an active permit under chapter 465, have a common ownership, and
295 are operating in a freestanding end-stage renal dialysis clinic,
296 if such distributions are made to meet the immediate emergency
297 medical needs of specifically identified patients and do not
298 occur with such frequency as to amount to the regular and
299 systematic supplying of that drug between the pharmacies. The
300 department shall adopt rules establishing when the distribution

301 of a prescription drug under this subparagraph amounts to the
302 regular and systematic supplying of that drug.
303 6. A restricted prescription drug distributor permit is
304 not required for distributing medicinal drugs or prepackaged
305 drug products between entities under common control that each
306 hold either an active Class III institutional pharmacy permit
307 under chapter 465 or an active health care clinic establishment
308 permit under paragraph (2)(r). For purposes of this
309 subparagraph, the term "common control" has the same meaning as
310 in s. 499.003(48)(a)3.
311 ~~(5) A prescription drug repackager permit issued under~~
312 ~~this part is not required for a restricted prescription drug~~
313 ~~distributor permitholder that is a health care entity to~~
314 ~~repackage prescription drugs in this state for its own use or~~
315 ~~for distribution to hospitals or other health care entities in~~
316 ~~the state for their own use, pursuant to s. 499.003(48)(a)3.,~~
317 ~~if:~~
318 ~~(a) The prescription drug distributor notifies the~~
319 ~~department, in writing, of its intention to engage in~~
320 ~~repackaging under this exemption, 30 days before engaging in the~~
321 ~~repackaging of prescription drugs at the permitted~~
322 ~~establishment;~~
323 ~~(b) The prescription drug distributor is under common~~
324 ~~control with the hospitals or other health care entities to~~
325 ~~which the prescription drug distributor is distributing~~

326 ~~prescription drugs. As used in this paragraph, "common control"~~
327 ~~means the power to direct or cause the direction of the~~
328 ~~management and policies of a person or an organization, whether~~
329 ~~by ownership of stock, voting rights, contract, or otherwise;~~
330 ~~(c) The prescription drug distributor repackages the~~
331 ~~prescription drugs in accordance with current state and federal~~
332 ~~good manufacturing practices; and~~
333 ~~(d) The prescription drug distributor labels the~~
334 ~~prescription drug it repackages in accordance with state and~~
335 ~~federal laws and rules.~~
336
337 ~~The prescription drug distributor is exempt from the product~~
338 ~~registration requirements of s. 499.015 with regard to the~~
339 ~~prescription drugs that it repackages and distributes under this~~
340 ~~subsection. A prescription drug distributor that repackages and~~
341 ~~distributes prescription drugs under this subsection to a not-~~
342 ~~for-profit rural hospital, as defined in s. 395.602, is not~~
343 ~~required to comply with paragraph (c) or paragraph (d), but must~~
344 ~~provide to each health care entity for which it repackages, for~~
345 ~~each prescription drug that is repackaged and distributed, the~~
346 ~~information required by department rule for labeling~~
347 ~~prescription drugs. The department shall adopt rules to ensure~~
348 ~~the safety and integrity of prescription drugs repackaged and~~
349 ~~distributed under this subsection, including rules regarding~~
350 ~~prescription drug manufacturing and labeling requirements.~~

351 Section 7. This act shall take effect July 1, 2018.