

**BOARD OF PHARMACY  
JOINT RULES COMMITTEE  
RULES WORKSHOP  
July 29, 2020  
9:00 A.M. ET  
Call In Number: (888) 585-9008  
Conference Code: 599-196-982(#)**

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the board's website.

**I. CALL TO ORDER/ROLL CALL**

**MEMBERS PRESENT**

Jeffrey Mesaros, PharmD, JD, Chair  
Jeenu Philip, BPharm,  
Jonathan Hickman, PharmD  
Mark Mikhael, PharmD  
David Wright, BPharm

**BOARD OF MEDICINE MEMBERS:**

Hector Vila, MD

**STAFF PRESENT**

Jessica Sapp, Executive Director  
Traci Zeh, Program Administrator

**BOARD COUNSEL**

David Flynn, Esq.  
Senior Assistant Attorney General  
Christopher Dierlam, Esq.  
Assistant Attorney General

**BOARD OF OSTEOPATHIC MEDICINE MEMBERS:**

Joel B. Rose, DO  
Michelle R. Mendez, DO

**COURT REPORTER**

For the Record  
150 Mahan Drive, Suite 140  
Tallahassee, FL 32308  
(850) 222-5491  
(850) 224-5316 (Fax)

**II. RULES DEVELOPMENT WORKSHOP**

- a. 64B16-31.007, F.A.C., Collaborative Practice Certification: Chronic Health Conditions
- b. 64B16-31.039, F.A.C., Test and Treat Certification: Formulary of Medicinal Drugs

**III. RULES DISCUSSION**

- a. HB 389 Practice of Pharmacy
  - i. Chapter 64B16-31, F.A.C., Collaborative Practice and Test and Treat Certifications

**IV. ADJOURNMENT**

## **64B16-31.007 Collaborative Practice Certification: Chronic Health Conditions.**

Pursuant to Section 465.1865, F.S., the Board hereby adopts the following list of chronic health conditions for which a pharmacist certified pursuant to section 465.1865, F.S., can provide specified patient care services to patients of a collaborating physician pursuant to a pending Collaborative Pharmacy Practice Agreement:

- 1) Hyperlipidemia;
- 2) Hypertension;
- 3) Anti-coagulation management;
- 4) Smoking cessation;
- 5) Osteoporosis and Osteoarthritis;
- 6) Opioid use disorder; and
- 7) Those chronic health conditions enumerated in section 465.1865(1)(b), F.S.
- 8) Any disease state that is expected to last greater than one (1) year or more and will require ongoing medical treatment and drug therapy services.

## **64B16-31.039 Test and Treat Certification: Formulary of Medical Drugs**

(1) Pursuant to section 465.1895, F.S., the Board hereby incorporates all medicinal drugs approved by the United States Food and Drug Administration (“FDA”) as the formulary of medicinal drugs that a pharmacist may prescribe pursuant to a written test and treat protocol.

~~(b) All compounded medicinal drugs that utilize only active pharmaceutical ingredients approved by the FDA.~~

(2) A pharmacist may not prescribe controlled substances as described in s. 893.03 or 21 U.S.C. s. 812.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

## Zeh, Traci

---

**Subject:** FW: Proposed Rule 64B16-31.007

**From:** Sapp, Jessica

**Sent:** Thursday, July 2, 2020 12:29 PM

**To:** 'Mary Thomas' <[MThomas@flmedical.org](mailto:MThomas@flmedical.org)>; [nulandlaw@aol.com](mailto:nulandlaw@aol.com); [David.Flynn@myfloridalegal.com](mailto:David.Flynn@myfloridalegal.com)

**Cc:** Winn, Jason D. <[jwinn@jwinnlaw.com](mailto:jwinn@jwinnlaw.com)>

**Subject:** RE: Proposed Rule 64B16-31.007

Good afternoon,

This is to inform you that a rule development workshop on proposed rules 64B16-31.007, F.A.C. and 31.039, F.A.C. has been scheduled in conjunction with our joint rules committee meeting for Wednesday, July 29, 2020 at 9:00 a.m.

Regards,

**Jessica Sapp**

**Executive Director**

Department of Health | Division of Medical Quality Assurance

Bureau of Health Care Practitioner Regulation

4052 Bald Cypress Way Bin C-04

Tallahassee, FL 32399-1708

Phone 850/245-4463

[www.FloridasDentistry.gov](http://www.FloridasDentistry.gov)

[www.FloridasPharmacy.gov](http://www.FloridasPharmacy.gov)



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**From:** Mary Thomas <[MThomas@flmedical.org](mailto:MThomas@flmedical.org)>

**Sent:** Monday, June 29, 2020 12:34 PM

**To:** [nulandlaw@aol.com](mailto:nulandlaw@aol.com); Sapp, Jessica <[Jessica.Sapp@flhealth.gov](mailto:Jessica.Sapp@flhealth.gov)>; [David.Flynn@myfloridalegal.com](mailto:David.Flynn@myfloridalegal.com)

**Cc:** Winn, Jason D. <[jwinn@jwinnlaw.com](mailto:jwinn@jwinnlaw.com)>

**Subject:** RE: Proposed Rule 64B16-31.007

Ms. Sapp,

On behalf of the Florida Medical Association and the Florida Osteopathic Medical Association, I would like to echo Mr. Nuland's comments and concerns and formally request a rule development workshop on the proposed rules within Chapter 64B16-31, F.A.C.

Thank you,

Mary



Mary Thomas, Esq.  
Assistant General Counsel  
1430 Piedmont Dr. E  
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**From:** CHRIS NULAND <[nulandlaw@aol.com](mailto:nulandlaw@aol.com)>  
**Sent:** Monday, June 29, 2020 11:56 AM  
**To:** [Jessica.Sapp@flhealth.gov](mailto:Jessica.Sapp@flhealth.gov); [David.Flynn@myfloridalegal.com](mailto:David.Flynn@myfloridalegal.com)  
**Subject:** Proposed Rule 64B16-31.007

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**Law Offices of Christopher L. Nuland, P.A.**  
4427 Herschel Street  
Jacksonville, FL 32210  
(904) 355-1555  
[nulandlaw@aol.com](mailto:nulandlaw@aol.com)

Dear Ms. Sapp:

Thank you for the opportunity to have spoken briefly at last week's Board of Pharmacy Rules Committee meeting with regard to the above rule.

As I and my clients believe that questions still remain as to whether the existence of subsection (8) is supported by sufficient statutory authority, is arbitrary and capricious in its wording, as well as whether the addition of certain diseases has been supported by competent substantial evidence, the Florida Chapter of the American College of Physicians and the Florida Academy of Family Physicians would like to request a formal workshop on the proposed rule.

Thank you for your time and consideration of this request, and I hope you all stay well.

Sincerely,

CHRIS NULAND  
[nulandlaw@aol.com](mailto:nulandlaw@aol.com)

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Executive Director

TEENA DIOTTE  
Executive Manager

Thursday, July 2, 2020

Florida Board of Pharmacy  
4052 Bald Cypress Way Bin C-04  
Tallahassee, FL 32399-3258

## RE: Rule Making Authority 465.1865, 64B16-31.007 Collaborative Practice Certification – Chronic Health Conditions

Dear Board of Pharmacy Committee Members,

The Florida Society of Rheumatology (FSR) represents the physicians and other medical professionals practicing rheumatology in the state of Florida and facilitates the recognition of the role of the rheumatologist as the provider of choice for patients with arthritis, chronic pain, osteoporosis, and musculoskeletal disease.

We manage a select, specific group of highly complex autoimmune diseases that require specialized medications that modulate the immune system - much like oncologists who use chemotherapy, immunomodulatory and at times immunosuppressive medications to treat cancer. These medications have specific indications, target the immune system, and have to prescribe with great care and consideration to the appropriate patient, in order to maximize effectiveness and minimize side effects.

In response to the Collaborative Practice Certification – Chronic Health Conditions, the FSR respectfully requests that **section (8) eight, “any disease state that is expected to last greater than (1) year or more and will require ongoing medical treatment and drug therapy services”** be deleted from the proposed rule. The FSR agrees that the Board of Pharmacy has the authority to approve certain chronic health conditions, but to unilaterally allow all chronic health conditions to be subjected to this agreement raises serious concerns for the care and safety of our patient community.

FSR believes the Board of Pharmacy shares our concern to protect the health, safety and welfare of our unique patient population, and each condition should be considered prior to inclusion. Just because a health condition is expected to last greater than (1) year, does nothing in the consideration as to if the disease state lends itself well to a written constraints of collaborative practice and if comorbidities outside the chronic condition also need to be part of the management of the drug therapies in question.



@FloridaRheums

After all, the pharmacist is not managing the disease, but the drug therapies to be used in treating that disease, and the pharmacist does not go to school or have the required training to be a specialist in any one disease type, so we believe training must be added to the CME requirements for each disease state added.

Furthermore, the FSR opposes the BOP from including **“osteoporosis” in section (5) five of the Collaborative Practice Certification – Chronic Health Conditions**. There are many choices in the treatment of osteoporosis. The choice of the right treatment depends on the severity of the disease as well as comorbidities. It is not a simple decision in many cases whether the patient should or should not receive treatment. There are many drug choices for therapy in osteoporosis. The choice of which drug should be used not only depends on the severity of disease but also other additional diseases the patient may have, or comorbidities. So, the choice of which drug to use in a specific patient is a complex decision, within a mostly elder and fragile patient population.

The diagnosis must be verified by thorough review of the patient’s history, bone mineral density scan results and often, imaging study. Cognitive evaluation is also done by the physician to verify the diagnosis and severity of disease to select the right drug. After verifying that the diagnosis is, in fact, osteoporosis, the patient’s history of related comorbidities is determined and the severity of each of those must be ascertained to select the medication which will not only be the most effective, but importantly, the safest for that unique patient.

Osteoporosis is complex to manage and could result in permanent negative patient outcomes if treated improperly. There are a number of underlying causes/contributing factors for osteoporosis which must be evaluated and treated differently for optimal treatment results. We oppose the management of this condition by consulting pharmacists, and this disease does not fit into a simple algorithm of care such as the other conditions contemplated under a collaborative agreement.

We do not object to **“osteoarthritis” being included in section (5) five**. When treating osteoarthritis, care pathways are more straightforward algorithms of care, conducive to a collaborative agreement.

However, many of our patients have arthritis that represents an inflammatory and/or autoimmune disease. These are complex diseases that even physicians outside of our specialty do not manage. These diseases require complex assessments to ascertain whether the current treatment is effective and safe. Conducting these assessments is not simple and straightforward. It is often not obvious whether a treatment regimen should be changed. It takes specialized training and experience to be skilled enough to conduct these assessments competently.

In the case of the best known of these diseases, rheumatoid arthritis, such assessment includes obtaining validated patient reported outcomes, conducting a physical exam including a swollen and tender joint count, as well as review of radiology and laboratory findings. Synthesizing this information and then making the decision whether treatment should be changed is something that is beyond the scope of a consulting pharmacist. After the decision is made to change therapy, the decision of what the next best treatment regimen is also complex. This capacity takes experience and specialized training, beyond the scope of a consulting pharmacist.

Other examples of complex inflammatory and autoimmune diseases that FSR believes should not be managed by a consulting pharmacist include systemic lupus erythematosus and psoriatic arthritis. This is not an inclusive list as there are many more diseases in this category of inflammatory and autoimmune

arthritis. It is the firm opinion of FSR that Consulting Pharmacists should not be allowed to manage these forms of inflammatory and autoimmune diseases.

FSR stands committed in working with the Florida Board of Pharmacy in helping provide the best treatment options for Floridians with chronic conditions. Toward that end, please include us as an interested party in any future communications regarding the proposed rule. Thank you for your consideration.

Respectfully,

A handwritten signature in black ink, appearing to read 'G. Valenzuela', is positioned above the typed name.

Guillermo J. Valenzuela, MD  
President  
Florida Society of Rheumatology

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1  
2 An act relating to the practice of pharmacy; amending  
3 s. 381.0031, F.S.; requiring specified licensed  
4 pharmacists to report certain information relating to  
5 public health to the Department of Health; amending s.  
6 465.003, F.S.; revising the definition of the term  
7 "practice of the profession of pharmacy"; creating s.  
8 465.1865, F.S.; providing definitions; providing  
9 requirements for pharmacists to provide services under  
10 a collaborative pharmacy practice agreement; requiring  
11 the terms and conditions of such agreement to be  
12 appropriate to the training of the pharmacist and the  
13 scope of practice of the physician; requiring  
14 notification to the board upon practicing under a  
15 collaborative pharmacy practice agreement; requiring  
16 pharmacists to submit a copy of the signed  
17 collaborative pharmacy practice agreement to the Board  
18 of Pharmacy; providing for the maintenance of patient  
19 records for a certain period of time; providing for  
20 renewal of such agreement; requiring a pharmacist and  
21 the collaborating physician to maintain on file and  
22 make available the collaborative pharmacy practice  
23 agreement; prohibiting certain actions relating to  
24 such agreement; requiring specified continuing  
25 education for a pharmacist who practices under a

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26 | collaborative pharmacy practice agreement; requiring  
27 | the Board of Pharmacy to adopt rules in consultation  
28 | with the Board of Medicine and the Board of  
29 | Osteopathic Medicine; creating s. 465.1895, F.S.;  
30 | requiring the Board of Pharmacy to identify minor,  
31 | nonchronic health conditions that a pharmacist may  
32 | test or screen for and treat; providing requirements  
33 | for a pharmacist to test or screen for and treat  
34 | minor, nonchronic health conditions; requiring the  
35 | board to develop a formulary of medicinal drugs that a  
36 | pharmacist may prescribe; providing requirements for  
37 | the written protocol between a pharmacist and a  
38 | supervising physician; prohibiting a pharmacist from  
39 | providing certain services under certain  
40 | circumstances; requiring a pharmacist to complete a  
41 | specified amount of continuing education; providing  
42 | additional requirements for pharmacists and pharmacies  
43 | providing testing and screening services; providing  
44 | for applicability; providing an effective date.

45 |  
46 | Be It Enacted by the Legislature of the State of Florida:

47 |  
48 | Section 1. Subsection (2) of section 381.0031, Florida  
49 | Statutes, is amended to read:

50 | 381.0031 Epidemiological research; report of diseases of

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51 public health significance to department.—

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

65 Section 2. Subsection (13) of section 465.003, Florida  
 66 Statutes, is amended to read:

67 465.003 Definitions.—As used in this chapter, the term:

68 (13) "Practice of the profession of pharmacy" includes  
 69 compounding, dispensing, and consulting concerning contents,  
 70 therapeutic values, and uses of any medicinal drug; consulting  
 71 concerning therapeutic values and interactions of patent or  
 72 proprietary preparations, whether pursuant to prescriptions or  
 73 in the absence and entirely independent of such prescriptions or  
 74 orders; and conducting other pharmaceutical services. For  
 75 purposes of this subsection, "other pharmaceutical services"

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76 | means the monitoring of the patient's drug therapy and assisting  
77 | the patient in the management of his or her drug therapy, and  
78 | includes review of the patient's drug therapy and communication  
79 | with the patient's prescribing health care provider as licensed  
80 | under chapter 458, chapter 459, chapter 461, or chapter 466, or  
81 | similar statutory provision in another jurisdiction, or such  
82 | provider's agent or such other persons as specifically  
83 | authorized by the patient, regarding the drug therapy; and  
84 | initiating, modifying, or discontinuing drug therapy for a  
85 | chronic health condition under a collaborative pharmacy practice  
86 | agreement. ~~However,~~ Nothing in this subsection may be  
87 | interpreted to permit an alteration of a prescriber's  
88 | directions, the diagnosis or treatment of any disease, the  
89 | initiation of any drug therapy, the practice of medicine, or the  
90 | practice of osteopathic medicine, unless otherwise permitted by  
91 | law or specifically authorized by s. 465.1865 or s. 465.1895.  
92 | "Practice of the profession of pharmacy" also includes any other  
93 | act, service, operation, research, or transaction incidental to,  
94 | or forming a part of, any of the foregoing acts, requiring,  
95 | involving, or employing the science or art of any branch of the  
96 | pharmaceutical profession, study, or training, and shall  
97 | expressly permit a pharmacist to transmit information from  
98 | persons authorized to prescribe medicinal drugs to their  
99 | patients. The practice of the profession of pharmacy also  
100 | includes the administration of vaccines to adults pursuant to s.

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101 465.189, the testing or screening for and treatment of minor,  
 102 nonchronic health conditions pursuant to s. 465.1895, and the  
 103 preparation of prepackaged drug products in facilities holding  
 104 Class III institutional pharmacy permits.

105 Section 3. Section 465.1865, Florida Statutes, is created  
 106 to read:

107 465.1865 Collaborative pharmacy practice for chronic  
 108 health conditions.-

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

110 (a) "Collaborative pharmacy practice agreement" means a  
 111 written agreement between a pharmacist who meets the  
 112 qualifications of this section and a physician licensed under  
 113 chapter 458 or chapter 459 in which a collaborating physician  
 114 authorizes a pharmacist to provide specified patient care  
 115 services to the collaborating physician's patients.

116 (b) "Chronic health condition" means:

117 1. Arthritis;

118 2. Asthma;

119 3. Chronic obstructive pulmonary diseases;

120 4. Type 2 diabetes;

121 5. Human immunodeficiency virus or acquired immune  
 122 deficiency syndrome;

123 6. Obesity; or

124 7. Any other chronic condition adopted in rule by the  
 125 board, in consultation with the Board of Medicine and Board of

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126 Osteopathic Medicine.

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

132 (a) Hold an active and unencumbered license to practice  
133 pharmacy in this state.

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

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

140 1. Performance of patient assessments.

141 2. Ordering, performing, and interpreting clinical and  
142 laboratory tests related to collaborative pharmacy practice.

143 3. Evaluating and managing diseases and health conditions  
144 in collaboration with other health care practitioners.

145 4. Any other area required by board.

146 (d) Maintain at least \$250,000 of professional liability  
147 insurance coverage. However, a pharmacist who maintains  
148 professional liability insurance coverage pursuant to s.  
149 465.1895 satisfies this requirement.

150 (e) Have established a system to maintain records of all

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151 patients receiving services under a collaborative pharmacy  
152 practice agreement for a period of 5 years from each patient's  
153 most recent provision of service.

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

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

163 1. Name of the collaborating physician's patient or  
164 patients for whom a pharmacist may provide services.

165 2. Each chronic health condition to be collaboratively  
166 managed.

167 3. Specific medicinal drug or drugs to be managed by the  
168 pharmacist for each patient.

169 4. Circumstances under which the pharmacist may order or  
170 perform and evaluate laboratory or clinical tests.

171 5. Conditions and events upon which the pharmacist must  
172 notify the collaborating physician and the manner and timeframe  
173 in which such notification must occur.

174 6. Beginning and ending dates for the collaborative  
175 pharmacy practice agreement and termination procedures,

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176 | including procedures for patient notification and medical  
 177 | records transfers.

178 | 7. A statement that the collaborative pharmacy practice  
 179 | agreement may be terminated, in writing, by either party at any  
 180 | time.

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

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

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

191 | (4) A pharmacist may not:

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

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

198 | (5) A physician may not delegate the authority to initiate  
 199 | or prescribe a controlled substance as described in s. 893.03 or  
 200 | 21 U.S.C. s. 812 to a pharmacist.

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

211       (7) The board, in consultation with the Board of Medicine  
 212 and the Board of Osteopathic Medicine, shall adopt rules  
 213 pursuant to ss. 120.536(1) and 120.54 to implement this section.

214       Section 4. Section 465.1895, Florida Statutes, is created  
 215 to read:

216       465.1895 Testing or screening for and treatment of minor,  
 217 nonchronic health conditions.—

218       (1) A pharmacist may test or screen for and treat minor,  
 219 nonchronic health conditions within the framework of an  
 220 established written protocol with a supervising physician  
 221 licensed under chapter 458 or chapter 459. For purposes of this  
 222 section, a minor, nonchronic health condition is typically a  
 223 short-term condition that is generally managed with minimal  
 224 treatment or self-care, and includes:

225       (a) Influenza.

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226        (b) Streptococcus.  
 227        (c) Lice.  
 228        (d) Skin conditions, such as ringworm and athlete's foot.  
 229        (e) Minor, uncomplicated infections.  
 230        (2) A pharmacist who tests or screens for and treats  
 231 minor, nonchronic health conditions under this section must:  
 232        (a) Hold an active and unencumbered license to practice  
 233 pharmacy in the state.  
 234        (b) Hold a certification issued by the board to test and  
 235 screen for and treat minor, nonchronic health conditions, in  
 236 accordance with requirements established by the board in rule in  
 237 consultation with the Board of Medicine and Board of Osteopathic  
 238 Medicine. The certification must require a pharmacist to  
 239 complete, on a one-time basis, a 20-hour education course  
 240 approved by the board in consultation with the Board of Medicine  
 241 and the Board of Osteopathic Medicine. The course, at a minimum,  
 242 must address patient assessments; point-of-care testing  
 243 procedures; safe and effective treatment of minor, nonchronic  
 244 health conditions; and identification of contraindications.  
 245        (c) Maintain at least \$250,000 of liability coverage. A  
 246 pharmacist who maintains liability coverage pursuant to s.  
 247 465.1865 satisfies this requirement.  
 248        (d) Report a diagnosis or suspected existence of a disease  
 249 of public health significance to the department pursuant to s.  
 250 381.0031.

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

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

256 (3) The board shall adopt, by rule, a formulary of  
 257 medicinal drugs that a pharmacist may prescribe for the minor,  
 258 nonchronic health conditions approved under subsection (1). The  
 259 formulary must include medicinal drugs approved by the United  
 260 States Food and Drug Administration which are indicated for  
 261 treatment of the minor, nonchronic health condition. The  
 262 formulary may not include any controlled substance as described  
 263 in s. 893.03 or 21 U.S.C. s. 812.

264 (4) A pharmacist who tests or screens for and treats  
 265 minor, nonchronic health conditions under this section may use  
 266 any tests that may guide diagnosis or clinical decisionmaking  
 267 which the Centers for Medicare and Medicaid Services has  
 268 determined qualifies for a waiver under the federal Clinical  
 269 Laboratory Improvement Amendments of 1988, or the federal rules  
 270 adopted thereunder, or any established screening procedures that  
 271 can safely be performed by a pharmacist.

272 (5) The written protocol between a pharmacist and  
 273 supervising physician under this subsection must include  
 274 particular terms and conditions imposed by the supervising  
 275 physician relating to the testing and screening for and

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2020 Legislature

276 treatment of minor, nonchronic health conditions under this  
277 section. The terms and conditions must be appropriate to the  
278 pharmacist's training. A pharmacist who enters into such a  
279 protocol with a supervising physician must submit the protocol  
280 to the board.

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

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

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

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

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

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

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

300 (b) A pharmacist authorized to test and screen for and

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2020 Legislature

301 treat minor, nonchronic conditions under a protocol shall  
302 provide evidence of current certification by the board to the  
303 supervising physician. A supervising physician shall review the  
304 pharmacist's actions in accordance with the protocol.

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

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

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

323 (9) The pharmacy in which a pharmacist tests and screens  
324 for and treats minor, nonchronic health conditions must  
325 prominently display signage indicating that any patient

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2020 Legislature

326 | receiving testing, screening, or treatment services under this  
 327 | section is advised to seek followup care from his or her primary  
 328 | care physician.

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

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

335 | Section 5. This act shall take effect July 1, 2020.  
 336 |

Board of Pharmacy  
Implementation Working Draft for Ch. 2020-7, Laws of Fla.<sup>1</sup> (CS HB  
No. 389<sup>2</sup>) (Eff. July 1, 2020).

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**CHAPTER 64B16-31**  
**COLLABORATIVE PRACTICE AND TEST AND TREAT CERTIFICATIONS**

64B16-31.001	Collaborative Practice Certification (CPC)
64B16-31.003	Collaborative Practice Certification: Initial Certification Course
64B16-31.005	Collaborative Practice Certification: Collaborative Pharmacy Practice Agreement Submission
64B16-31.007	Collaborative Practice Certification: Chronic Health Condition
64B16-31.009	Collaborative Practice Certification: Mandatory Continuing Education
64B16-31.033	Test and Treat Certification (TTC)
64B16-31.035	Test and Treat Certification: Initial Certification Course
64B16-31.037	Test and Treat Certification: Written Protocol and Written Protocol Submission
64B16-31.039	Test and Treat Certification: Formulary of Medicinal Drugs
64B16-31.041	Test and Treat Certification: Patient Records
64B16-31.043	Test and Treat Certification: Follow-Up Care
64B16-31.045	Test and Treat Certification: Mandatory Continuing Education
64B16-31.050	Mandatory Review of Rule Chapter 64B16-31, F.A.C.

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<sup>1</sup> Please See Appendix A for a Copy of [Chapter 2020-7, Laws of Florida](#).

<sup>2</sup> Please See Appendix B for a Copy of [Committee Substitute for House Bill No. 389](#).

### **64B16-31.001 Collaborative Practice Certification (CPC).**

Applicants for CPC shall submit an application using Form DH-MQA XXXX (eff. 0X/20), “Application for Pharmacist Collaborative Practice Certification<sup>3</sup>” that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX> or <http://floridapharmacy.gov>. Applicants for certification shall ~~must~~ meet and comply with all requirements in Section 465.1865, F.S.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

### **64B16-31.003 Collaborative Practice Certification: Initial Certification Course.**

(1) Applicants for Initial Certification Course approval shall submit an application using Form DH-MQA XXX (eff. XX/20) “Application for Initial Collaborative Practice Certification Course<sup>4</sup>” that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX> or <http://floridapharmacy.gov>.

(2) Initial collaborative practice certification courses shall be a minimum of 20 hours in duration, and shall meet all the following mandatory requirements:

(a) The course may only be offered by a program provider who is accredited by the Accreditation Council for Pharmacy Education (ACPE), ~~or~~ a program provider who is accredited to provide educational activities designated for the American Medical Association Physician’s Recognition Award Category 1 credit, or a program provider approved by the American Osteopathic Association Category 1-A to offer continuing medical education credits.

(b) The course content and objectives offered by an approved provider shall be developed in conjunction with an individual licensed to practice pharmacy and an individual who is a licensed allopathic or osteopathic physician, or an individual who is dual licensed in both pharmacy and allopathic medicine or osteopathic medicine.

(c) The course content shall include all those areas enumerated in section 465.1865 (2)(c), F.S., and shall also cover the following areas:

<sup>3</sup> Please See Appendix C for a Copy of the [Application](#).

<sup>4</sup> Please See Appendix D for a Copy of the [Application](#).

1. Laws and rules applicable to the collaborative practice for the treatment of chronic health care conditions; and

2. Writing and entering into a collaborative practice agreement.

(d) No less than 12 hours of the course shall be offered through a live seminar or a live video teleconference.

(3) A pharmacist who successfully completes a board approved collaborative practice certification course shall be awarded 20 hours of general continuing education credits.

Place holder for consultation with BOM and BOOM.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

#### **64B16-31.005 Collaborative Practice Certification: Collaborative Pharmacy Practice Agreement Submission.**

(1) Prior to providing or implementing patient care services under a Collaborative Pharmacy Practice Agreement or immediately after the renewal of such an Agreement, the Pharmacist shall submit the executed Agreement to the Board Office through the pharmacist’s online licensure account at <http://www.flhealthsource.gov> or via U.S. Mail to 4052 Bald Cypress Way, Bin C-04, Tallahassee, FL 32399.

(2) In the event of an addendum to the material terms of an existing collaborative pharmacy practice agreement, the pharmacist shall maintain a copy of the addendum and the initial agreement pursuant to Section 465.1865(3)(c), F.S. Material terms shall be defined as those terms enumerated in Section 465.1865(3)(a), F.S.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

#### **64B16-31.007 Collaborative Practice Certification: Chronic Health Conditions.**

Pursuant to Section 465.1865, F.S., the Board hereby adopts the following list of chronic health conditions for which a pharmacist certified pursuant to section 465.1865, F.S., can provide specified patient care services to patients of a collaborating physician pursuant to a pending Collaborative Pharmacy Practice Agreement:

- 1) Hyperlipidemia;
- 2) Hypertension;
- 3) Anti-coagulation management;
- 4) Smoking cessation;

- 5) Osteoporosis and Osteoarthritis;
- 6) Opioid use disorder; and
- 7) Those chronic health conditions enumerated in section 465.1865(1)(b), F.S.
- 8) Any disease state that is expected to last greater than one (1) year or more and will require ongoing medical treatment and drug therapy services.

Place holder for discussion with Board to determine appropriate list of chronic health conditions in consultation with BOM and BOOM.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

### **64B16-31.009 Collaborative Practice Certification: Mandatory Continuing Education.**

A licensee shall not be required to complete the 8-hour continuing education related to collaborative pharmacy practice if the initial certificate was issued less than 12 months prior to the expiration date of the license.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

### **64B16-31.033 Test and Treat Certification (TTC)**

Applicants for TTC shall submit an application using Form DH-MQA XXXX (eff. 0X/20), “Application for Pharmacist Test and Treat Certification<sup>5</sup>” that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX> or <http://floridapharmacy.gov>. Applicants for certification shall must meet and comply with all requirements in Section 465.1895, F.S.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

### **64B16-31.035 Test and Treat Certification: Initial Certification Course**

(1) Applicants for Initial Certification Course approval shall submit an application using Form DH-MQA XXX (eff. XX/20) “Application for Initial Test and Treat Certification Course<sup>6</sup>” that is hereby incorporated by reference and available at

<sup>5</sup> Please See Appendix E for a Copy of the [Application](#).

<sup>6</sup> Please See Appendix F for a Copy of the [Application](#).

<http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX>\_\_\_\_\_ or  
<http://floridapharmacy.gov>.

(2) Initial test and treat certification courses shall be a minimum of 20 hours in duration, and shall meet all the following mandatory requirements:

(a) The course may only be offered by a program provider who is accredited by the Accreditation Council for Pharmacy Education (ACPE), ~~or~~ a program provider who is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit, or a program provider approved by the American Osteopathic Association ~~Category 1-A~~ to offer continuing medical education credits.

(b) The course content and objectives offered by an approved provider shall be developed in conjunction with an individual licensed to practice pharmacy and an individual who is a licensed allopathic or osteopathic physician, or an individual who is dual licensed in both pharmacy and allopathic medicine or osteopathic medicine.

(c) The course content shall include all those areas enumerated in section 465.1895 (2)(b), F.S., and shall also cover the following areas:

1. Laws and rules applicable to test and treat certifications; and
2. Writing and entering into a written protocol.

(d) No less than ~~12~~ 8 hours of the course shall be offered through a live seminar or a live video teleconference.

(3) A pharmacist who successfully completes a board approved test and treat certification course shall be awarded 20 hours of general continuing education credits.

Place holder for consultation with BOM and BOOM.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

### **64B16-31.037 Test and Treat Certification: Written Protocol and Written Protocol Submission**

(1) Within 5 business days of entering into a written protocol with a supervising physician pursuant to section 465.1895, F.S., the pharmacist shall submit a copy of

the written agreement to the Board Office through the pharmacist's online licensure account at <http://www.flhealthsource.gov> or via U.S. Mail to 4052 Bald Cypress Way, Bin C-04, Tallahassee, FL 32399.

(2) In the event of an addendum to the material terms of an existing written protocol, the pharmacist shall maintain a copy of the addendum and the initial agreement. Material terms shall be defined as those terms enumerated in Section 465.1895(5)(a), F.S.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

### **64B16-31.039 Test and Treat Certification: Formulary of Medical Drugs**

(1) Pursuant to section 465.1895, F.S., the Board hereby incorporates all medicinal drugs approved by the United States Food and Drug Administration (“FDA”) as the formulary of medicinal drugs that a pharmacist may prescribe pursuant to a written test and treat protocol.

~~(b) All compounded medicinal drugs that utilize only active pharmaceutical ingredients approved by the FDA.~~

(2) A pharmacist may not prescribe controlled substances as described in s. 893.03 or 21 U.S.C. s. 812.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

### **64B16-31.041 Test and Treat Certification: Patient Records**

Upon receipt of a patient request, a pharmacist shall furnish patient records to a health care practitioner designated by the patient within a reasonable time frame, not to exceed 5 business days.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

### **64B16-31.043 Test and Treat Certification: Follow-up Care**

A pharmacist must provide written information to the patient advising the patient when to seek follow-up care from his or her primary care physician. A pharmacist shall provide follow-up care written information:

- (1) Immediately prior to performing testing, screening, or treatment services on a patient for the first time;
- (2) As outlined in the written protocol; and
- (3) When the pharmacist determines in his or her judgment that the patient should follow-up with his or her primary care provider.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

#### **64B16-31.045 Test and Treat Certification: Mandatory Continuing Education.**

A licensee shall not be required to complete the 3-hour continuing education related to minor, nonchronic health conditions if the initial certificate was issued less than 12 months prior to the expiration date of the license.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

#### **64B16-31.050 Mandatory Review of Rule Chapter 64B16-31, F.A.C.**

- (1) No later than 90 days prior to December 31, 2025, the Board shall review each rule in this Chapter and amend, modify or repeal any rule that creates barriers to entry for private business competition, is duplicative, outdated, obsolete, overly burdensome, or imposes excessive costs.
- (2) In the event the Board fails to complete this review, the board, for any rule that has not been reviewed in accordance with subsection (1), shall begin the rule repeal process in accordance with the Administrative Procedures Act.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*



Application  
*for*  
Pharmacist Collaborative Practice Certification

**Board of Pharmacy**  
P.O. Box 6330  
Tallahassee, FL 32314-6330  
Website: <https://floridaspharmacy.gov/>  
Email: [info@floridaspharmacy.gov](mailto:info@floridaspharmacy.gov)  
Phone: (850) 245-4474  
Fax: (850) 921-5389



# Application for Pharmacist Collaborative Practice Certification

Board of Pharmacy  
P.O. Box 6330  
Tallahassee, FL 32314-6330  
Fax: (850) 921-5389  
Email: info@floridaspharmacy.gov

All applicants must hold a current Florida Pharmacist license that is active and in good standing.

## Pharmacist Collaborative Practice Certification

Prior to providing services under a collaborative pharmacy practice agreement, a pharmacist must be certified by the board. Additionally, a pharmacist must enter into a written agreement with a physician licensed under Chapter 458 or Chapter 459, Florida Statutes, in which a collaborating physician authorizes a pharmacist to provide specified patient care services for chronic health conditions. Please refer to section 465.1865, Florida Statutes, prior to submitting your application.

### 1. PERSONAL INFORMATION

Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
Last/Surname First Middle MM/DD/YYYY

Mailing Address: (This address is where mail and your certification will be sent)

Street/P.O. Box Apt. No. City

State ZIP Country Home/Cell Telephone (Input without dashes)

Physical Location: (Required if mailing address is a P.O. Box – this address will be posted on the Department of Health’s website)

Street Apt. No. City

State ZIP Country Business Telephone (Input without dashes)

Email Notification: To be notified of the status of your application by email, check the “Yes” box and fill in your email address on the line provided. If you choose to be notified via email you will be responsible for checking your email regularly and updating your email address with the board office.

Yes  No Email Address: \_\_\_\_\_

Under Florida law, email addresses are public records. If you do not want your email 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.

Name: \_\_\_\_\_

## 2. LICENSURE HISTORY

A. What is your Florida Pharmacist (PS) license number? \_\_\_\_\_

## 3. CERTIFICATION TRAINING

To qualify for certification, an applicant must have completed an initial 20-hour certification course that meets the statutory and rule requirements of section 465.1865, Florida Statutes, and Rule 64B16-31.003, F.A.C.

B. Have you successfully completed an initial 20-hour course approved by the Florida Board of Pharmacy?  Yes  No

If **yes**, provide a copy of the certificate of completion and the following information.

Provider Name	Provider Number	Date of Completion	Certificate Number

## 4. APPLICANT BACKGROUND

To qualify for certification, an applicant must have earned a degree of doctor of pharmacy or have completed 5 years of experience as a licensed pharmacist.

A. Have you earned a degree of doctor of pharmacy?  Yes  No

If **yes**, please list the name of university, college, or school of pharmacy you attended.

School Name	City/State or Country	Graduation Date	Degree Awarded

B. Have you completed 5 years of experience as a licensed pharmacist?  Yes  No

If **yes**, please list your experience below.

Employer	Location Address	Dates (From-To) MM/DD/YYYY

Name: \_\_\_\_\_

## 5. PROFESSIONAL LIABILITY INSURANCE

To provide services under a collaborative pharmacy practice agreement, a pharmacist must maintain at least \$250,000 of professional liability insurance coverage. A pharmacist who maintains professional liability insurance coverage as a requirement of the Test and Treat Certification, pursuant to section 465.1895, Florida Statutes, satisfies this requirement.

A. Do you maintain at least \$250,000 of professional liability insurance?  Yes  No

If “Yes,” provide the following information:

Insurance Provider Name	Policy Number	Policy Expiration Date

## 6. SYSTEM TO MAINTAIN RECORDS

To provide services under a collaborative pharmacy practice agreement, a pharmacist must have established a system to maintain records of all patients receiving services under a collaborative pharmacy practice agreement for a period of 5 years from each patient’s most recent provision of services, pursuant to section 465.1865, Florida Statutes.

A. Have you established a system to maintain records of all patients receiving services under a collaborative pharmacy practice agreement?  Yes  No

## 7. COLLABORATING PHYSICIAN

If available, provide the following information for the physician licensed under chapter 458 or 459, Florida Statutes, with whom you have entered into an agreement.

Physician Name: \_\_\_\_\_

Physician License #: \_\_\_\_\_

## COLLABORATIVE PHARMACY PRACTICE AGREEMENT INFORMATION

Section 465.1865(3), Florida Statutes, requires each collaborative pharmacy practice agreement include terms and conditions that are appropriate to the pharmacist’s training and the services delegated to the pharmacist must be within the collaborating physician’s scope of practice.

The collaborative practice agreement must include the following information:

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

The collaborative pharmacy practice agreement shall automatically terminate 2 years after execution if not renewed. The pharmacist, along with the collaborating physician, must maintain on file the collaborative pharmacy practice agreement at his or her practice location, and must make such agreements available to the department or board upon request or inspection.

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

**8. SOCIAL SECURITY DISCLOSURE**

**This information is exempt from public records disclosure.**

Pursuant to Title 42 United States Code § 666(a)(13), the department is required and authorized to collect Social Security numbers relating to applications for professional licensure. Additionally, section (s.) 456.013(1)(a), Florida Statutes (F.S.), authorizes the collection of Social Security numbers as part of the general licensing provisions.

**Last Name:** \_\_\_\_\_

**First Name:** \_\_\_\_\_

**Middle Name:** \_\_\_\_\_

**Social Security Number:** \_\_\_\_\_

(Input without dashes)

**Social Security Information-** \* Under the Federal Privacy Act, disclosure of Social Security numbers is voluntary unless specifically required by federal statute. In this instance, Social Security numbers are mandatory pursuant to Title 42 United States Code § 653 and 654; and s. 456.013(1), 409.2577, and 409.2598, F.S. Social Security numbers are used to allow efficient screening of applicants and licensees by a Title IV-D child support agency to ensure compliance with child support obligations. Social Security numbers must also be recorded on all professional and occupational license applications and will be used for license identification pursuant to Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Welfare Reform Act. 104 Pub. L. Section 317). Clarification of the SSA process may be reviewed at [www.ssa.gov](http://www.ssa.gov) or by calling 1-800-772-1213.

Name: \_\_\_\_\_

**9. APPLICANT SIGNATURE**

I, the undersigned, state that I am the person referred to in this application for certification in the state of Florida.

I recognize that providing false information may result in disciplinary action against my license or criminal penalties pursuant to s. 456.067 and 775.083, Florida Statutes.

Florida law requires me to immediately inform the board of any material change in any circumstances or condition stated in the application which takes place between the initial filing and the final granting or denial of the license and to supplement the information on this application as needed.

Section 456.013(1)(a), Florida Statutes, provides that an incomplete application shall expire one year after the initial filing with the department.

Applicant Signature \_\_\_\_\_ Date \_\_\_\_\_  
*You may print out this application and sign it or sign it digitally.* MM/DD/YYYY

Documentation must be sent to the board office at [info@floridaspharmacy.gov](mailto:info@floridaspharmacy.gov), or mailed to:

**Board of Pharmacy**  
4052 Bald Cypress Way Bin C-04  
Tallahassee, FL 32399-3258



Application  
*for*  
Pharmacist Test and Treat Certification

**Board of Pharmacy**  
P.O. Box 6330  
Tallahassee, FL 32314-6330  
Website: <https://floridaspharmacy.gov/>  
Email: [info@floridaspharmacy.gov](mailto:info@floridaspharmacy.gov)  
Phone: (850) 245-4474  
Fax: (850) 921-5389



# Pharmacist Test and Treat Certification Application

Board of Pharmacy  
P.O. Box 6330  
Tallahassee, FL 32314-6330  
Fax: (850) 921-5389  
Email: info@floridaspharmacy.gov

All applicants must hold a current Florida Pharmacist license that is active and in good standing.

## Pharmacist Test and Treat Certification

Prior to testing or screening for and treating minor, nonchronic health conditions under a written protocol, a pharmacist must be certified by the board. Additionally, a pharmacist must practice within the framework of a written protocol with a supervising physician licensed under Chapter 458, Florida Statutes, or Chapter 459, Florida Statutes. Please refer to Section 465.1895, Florida Statutes, prior to submitting your application.

### 1. PERSONAL INFORMATION

Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
Last/Surname First Middle MM/DD/YYYY

Mailing Address: (This address is where mail and your certification should be sent)

\_\_\_\_\_  
Street/P.O. Box Apt. No. City  
\_\_\_\_\_  
State ZIP Country Home/Cell Telephone (Input without dashes)

Physical Location: (Required if mailing address is a P.O. Box – this address will be posted on the Department of Health’s website)

\_\_\_\_\_  
Street Apt. No. City  
\_\_\_\_\_  
State ZIP Country Business Telephone (Input without dashes)

Email Notification: To be notified of the status of your application by email, check the “Yes” box and fill in your email address on the line provided. If you choose to be notified via email you will be responsible for checking your email regularly and updating your email address with the board office.

Yes  No Email Address: \_\_\_\_\_

Under Florida law, email addresses are public records. If you do not want your email 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.

Name: \_\_\_\_\_

## 2. LICENSURE HISTORY

- A. What is your Florida Pharmacist (PS) license number? \_\_\_\_\_

## 3. CERTIFICATION TRAINING

To qualify for certification, an applicant must have completed an initial 20-hour certification course that meets the statutory and rule requirements of section 465.1895, Florida Statutes, and Rule 64B31.035, F.A.C.

- A. Have you successfully completed an initial 20-hour course approved by the Florida Board of Pharmacy?  Yes  No

If “Yes,” provide a copy of the certificate of completion and the following information.

Provider Name	Provider Number	Date of Completion	Certificate Number

## 4. PROFESSIONAL LIABILITY INSURANCE

To test or screen for and treat minor, nonchronic health conditions within the framework of a written protocol, a pharmacist must maintain at least \$250,000 of professional liability insurance coverage. A pharmacist who maintains professional liability coverage as a requirement of their Collaborative Practice Certification satisfies this requirement.

- A. Do you maintain at least \$250,000 of professional liability insurance?  Yes  No

If “Yes,” provide the following information:

Insurance Provider Name	Policy Number	Policy Expiration Date

## 5. REPORTING REQUIREMENTS

To test or screen for and treat minor, nonchronic health conditions within the framework of a written protocol, a pharmacist must report a diagnosis or suspected existence of a disease of public health significance to the Department of Health pursuant to section 381.0031, Florida Statutes.

- A. Have you reviewed the Disease Reporting and Management Information at <http://www.floridahealth.gov/diseases-and-conditions/index.html>?  Yes  No

## 6. SYSTEM TO MAINTAIN RECORDS

To test or screen for and treat minor, nonchronic health conditions within the framework of a written protocol, a pharmacist must furnish patient records to a health care practitioner designated by the patient upon request. Additionally, a pharmacist must maintain records of all patients receiving services for a period of five (5) years from each patient’s most recent provision of service.

- A. Have you established a system to maintain records of all patients receiving services within the framework of a written protocol?  Yes  No

Name: \_\_\_\_\_

## 7. SUPERVISING PHYSICIAN

If available, provide the following information for the physician licensed under chapter 458 or 459, Florida Statutes (F.S.), with whom you have entered into a protocol.

Physician Name: \_\_\_\_\_

Physician License #: \_\_\_\_\_

## 8. WRITTEN PROTOCOL INFORMATION

Each written protocol must include particular terms and conditions imposed by the supervising physician relating to the testing and screening for and treatment of minor, nonchronic health conditions. The terms and conditions must be appropriate to the pharmacist's training.

The written protocol must include, at a minimum, the following information:

1. Specific categories of patients who the pharmacist is authorized to test or screen for and treat minor, nonchronic health conditions.
2. The physician's instructions for obtaining relevant patient medical history for the purpose of identifying disqualifying health conditions, adverse reactions, and contraindications to the approved course of treatment.
3. The physician's instructions for the treatment of minor, nonchronic health conditions based on the patient's age, symptoms, and test results, including negative results.
4. A process and schedule for the physician to review the pharmacist's actions under the protocol.
5. A process and schedule for the pharmacist to notify the physician of the patient's condition, tests administered, test results, and course of treatment.

A pharmacist who enters into a written protocol must submit a copy of the protocol to the board.

## 9. SOCIAL SECURITY DISCLOSURE

**This information is exempt from public records disclosure.**

Pursuant to Title 42 United States Code § 666(a)(13), the department is required and authorized to collect Social Security numbers relating to applications for professional licensure. Additionally, section (s.) 456.013(1)(a), Florida Statutes (F.S.), authorizes the collection of Social Security numbers as part of the general licensing provisions.

**Last Name:** \_\_\_\_\_

**First Name:** \_\_\_\_\_

**Middle Name:** \_\_\_\_\_

**Social Security Number:** \_\_\_\_\_  
(Input without dashes)

**Social Security Information-** \* Under the Federal Privacy Act, disclosure of Social Security numbers is voluntary unless specifically required by federal statute. In this instance, Social Security numbers are mandatory pursuant to Title 42 United States Code § 653 and 654; and s. 456.013(1), 409.2577, and 409.2598, F.S. Social Security numbers are used to allow efficient screening of applicants and licensees by a Title IV-D child support agency to ensure compliance with child support obligations. Social Security numbers must also be recorded on all professional and occupational license applications and will be used for license identification pursuant to Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Welfare Reform Act. 104 Pub. L. Section 317). Clarification of the SSA process may be reviewed at [www.ssa.gov](http://www.ssa.gov) or by calling 1-800-772-1213.

Name: \_\_\_\_\_

**10. APPLICANT SIGNATURE**

I, the undersigned, state that I am the person referred to in this application for certification in the state of Florida.

I recognize that providing false information may result in disciplinary action against my license or criminal penalties pursuant to s. 456.067 and 775.083, F.S.

I am aware that my certification may be suspended or revoked if I violate any pharmacy law, rule or regulation, or the Florida Board of Pharmacy Code of Conduct.

Florida law requires me to immediately inform the board of any material change in any circumstances or condition stated in the application which takes place between the initial filing and the final granting or denial of the license and to supplement the information on this application as needed.

Section 456.013(1)(a), F.S., provides that an incomplete application shall expire one year after the initial filing with the department.

Applicant Signature \_\_\_\_\_ Date \_\_\_\_\_  
*You may print out this application and sign it or sign it digitally.* MM/DD/YYYY

Documentation must be sent to the board office at [info@floridaspharmacy.gov](mailto:info@floridaspharmacy.gov), or mailed to:

**Board of Pharmacy**  
4052 Bald Cypress Way Bin C-04  
Tallahassee, FL 32399-3258



Application  
*for*  
Initial Collaborative Practice Certification  
Course

**Board of Pharmacy**  
P.O. Box 6330  
Tallahassee, FL 32314-6330  
Website: <https://floridaspharmacy.gov/>  
Email: [info@floridaspharmacy.gov](mailto:info@floridaspharmacy.gov)  
Phone: (850) 245-4474  
Fax: (850) 921-5389



# Pharmacist Collaborative Practice Certification

## Provider Application

Board of Pharmacy  
4052 Bald Cypress Way Bin C-04  
Tallahassee, FL 32314-6330  
Fax: (850) 921-5389  
Email: info@floridaspharmacy.gov

The offering approval submitted must adhere to the Rules for Collaborative Pharmacy Practice Certification, Section 64B16-31.003, F.A.C., to be eligible for Provider Approval by the Board of Pharmacy.

Please read the following before completing this application:

1. All information must be legibly printed or typed.
2. Complete all sections.
3. Identify all attachments with your organization's name.

### 1. CONTACT INFORMATION

Contact Person Name: \_\_\_\_\_  
Last/Surname First Middle

Title: \_\_\_\_\_

Name of Organization, Institution or Agency (Do not use initials of abbreviations):  
\_\_\_\_\_

Mailing Address:

\_\_\_\_\_  
Street/P.O. Box Apt. No. City

\_\_\_\_\_  
Business Telephone (Input without dashes)

**Email Notification:** To be notified of the status of your application by email, check the "Yes" box and fill in your email address on the line provided. If you choose to be notified via email you will be responsible for checking your email regularly and updating your email address with the board office.

Yes No Email Address: \_\_\_\_\_

Under Florida law, email addresses are public records. If you do not want your email 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.

**1. ADMINISTRATION AND ORGANIZATION**

A. Administrative Authority:

Provide the name and title of the person in charge of the program of study. (If responsibilities are shared by more than one individual, please indicate responsibilities of each person using supplementary sheets.)

NAME \_\_\_\_\_ TITLE \_\_\_\_\_

NAME \_\_\_\_\_ TITLE \_\_\_\_\_

B. Please provide your Accreditation Council for Pharmacy Education (ACPE), American Medical Association (AMA), or Florida Osteopathic Medical Association (FOMA) provider number.

\_\_\_\_\_

C. Describe the nature of the applicant’s role relative to the program of study and coursework.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**2. ADMINISTRATIVE REQUIREMENTS**

A. Please describe the nature of the system used for the maintenance and availability of records of participation in this program.

\_\_\_\_\_  
\_\_\_\_\_

B. Attach a sample certificate, letter or other document that is generally used as evidence to participants of satisfactory completion of the program of study for initial certification. Indicate the manner in which this document is distributed.

C. Indicate the number of course hours and type of study requested:

\_\_\_\_\_ Live \_\_\_\_\_ Home Study

**3. EDUCATIONAL CONTENT DEVELOPMENT**

A. Briefly describe the process for identifying educational needs and the manner in which topics for programs are usually determined.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

B. Describe the goals and objectives of your overall educational effort.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

- C. Briefly describe the usual planning process for an individual program. Indicate the time frame that may typically be involved.

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#### 4. METHODS OF DELIVERY

- A. What factors are taken into consideration in choosing the method of delivery for a particular program?

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- B. What is the review process that a home study program (audio-visual components, programmed learning, correspondence course, etc.) might undergo before it is offered to a new audience if utilized?

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#### 5. FACILITIES

- A. Name the facilities utilized for the past two programs presented.

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- B. What factors are considered in choosing facilities for programs?

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- C. If the preparation of educational offerings during the past year involved the production of audio-visual or other mediated materials such as programmed learning or correspondence course, etc., describe the facilities and equipment available and utilized for such preparations.

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#### 6. EVALUATION

- A. What opportunities are given for the participant to assess his/her evaluation of course objectives?

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B. Describe the methods employed to evaluate the effectiveness of the provider's programming and its presentation.

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C. Please attach a sample attendee evaluation instrument.

**Please submit completed application to CEBroker at [www.CEBroker.com](http://www.CEBroker.com)**



Application  
*for*  
Initial Test and Treat Certification  
Course

**Board of Pharmacy**  
4052 Bald Cypress Way Bin C-04  
Tallahassee, FL 32314-6330  
Website: <https://floridaspharmacy.gov/>  
Email: [info@floridaspharmacy.gov](mailto:info@floridaspharmacy.gov)  
Phone: (850) 245-4474  
Fax: (850) 921-5389



# Initial Test and Treat Certification Course Application

Board of Pharmacy  
4052 Bald Cypress Way Bin C-04  
Tallahassee, FL 32314-6330  
Fax: (850) 921-5389  
Email: info@floridaspharmacy.gov

The offering approval submitted must adhere to the Rules for Test and Treat Certification, Section 64B16-31.035, F.A.C., to be eligible for Provider Approval by the Board of Pharmacy.

Please read the following before completing this application:

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2. Complete all sections.
3. Identify all attachments with your organization's name.

## 1. CONTACT INFORMATION

**Contact Person Name:** \_\_\_\_\_  
Last/Surname First Middle

**Title:** \_\_\_\_\_

**Name of Organization, Institution or Agency (Do not use initials of abbreviations):**  
\_\_\_\_\_

**Mailing Address:**

\_\_\_\_\_  
Street/P.O. Box Apt. No. City

\_\_\_\_\_  
Business Telephone (Input without dashes)

**Email Notification:** To be notified of the status of your application by email, check the "Yes" box and fill in your email address on the line provided. If you choose to be notified via email you will be responsible for checking your email regularly and updating your email address with the board office.

Yes No Email Address: \_\_\_\_\_

Under Florida law, email addresses are public records. If you do not want your email 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.

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NAME \_\_\_\_\_ TITLE \_\_\_\_\_

NAME \_\_\_\_\_ TITLE \_\_\_\_\_

B. Please provide your Accreditation Council for Pharmacy Education (ACPE), American Medical Association (AMA), or Florida Osteopathic Medical Association (FOMA) provider number.

\_\_\_\_\_

C. Describe the nature of the applicant's role relative to the program of study and coursework.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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C. Indicate the number of course hours and type of study requested:

\_\_\_\_\_ Live \_\_\_\_\_ Home Study

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\_\_\_\_\_

B. Describe the goals and objectives of your overall educational effort.

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\_\_\_\_\_  
\_\_\_\_\_

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- A. What opportunities are given for the participant to assess his/her evaluation of course objectives?

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B. Describe the methods employed to evaluate the effectiveness of the provider's programming and its presentation.

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C. Please attach a sample attendee evaluation instrument.

**Please submit completed application to CEBroker at [www.CEBroker.com](http://www.CEBroker.com).**

**BOARD OF PHARMACY  
JOINT RULES COMMITTEE  
DRAFT MINUTES  
June 25, 2020  
9:00 A.M. ET  
Call In Number: (888) 585-9008  
Conference Code: 599-196-982(#)**

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the board's website.

**I. CALL TO ORDER/ROLL CALL**

Dr. Mesaros called the meeting to order at 9:00 a.m. ET.

**MEMBERS PRESENT**

Jeffrey Mesaros, PharmD, JD, Chair  
Jeenu Philip, BPharm,  
Jonathan Hickman, PharmD  
Mark Mikhael, PharmD  
David Wright, BPharm

**STAFF PRESENT**

Jessica Sapp, Executive Director  
Traci Zeh, Program Administrator

**BOARD COUNSEL**

David Flynn, Esq.  
Senior Assistant Attorney General  
Christopher Dierlam, Esq.  
Assistant Attorney General

**BOARD OF MEDICINE MEMBERS:**

Hector Vila, MD  
Sarvam TerKonda, MD

**BOARD OF OSTEOPATHIC MEDICINE MEMBERS:**

Joel B. Rose, DO  
Michelle R. Mendez, DO

**COURT REPORTER**

For the Record  
150 Mahan Drive, Suite 140  
Tallahassee, FL 32308  
(850) 222-5491  
(850) 224-5316 (Fax)

**II. RULES DISCUSSION**

- a. HB 389 Practice of Pharmacy
  - i. Chapter 64B16-31, F.A.C., Collaborative Practice and Test and Treat Certifications

This bill was enrolled and signed into law with an effective date of July 1, 2020. This adds to the definition of the practice of pharmacy the ability to initiate, modify, discontinue drug therapy under a collaborative practice agreement with a physician, for patients with chronic illnesses. It also allows a pharmacist to test for and treat certain nonchronic health conditions. The bill requires additional education and training requirements that will create two certification types: Collaborative Practice Certification (CPC) and the Test and Treat Certification (TTC). The bill outlines the requirements to

obtain the certifications as well as terms and conditions are to be included in a collaborative practice pharmacy agreement and in the written protocol between a pharmacist and a physician. The bill requires continuing education to maintain the certifications and it requires the Board to adopt by rule a formulary of medicinal drugs that a pharmacist may prescribe for the treatment of non-chronic health conditions.

The Board of Pharmacy Rules Committee held a meeting on June 2, 2020 to review and discuss draft rule language for Chapter 64B16-31, F.A.C. Subsequent to the Rules Committee Meeting, Ms. Sapp sent out invitations to the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) to request representatives from each Board in order to form a Joint Rules Committee to review the draft rule language.

The BOM reviewed and discussed the draft rule language during their June 3, 2020 Board Meeting and determined that Dr. Vila and Dr. TerKonda would represent the BOM. The BOOM held a meeting on June 9, 2020 to discuss and review the language and determined that Dr. Rose and Dr. Mendez would represent BOOM.

The Joint Committee reviewed the below proposed draft rule language.

The Committee along with BOM and BOOM determined to only discuss the rules that require collaboration between the three Boards.

**64B16-31.001 Collaborative Practice Certification (CPC).**

Applicants for CPC shall submit an application using Form DH-MQA XXXX (eff. 0X/20), "Application for Pharmacist Collaborative Practice Certification<sup>1</sup>" that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX> or <http://floridapharmacy.gov>. Applicants for certification must meet and comply with all requirements in Section 465.1865, F.S.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

**64B16-31.003 Collaborative Practice Certification: Initial Certification Course.**

(1) Applicants for Initial Certification Course approval shall submit an application using Form DH-MQA XXX (eff. XX/20) "Application for Initial Collaborative Practice Certification Course<sup>2</sup>" that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX> or <http://floridapharmacy.gov>.

(2) Initial collaborative practice certification courses shall be a minimum of 20 hours in duration, and shall meet all the following mandatory requirements:

(a) The course may only be offered by a program provider who is accredited by the Accreditation Council for Pharmacy Education (ACPE) or a program provider who is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit or the American Osteopathic Association Category 1-A continuing medical education credit.

(b) The course content shall include all those areas enumerated in section 465.1865 (2)(c), F.S., and shall also cover the following areas:

1. Laws and rules applicable to the collaborative practice for the treatment of chronic health care conditions;

2. Writing and entering into a collaborative practice agreement;

3. Place holder for discussion with Board to determine appropriate content list in consultation with BOM and BOOM.

(c) No less than 12 hours of the course shall be offered through a live seminar or a live video teleconference.

Place holder for discussion with Board to determine appropriate format of specific hour requirements with BOM and BOOM.

(3) A pharmacist who successfully completes a board approved collaborative practice certification course shall be awarded 20 hours of general continuing education credits.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

**64B16-31.005 Collaborative Practice Certification: Collaborative Pharmacy Practice Agreement Submission.**

(1) Prior to providing or implementing patient care services under a Collaborative Pharmacy Practice Agreement or immediately after the renewal of such an Agreement, the Pharmacist shall submit the executed Agreement to the Board Office through the pharmacist's online licensure account at <http://www.flhealthsource.gov> or via U.S. Mail to 4052 Bald Cypress Way, Bin C-04, Tallahassee, FL 32399.

(2) In the event of an addendum to the material terms of an existing collaborative pharmacy practice agreement, the pharmacist shall maintain a copy of the addendum and the initial agreement pursuant to Section 465.1865(3)(c), F.S. Material terms shall be defined as those terms enumerated in Section 465.1865(3)(a), F.S.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

**64B16-31.007 Collaborative Practice Certification: Chronic Health Conditions.**

Pursuant to Section 465.1865, F.S., the Board hereby adopts the following list of chronic health conditions for which a pharmacist certified pursuant to section 465.1865, F.S., can provide specified patient care services to patients of a collaborating physician pursuant to a pending Collaborative Pharmacy Practice Agreement:

1) Hyperlipidemia;

2) Hypertension;

3) Anti-coagulation management;

4) Smoking cessation;

5) Osteoporosis and osteo-arthritis;

6) Opioid use disorder;

7) Those chronic health conditions enumerated in section 465.1865(1)(b), F.S.; and

8) Any disease state that is expected to last greater than one (1) year or more and will require ongoing medical treatment and drug therapy services.

Place holder for discussion with Board to determine appropriate list of chronic health conditions in consultation with BOM and BOOM.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

**64B16-31.009 Collaborative Practice Certification: Mandatory Continuing Education.**

A licensee shall not be required to complete the 8-hour continuing education related to collaborative pharmacy practice if the initial certificate was issued less than 12 months prior to the expiration date of the license.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

#### **64B16-31.033 Test and Treat Certification (TTC)**

Applicants for TTC shall submit an application using Form DH-MQA XXXX (eff. 0X/20), “Application for Pharmacist Test and Treat Certification<sup>3</sup>” that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX> or <http://floridapharmacy.gov>. Applicants for certification must meet and comply with all requirements in Section 465.1895, F.S.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

#### **64B16-31.035 Test and Treat Certification: Initial Certification Course**

(1) Applicants for Initial Certification Course approval shall submit an application using Form DH-MQA XXX (eff. XX/20) “Application for Initial Test and Treat Certification Course<sup>4</sup>” that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX> or <http://floridapharmacy.gov>.

(2) Initial test and treat certification courses shall be a minimum of 20 hours in duration, and shall meet all the following mandatory requirements:

(a) The course may only be offered by a program provider who is accredited by the Accreditation Council for Pharmacy Education (ACPE) or a program provider who is accredited to provide educational activities designated for the American Medical Association Physician’s Recognition Award Category 1 credit or the American Osteopathic Association Category 1-A continuing medical education credit.

(b) The course content shall include all those areas enumerated in section 465.1895 (2)(b), F.S., and shall also cover the following areas:

1. Laws and rules applicable to test and treat certifications;

2. Writing and entering into a written protocol;

3. Place holder for discussion with Board to determine appropriate content list in consultation with BOM and BOOM.

(c) No less than 12 hours of the course shall be offered through a live seminar or a live video teleconference.

(3) A pharmacist who successfully completes a board approved test and treat certification course shall be awarded 20 hours of general continuing education credits.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

#### **64B16-31.037 Test and Treat Certification: Written Protocol and Written Protocol Submission**

(1) Within 5 business days of entering into a written protocol with a supervising physician pursuant to section 465.1895, F.S., the pharmacist shall submit a copy of the written

agreement to the Board Office through the pharmacist's online licensure account at <http://www.flhealthsource.gov> or via U.S. Mail to 4052 Bald Cypress Way, Bin C-04, Tallahassee, FL 32399.

(2) In the event of an addendum to the material terms of an existing written protocol, the pharmacist shall maintain a copy of the addendum and the initial agreement. Material terms shall be defined as those terms enumerated in Section 465.1895(5)(a), F.S.

Place holder for discussion with Board to determine if it wants to provide additional requirements for the written protocol in consultation with BOOM and BOM pursuant to Section 465.1895(5)(a)6.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

#### **64B16-31.039 Test and Treat Certification: Formulary of Medical Drugs**

(1) Pursuant to section 465.1895, F.S., the Board hereby incorporates the following as the formulary of medicinal drugs that a pharmacist may prescribe pursuant to a written test and treat protocol:

(a) All medicinal drugs approved by the United States Food and Drug Administration ("FDA");

(b) All compounded medicinal drugs that utilize only active pharmaceutical ingredients approved by the FDA.

(2) A pharmacist may not prescribe controlled substances as described in s. 893.03 or 21 U.S.C. s. 812.

Placeholder for discussion with Boards regarding additional drugs that should be excluded.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

#### **64B16-31.041 Test and Treat Certification: Patient Records**

Upon receipt of a patient request, a pharmacist shall furnish patient records to a health care practitioner designated by the patient within a reasonable time frame, not to exceed 5 business days.

Place holder for discussion with Board regarding reasonable time frame for production of records.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

#### **64B16-31.043 Test and Treat Certification: Follow-up Care**

A pharmacist must provide written information to the patient advising the patient when to seek follow-up care from his or her primary care physician. A pharmacist shall provide follow-up care written information:

(1) Immediately prior to performing testing, screening, or treatment services on a patient for the first time;

(2) As outlined in the written protocol; and

(3) When the pharmacist determines in his or her judgment that the patient should follow-up with his or her primary care provider.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

**64B16-31.045 Test and Treat Certification: Mandatory Continuing Education.**

A licensee shall not be required to complete the 3-hour continuing education related to minor, nonchronic health conditions if the initial certificate was issued less than 12 months prior to the expiration date of the license.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

**64B16-31.050 Mandatory Review of Rule Chapter 64B16-31, F.A.C.**

(1) No later than 90 days prior to December 31, 2025, the Board shall review each rule in this Chapter and amend, modify or repeal any rule that creates barriers to entry for private business competition, is duplicative, outdated, obsolete, overly burdensome, or imposes excessive costs.

(2) In the event the Board fails to complete this review, the board, for any rule that has not been reviewed in accordance with subsection (1), shall begin the rule repeal process in accordance with the Administrative Procedures Act.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

The Joint Committee reviewed and began discussion on 64B16-31.003, F.A.C., Collaborative Practice Certification.

Dr. Rose addressed the Committee regarding (2)(a) and suggested to strike “category” in subsection (2)(a): American Osteopathic Association Category 1 A as they are subject to change.

Dr. Hickman addressed the Committee and inquired if taking the course by one of these associations listed in the rule, meet the requirements for the certification, or would the pharmacist need to complete a course that is specifically ACPE accredited.

Mr. Flynn confirmed that yes, this would apply in the state of Florida for general education credit hours if taken by one of the listed providers.

Dr. Vila addressed the Committee regarding the content of the course and suggested requiring specific hours in evaluation and management of chronic diseases and suggested those hours be completed on a human simulator.

Dr. Hickman confirmed that when the BOP reviews courses for approval, the course content will be reviewed to assure all requirements are being captured.

Mr. Philip addressed the Committee and agreed with Dr. Vila that the requirements of the evaluation and management is outlined in the statute and will be included in the approved course.

Dr. Mendez addressed the Committee regarding the intent of the certification and what setting it would be utilized in.

Mr. Philip stated the bill does not specify what setting the certification is to be utilized in and the intent is to be available to any practitioners whom qualify for the certifications.

Dr. Mendez stated that laboratory testing can be very different depending on what setting the pharmacist and collaborating physician are practicing.

Dr. Mikhael addressed the Committee and Dr. Mendez and confirmed that the intent is to increase patient access.

Dr. TerKonda addressed the Committee regarding the provider of the course and suggested the highlighted change in subsection (2)(a): The course may only be offered by a program provider who is accredited by the Accreditation Council for Pharmacy Education (ACPE) or and a program provider who is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit or the American Osteopathic Association Category 1-A continuing medical education credit as he would like to see the course be offered in conjunction with ACPE, AMA and AOMA.

Mr. Wright addressed the Committee regarding the benefits of the course being offered in conjunction with multiple accrediting bodies but was not sure if historically had ever been done.

Dr. Vila suggested splitting up the required course hours between the accrediting bodies and requiring specific hours per entity.

Mr. Flynn addressed the Committee and suggested requiring the instructor of the course be a licensed physician.

Dr. Mesaros summarized the discussion.

Dr. Villa inquired with the Committee regarding how the rule will capture the requirement of the patient's medical records and the communication between the pharmacist and the collaborating physician.

Mr. Philip addressed Dr. Villa's inquiry and stated the rule should not be prescriptive, as that would be outlined in the collaborative practice agreement and the certification should capture if a pharmacist has the knowledge, skills, and ability to enter into an agreement.

Dr. Mesaros opened the floor to additional Board Members.

No additional Board Member comments were provided.

Dr. Mesaros opened the floor for public comment.

Nicole Garrett, Clinical Ambulatory Pharmacist in Florida, addressed the Committee regarding the term CPA and that the statute requires the delegation be appropriate to the pharmacist's education and training and to the physician's scope of practice. She indicated pharmacists and physicians will only enter into an agreement in which both parties feel comfortable.

Mary Thomas, representing the Florida Medical Association (FMA) and the Florida Osteopathic Medical Association (FOMA), addressed the Committee regarding the continuing education requirements for physicians in order to diagnose patients and inquired what the process will be for approving the continuing education courses.

Ms. Sapp addressed the Committee regarding the process of approving continuing education courses and indicated that through this rulemaking the process, the rule shall outline who the course will be given by and what requirements will be included in the course. Courses will be reviewed by our staff pharmacist to ensure they meet the requirements in the statute and rule.

Mr. Flynn confirmed that the course will be approved by the Board of Pharmacy.

Dr. Vila suggested having multiple courses depending on the subject area.

Mr. Dierlam addressed the Committee indicating the bill requires a 20-hour course and outlines the requirements of the course and suggested the course be widely applicable.

Dr. Schwimmer, Vice-Chair of the BOOM, addressed the Committee and asked Mr. Flynn if anything in the statute prohibits the physician from requiring additional training for the pharmacists.

Mr. Flynn addressed Dr. Schwimmer and the Committee and confirmed, the CPA is a contractual agreement that is driven by the physician. A physician has the authority to select, create, and enter into an agreement with their pharmacist of choice. A pharmacist may not enter into an agreement unless they are appropriately qualified. Mr. Flynn indicated that requiring additional training would strictly be up to the physician when entering into an agreement.

Dr. Hickman indicated this agreement is between one practitioner and one pharmacist for the specific patient and the agreement could not be applied to multiple patients.

Louis Adams addressed the Committee regarding if a consultant license would qualify a pharmacist for this certification.

Mr. Flynn stated this statute stands independently and would be a separate certification.

Mr. Dierlam addressed the Committee regarding the requirements of a Consultant Pharmacist.

Dr. Villa addressed the Committee regarding how the course would be presented, either live, online, or otherwise and suggested no less than three hours of the course be live with interactive patient scenarios.

Dr. Mikhael addressed Dr. Vila regarding the human simulator.

Dr. Hickman and Dr. Mikhael addressed the Committee and agree with Dr. Vila for a live interaction requirement within the course.

Dr. Rose and Dr. Schwimmer suggested to be cognizant of COVID-19 and the difficulties with live hours during these times.

Dr. Mesaros thanked everyone for the discussion and stated that the Committee would take the comments into consideration when amending the draft rule language.

The Joint Committee began discussion on Rule 64B16-31.007, F.A.C., Collaborative Practice Certification: Chronic Health Conditions.

Dr. Mesaros summarized the proposed rule language and opened the floor for discussion.

Mr. Philip addressed the Committee regarding the chronic health conditions outlined in the rule. He indicated the agreement entered will be between a single physician and single pharmacist to manage a specific patient. The goal is to work together to ensure that the patient's quality of care is improved. Terms and conditions must be appropriate to a pharmacist's education and training to assure the pharmacist participating in the agreement be educated and prepared for that specific condition of the patient.

Mr. Wright addressed the Committee and agrees with, (7) Those chronic health conditions enumerated in section 465.1865(1)(b), F.S.; and stated this lets the physician determine states of the disease that can be covered.

Dr. Hickman addressed the Committee and agreed with Mr. Philip regarding evidence based in improving patient care and advised that, (8) Any disease state that is expected to last greater than one (1) year or more and will require ongoing medical treatment and drug therapy services., is necessary as there are a lot of additional chronic medical conditions that are not listed within the proposed rule.

Dr. Rose addressed the Committee regarding subsection 8 and expressed the intent of the legislature was not to put a catch all. He stated this option would bypass the ability for the Boards to collaborate on what chronic diseases could listed and would prefer to only list what is outlined in the bill.

Dr. Mendez addressed the Committee and would prefer to start slow and be deliberate when considering additional chronic conditions.

Dr. TerKonda addressed the Committee and agreed with Dr. Rose regarding his concerns with subsection 8.

Dr. Vila addressed the Committee and stated he has no opposition with the six additional diseases listed; however, would like to remove subsection 8.

Chris Nuland, representing the Florida Chapter, American College of Physicians, addressed the Committee and recommended the deletion of subsection 8.

Dr. Schwimmer, addressed the Committee and agreed with the deletion of subsection 8 and suggested adding behavioral health conditions.

Dr. Mikhael addressed the Committee regarding becoming too restrictive and expressed he believes the intent of subsection 8 was to fall back on the physician's responsibility with the pharmacist to determine what conditions are appropriate. Deleting this addition could be doing a disservice to accessing patient care.

Toni Large, representing the Florida Society of Rheumatology, addressed the Committee in opposition to (5) Osteoporosis and osteo-arthritis and expressed that most patients who go to a rheumatologist have potentially been treated by several physicians prior to being under the care a specialist to manage their conditions.

Mary Thomas, FMA, addressed the Committee in opposition of subsection 8 and suggested the bill does not authorize a catchall provision.

Kathy Baldwin, representing the Florida Society of Health-System Pharmacists (FSHP), addressed the Committee regarding the benefits of physicians collaborating with pharmacists as pharmacists can effectively manage medications and create an efficient path for patient access.

Jason Wynn, representing the Florida Osteopathic Medical Association, addressed the Committee in opposition of subsection 8.

Dr. Vila addressed the Committee regarding what items should be listed in the CPA.

Mr. Philip addressed Dr. Villa and the Committee and confirmed that the requirements of the CPA are outlined in the statute and those are also identified in the proposed application.

Mr. Flynn addressed the Committee regarding the statutory requirements of rulemaking and confirmed a statute should not be duplicated in rule.

Dr. TerKonda dismissed himself from the call.

Dr. Mendez dismissed herself from the call.

The Joint Committee began discussion on Rule 64B16-31.035, F.A.C., Test and Treat Certification: Initial Certification Course

Dr. Mesaros addressed the Committee and indicated that comments and suggestions from the discussion regarding the Collaborative Practice Certification will be incorporated in the Test and Treat Certification proposed rule language.

Mr. Philip addressed the Committee and stated he had no additional content areas to be added to the list as they are outlined in the statute and suggested lowering the requirement for live hours from twelve to eight.

Dr. Vila addressed the Committee regarding adopting the philosophy of not being too broad as that will delay the implementation of the proposed rules.

Dr. Rose addressed the Committee regarding the follow up care requirement.

Mr. Flynn indicated that the follow up requirement will be outlined within Rule 64B16-31.043, F.A.C., Test and Treat Certification: Follow-up Care.

Dr. Rose commented on the authority for compounded drugs within the drug formulary outlined in (b) All compounded medicinal drugs that utilize only active pharmaceutical ingredients approved by the FDA.

Dr. Hickman addressed the Committee and confirmed (b) was outlined due to the Tamiflu shortage.

Mr. Flynn confirmed the rule will be dictated by what is in the written protocol and indicated he indicated the current language will be clarified to specifically exclude controlled substances. The formulary shall include a list of US FDA approved active ingredients as the proposed language could be open for potential abuse of compounded drugs.

Dr. Rose dismissed himself from the meeting.

Dr. Schwimmer addressed the Committee regarding the formulary to Medicaid patients and should the rule address a Medicaid formulary.

Mr. Wright addressed the Committee regarding the formulary and how it may potentially alleviate the concern with compounding.

Dr. Hickman agreed with Mr. Wright and volunteered to work with Mr. Flynn on amending the proposed language to address the concerns.

Dr. Vila addressed the Committee and inquired about the electronic medical records.

Mr. Philip addressed Dr. Vila's concerns and confirmed this would depend on how communication is set up between each physician.

Dr. Mikhael addressed the Committee and extended his gratitude for the open discussion today.

Dr. Mesaros opened for public comment.

No public comments were received.

Ms. Sapp addressed the Committee and confirmed the comments from the discussion will be taken into consideration and amendments to the proposed rules will be presented at the next Committee Meeting.

### **III. ADJOURNMENT**

There being no further discussion, the meeting adjourned at 12:45 p.m.

## Zeh, Traci

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**From:** Sapp, Jessica  
**Sent:** Wednesday, July 1, 2020 1:36 PM  
**Subject:** Board of Pharmacy Joint Rules Committee Meeting

Good afternoon,

The Board of Pharmacy has scheduled a second Joint Rules Committee meeting for **July 29, 2020 at 9:00 a.m.** to review draft rules based on the discussion during the June 25 meeting. We have received a request for a Rules Workshop on proposed rules 64B16-31.007 and 31.039 which will also take place during this meeting. The meeting materials will be published to you approximately 10 days prior to the meeting. Please let me know if you have any questions or concerns.

All committee members, board counsels and staff have been blind copied on this email.

Regards,

**Jessica Sapp**

**Executive Director**

Department of Health | Division of Medical Quality Assurance

Bureau of Health Care Practitioner Regulation

4052 Bald Cypress Way Bin C-04

Tallahassee, FL 32399-1708

Phone 850/245-4463

[www.FloridasDentistry.gov](http://www.FloridasDentistry.gov)

[www.FloridasPharmacy.gov](http://www.FloridasPharmacy.gov)



**Mission:** To protect, promote and improve the health of all people in Florida through integrated state, county and community efforts.

**Note:** Florida has a very broad public records law. Most written communications to or from state officials regarding state business are public records available to the public and media upon request. Your email communication may therefore be subject to public disclosure.

PHARM/DEN  
JUL 09 2020

July 3rd, 2020

Richard Montgomery, BPharm, MBA  
Chair  
Florida Board of Pharmacy  
4052 Bald Cypress Way Bin C-04  
Tallahassee, FL 32399-3258

Re: Rulemaking process regarding CS/HB 389

Dear Mr. Montgomery,

I write to you today as a concerned pharmacist and very interested party in regards to the rulemaking surrounding FL CS/HB 389. My name is Kevin Duane, and I am a pharmacist and pharmacy owner in Jacksonville, FL.

The legislature made a very bold step in empowering pharmacists in this state to be able to aid in the management of chronic disease states, as well as to be able to provide a means for testing and treatment of certain acute conditions. While this was a bold step, it was certainly not one taken lightly by the legislature or the governor. Indeed, as we have seen these past few months we are in uncharted territory, and we must provide our practitioners with any and all tools possible to implement this legislation to the best of our ability for the betterment of patient care and health management.

As the owner of two pharmacies which are located within physician office buildings, I see this bill as a very good opportunity to bring care to patients who sorely need it. My pharmacies are located in very poor parts of Jacksonville, and many patients come to us for care because the primary care landscape poses many barriers to proper care whether that be financial, or personal. My rural colleagues express the same barriers to care, and these barriers are ones that this bill aims to begin to solve. Above all, the bill allows us to better care for our patients than we are able to do so currently.

The legislature's actions were promising and progressive in the best interest of the patient, and I believe that the board's rulemaking process should be as well. Therefore, I make the following suggestions:

1. Allow individual protocols, rather than preconstructed blank forms which must be followed strictly.

- a. Florida is a diverse state of over 21,000,000 people. We have densely populated city centers with dozens of pharmacies and physicians within walking distance. We have rural areas where oftentimes the pharmacy is the only health care entity for miles. Simply put, it is not a state that lends itself to a one-size-fits-all approach to this practice.
- b. Different pharmacy practice settings will have different goals for implementation - restricting the practice to a single protocol for each acute condition listed under 465.1895 (1)(a)-(e) F.S. will stifle the entrepreneurial aspirations of self-employed pharmacists like myself, and may provide perverse incentives for chain-pharmacies who do not have to share the profits with their pharmacist employees.
  - i. In this state we have consistently seen chain pharmacists that are being asked to do more and more work with less and less help. They have no decision making input into their staffing levels and no ability to enjoy their share of revenue generation they have created. Only allowing a single protocol eliminates the ability for such a pharmacist to be able to tailor their practice limitations or situations to suit their current employment circumstances. Furthermore, a single protocol will limit the ability of pharmacy owners such as myself to change their practice to fit the needs of their own business or their specific patient population. Ultimately, if a physician is to sign on to any protocol under this statute, whether or not it is standardized, they understand what is written within the protocol is what they are signing off on. The physician has the professional discretion to make responsible medical decisions concerning the collaborative programs in a way that is in the best interest of their patients' health management.
- c. Certain procedures outlined in the protocol may be impossible for some practitioners to meet.
  - i. For example, if it is obligated that the protocol is transmitted electronically only, and a physician and/or pharmacists does not have the technology available to do so, or is financially not in the position to spend hefty sums of money to upgrade to said technology for this purpose, why would the rule compel them to do so? If they are unable and thus cannot collaborate and provide

expertise for the benefit of Florida's public, that is a disservice to the citizens and not at all what the legislature had intended. There should not be any substantial financial limitations to a pharmacist being able to implement this in their practice.

2. Do not limit to only conditions specifically outlined in statute.

- a. The legislature recognized the need for pharmacists to be involved in this aspect of patient care. They also recognized the need to add in language to protect and preserve the pharmacist's and physician's ability to choose and augment those conditions with new or evolving conditions as time progressed.
  - i. Indeed, when this bill was filed in the fall no one had even considered a threat to Florida such as Covid-19, and yet it is now at the forefront of everyone's daily routine. To deny pharmacists and physicians the ability to agree to collaborate on conditions that the legislature was not able to contemplate is counter to what is in the public's interest, and frankly a disservice to the health of the citizens of the state of Florida. New progressions in treatment for conditions are developed constantly, and legislation and rulemaking will always lag behind. The rules must be left open for pharmacists and physicians to adopt protocols for new unforeseen illnesses and treatments. We know that leaving the inclusivity of conditions up to rule amendments by the board may take valuable time to implement. Time which could be spent helping patients with such a disease reach better outcomes and potentially save their quality of life.
  - ii. Additionally, being that a physician and a pharmacist are collaborating regarding the scope of services able to be provided, I feel it an unnecessary and improper intrusion by the government into the private agreement between these two parties.
  - iii. Finally, I believe that most of the commentary regarding the need to slow the development and limit the list of conditions eligible for collaboration under this protocol stems from physician discomfort surrounding the intrusion of pharmacy upon their scope of practice. Many physicians are not accepting of the vital role pharmacists can

play in the healthcare system due to their own personal reservations, rather than genuine concern for the patient. They do not seem to mind other physician extenders such as CNAs and MAs to play a large role in their patient care, and after all, they can always choose not to enter into such a collaborative agreement with pharmacists or other midlevel practitioners such as APRNs or PAs if they do not feel comfortable doing so. It was clearly the legislature's intent to allow other conditions to be collaborated on, and rulemaking (or delaying rulemaking) regarding such is counter to the body's intent.

3. Allow drug formularies to be defined by class, and do not allow negative drug formularies.
  - a. In the same way the landscape of disease has shifted so drastically in our lives, so too have treatments - and they will continue to do so! We need again to only look to the COVID-19 pandemic to see how a rigidly defined drug formulary could absolutely impede expert patient care from being delivered. Remdesivir was a drug initially designed for the ebola virus outbreak, and was found to be ineffective. Had a rigid formulary been in place, we would not have had the power to pick it back up and have it find its home as the mainstay of treatment in critically ill COVID-19 patients. Drugs that are the current mainstay of therapy for certain diseases may soon be discovered to have a certain side effect that makes it undesirable to use, or a previously unknown benefit that brings it from the last line of therapy to the first line. A defined drug formulary in rule makes changes like this very inflexible to do, and again impedes the collaborative aspect of the physician and the pharmacist. If the physician wishes for the pharmacist to use or not to use certain drugs for certain conditions, it should be left to them to decide that collaboratively rather than to rely on the long and arduous process of board rulemaking.
  - b. Limited formularies in rule do not consider that not all patients are the same. A certain first line treatment the patient may have an allergic reaction to. The FDA is notoriously slow and has often no impetus to change certain approvals. It is again only serving to hurt patient care by doing so. An APRN or PA does not have a formulary restriction, and in the same way the physician and the pharmacist should be the ones to be able to make these decisions collaboratively.

4. Do not allow exclusivity of initial training CE or renewal CE to one body
  - a. Currently, pharmacists are permitted to immunize patients, but only in the framework of a protocol in collaboration with a physician. In order to renew his or her license, though, the pharmacist must complete a continuing education program that "...shall be offered by a statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award (AMA PRA) Category I credit...". I believe that CS/HB 389 is a bill that fosters collaboration with pharmacists and physicians, and as such neither group should have a monopoly on the ability to offer continuing education. Allowing only one of the stakeholders to have full authority on the continuing education offerings necessarily tips the balance of control unfavorably away from the other stakeholders.

This bill adds a wonderful opportunity for pharmacists to be able to collaborate with physicians for the betterment of healthcare delivery to the citizens of the state. The theme of collaboration is well evidenced throughout the bill. I hope that this same theme carries itself well throughout the rulemaking process, and that the private collaborative agreement process between physician and pharmacists is respected and upheld. The above points serve to point out potential pitfalls that I hope the rulemaking process avoids. I am available via e-mail at [Kevin@PanamaRX.com](mailto:Kevin@PanamaRX.com) for any further input if it is needed. I appreciate the efforts of the Boards of Pharmacy, Medicine, and Osteopathic Medicine, and I am hopeful that the legislature's bold vision embodied in this bill carries forward and is evidenced in the final rulemaking product.

Respectfully,

A handwritten signature in black ink, appearing to read "Kevin J. Duane", with a long horizontal line extending to the right.

Kevin J. Duane, Pharm.D.  
President, Panama Pharmacy

## Zeh, Traci

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**From:** Kemp, Claudia J  
**Sent:** Thursday, July 23, 2020 8:08 AM  
**To:** Sapp, Jessica  
**Cc:** Zeh, Traci  
**Subject:** FW: Rule draft for Board of Pharmacy Rule Committee July 29 meeting/Collaborative practice

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Comment.

**From:** Robert London <rlondon10.bom@gmail.com>  
**Sent:** Thursday, July 23, 2020 7:47 AM  
**To:** Kemp, Claudia J <Claudia.Kemp2@flhealth.gov>  
**Cc:** Ed Tellechea <Ed.Tellechea@myfloridalegal.com>; Donna McNulty <Donna.McNulty@myfloridalegal.com>  
**Subject:** Re: Rule draft for Board of Pharmacy Rule Committee July 29 meeting/Collaborative practice

All,

Nothing in the following requires timely communication from the pharmacist to the treating physician of changes made to medications (dose, ,med changes), or new diagnoses and treatments. Deferring to the individual collaboration agreements invites inconsistencies in such communications, which may be at the expense of patient care.

Robert London MD.

### **64B16-31.041 Test and Treat Certification: Patient Records**

Upon receipt of a patient request, a pharmacist shall furnish patient records to a health care practitioner designated by the patient within a reasonable time frame, not to exceed 5 business days.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

### **64B16-31.043 Test and Treat Certification: Follow-up Care**

A pharmacist must provide written information to the patient advising the patient when to seek follow-up care from his or her primary care physician. A pharmacist shall provide follow-up care written information:

- (1) Immediately prior to performing testing, screening, or treatment services on a patient for the first time;
- (2) As outlined in the written protocol; and
- (3) When the pharmacist determines in his or her judgment that the patient should follow-up with his or her primary care provider.

On Wed, Jul 22, 2020 at 4:17 PM Kemp, Claudia J <[Claudia.Kemp2@flhealth.gov](mailto:Claudia.Kemp2@flhealth.gov)> wrote:

Members:

The public book for this meeting is available on our website and contains the attached rule draft along with other materials. Dr. Vila requested that I send you just the rule draft for review. As the board's representative at the meeting, Dr. Vila wants to have any input you would like to provide. Send comments/input to me and copy Ed and Donna. I will provide the comments/input to Dr. Vila and the Board of Pharmacy.

**Claudia Kemp, JD**

**Executive Director, Board of Medicine**

Department of Health | Division of Medical Quality Assurance | Health Care Practitioner Regulation

4052 Bald Cypress Way Bin C-03

Tallahassee, FL 32399-1708

Phone 850-245-4130



**Mission:** To protect, promote and improve the health of all people in Florida through integrated state, county and community efforts.

Collaborative Pharmacy Practice Agreement  
Chronic Health Conditions

Physician name:  
Florida License #

Physician's Patient Name:  
DOB  
Contact info:  
    Address  
    Tel. number

Pharmacist Name:  
Florida License Number:  
Collaborative Practice Certification: Attach copy as required by Statute

Chronic Health Condition to Be Collaborated (circle):

1. Arthritis
2. Asthma
3. COPD
4. Type 2 Diabetes
5. HIV
6. Obesity

Drug or Drugs to be managed by pharmacist:

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_

Circumstances that require ordering of laboratory or clinical tests:

Conditions and events that require physician notification within \_\_\_\_\_ days:

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_

Above notification should go to (email or physical address):

Beginning date \_\_\_\_\_ and Ending date \_\_\_\_\_. Procedure for notifying patient and transferring records:

This agreement may be terminated at any time by either party in writing and will automatically terminate in 2 years if not renewed.

This agreement must be submitted to the board before implementation.

Physician signature \_\_\_\_\_ Date: \_\_\_\_\_

Pharmacist signature \_\_\_\_\_ Date: \_\_\_\_\_

## Pharmacist Education and Training

Pharmacists are medication experts who enhance patient care and promote wellness. Pharmacists use their professional knowledge to prepare and dispense prescriptions, ensure medicines and doses are correct, prevent harmful drug interactions, and assist other health care professionals to select, monitor, and administer medications to improve patient health and outcomes. Below is a summary of minimum education requirements for a pharmacist as well as post-graduate education opportunities which are pursued by many pharmacy graduates today.

- **Minimum Education Requirements for a Pharmacist**

- To enter practice in the United States, the Doctor of Pharmacy (Pharm.D.) degree must be earned from a college or school accredited by the American Council for Pharmacy Education (ACPE). The Pharm.D. became the required entry-level degree into the profession in 2000.
- The minimum program length is 6 years including at least 2 years of undergraduate pre-requisite course work plus 4 years in the Doctor of Pharmacy program.
  - While a minimum of 2 years of undergraduate course work is required, many students complete bachelor's degrees prior to entry into pharmacy school. Approximately 60% of student pharmacists earn a bachelor's degree prior to entry into pharmacy school.
- Pharmacy school is typically comprised of at least 2 to 3 years of pre-clinical course work which includes foundational sciences, pharmaceutical and clinical sciences, and introductory pharmacy practice experiences (up to 300 hours split between institutional, community, and other practice settings).
- During the final year of the Pharm.D. program, students complete a minimum of 1440 hours (36 weeks) of clinical rotations. ACPE, the pharmacy education accrediting body, similar to the Liaison Committee for Medical Education (LCME) mandates that required rotation settings include:
  - 1) community pharmacy,
  - 2) hospital/health-system pharmacy,
  - 3) ambulatory patient care, and
  - 4) general inpatient medicine.
  - The remaining rotations should be a mix of patient care (e.g. clinical electives such as oncology, pediatrics, etc.) and non-patient care rotations (e.g. administration, research, etc.).
- The ACPE 2016 Standards for pharmacy education emphasize that pharmacy graduates must be "practice-ready" and "team-ready."
  - Practice-ready = provide direct-patient care in a variety of healthcare settings
  - Team-ready = contribute as a member of an interprofessional collaborative patient care team.
  - These standards emphasize early exposure to clinical care through practice skills laboratories, introductory pharmacy practice experiences, and intensive courses focused on optimal use of medications.

- In order to practice pharmacy in the state of Florida, graduates from an accredited college/school of pharmacy must pass two examinations – 1) The North American Pharmacists Licensure Examination (NAPLEX) and the 2) Multistate Pharmacy Jurisprudence Examination (MPJE) which evaluates candidates knowledge of state and national laws governing the practice of pharmacy. Both examinations are administered by the National Association of Boards of Pharmacy (NABP).

**Table 1. Comparison of Pharmacy with Medical Curricula**

	<b>Pharmacy</b>	<b>Medical</b>
<b>Accreditation Standards</b>	1. Foundational Knowledge 2. Essentials for Practice and Care 3. Approach to Practice and Care 4. Personal and Professional Development	1. Medical Knowledge 2. Patient Care 3. Systems-based practice 4. Interpersonal communication and skills 5. Professionalism 6. Practice-based learning and improvement
<b>Requirement for Team-Based Care</b>	YES – defined accreditation standard	YES – (2017-2018)
<b>Education on medications</b>	3 didactic years	Portion of body system curriculum OR 1 semester concentrated course

- **Post-Graduate Education**

- While not required, many pharmacy graduates pursue post-graduate training in residency programs. Pharmacy residency programs are 1 to 2 years in length and are accredited by the American Society of Health-System Pharmacists (ASHP).
- PGY-1 (post-graduate year 1) residency programs are 12-months in length and include goals and objectives to ensure graduates can care for patients in a broad variety of practice settings. Accredited program types for PGY-1 residencies include: Pharmacy Practice, Managed Care, and Community Practice
- PGY-2 (post-graduate year 2) residency programs are 12-months in length and allow the graduate to focus in a specialized area of practice. Types of PGY-2 residency programs include – ambulatory care, infectious disease, cardiology, critical care, and pediatrics, among others.
- Pharmacy graduates match into residency programs similar to the process for medical students to match into medical residencies.
- In 2020
  - 2118 residency programs (PGY-1 and PGY-2) participated in the ASHP match.
  - 7364 applicants participated in the match.
  - 4768 applicants matched into residency programs.

- **Additional post-graduate education**

- Pharmacists can also pursue additional certifications following gradation or completion of a residency program. Examples of these certifications include:
  - Board Certification through the Board of Pharmacy Specialties (BPS). Certification includes passing a competency examination and additional continuing education hours to maintain certification. As of 2019, there are 46,000 BPS Board Certified Pharmacists. Current specialties for board certification include:
    - Ambulatory Care
    - Cardiology Pharmacy
    - Compounded Sterile Preparations Pharmacy
    - Critical Care Pharmacy
    - Geriatric Pharmacy
    - Infectious Disease Pharmacy
    - Nuclear Pharmacy
    - Nutrition Support Pharmacy
    - Oncology Pharmacy
    - Pediatric Pharmacy
    - Pharmacotherapy
    - Psychiatric Pharmacy
    - Solid Organ Transplantation
- Pharmacists can also pursue disease or condition specific certification opportunities. These include:
  - Certified Diabetes Care & Education Specialists (CDCES) (formerly a certified diabetes educator)
  - Board Certified Advanced Diabetes Manager (BC-ADM)
  - American Society of Hypertension (ASH) Certified Hypertension Clinician (ASH-CHC)
  - Certified Anticoagulation Care Provider (CACP)
  - Certified Tobacco Treatment Specialists (CTTS)

# SELF-CARE CONDITIONS PROTOCOL: DIABETES TESTING SUPPLIES

**Approved 12/11/2019**

## PURPOSE

This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of diabetes testing supplies for diabetes self-care/management.

## PHARMACIST EDUCATION AND TRAINING

Prior to initiating the dispensing of diabetes testing supplies under this protocol, pharmacist(s) must have received education and training in diabetes and the supplies necessary to test blood glucose levels, including review of the most current American Diabetes Association (ADA) Standards of Medical Care in Diabetes and the monitoring parameters associated with pharmacologic therapies for the treatment of diabetes. The education of pharmacist(s) must be conducted by a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable provider approved by the Kentucky Board of Pharmacy.

Provider of Training: \_\_\_\_\_

Date Training Completed: \_\_\_\_\_

## CRITERIA

Pharmacist(s) authorized to dispense diabetes testing supplies will follow the most current ADA Standards of Medical Care in Diabetes for pharmacologic options and the associated blood glucose monitoring guidelines.

### *Inclusion criteria:*

- Any individual who currently has a diagnosis of diabetes, as defined by the ADA Standards of Medical Care for Diabetes, and is interested in obtaining diabetic testing supplies for self-care purposes in an outpatient setting.

### *Exclusion criteria:*

- Any individual who exhibits symptoms of hyperglycemic crisis. For both diabetic ketoacidosis (DKA) and hyperosmolar hyperglycemic state (HHS), the classic clinical picture includes a history of polyuria, polydipsia, weight loss, vomiting, dehydration,

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Resources

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Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S13-S27. Web. 27 Dec. 2017.

Glycemic Targets: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S55-S64. Web. 27 Dec. 2017.

weakness, and mental status change. These individuals should be referred to a setting where they can receive immediate medical attention.

### **DIABETES TESTING SUPPLIES**

This protocol authorizes pharmacist(s) to initiate the dispensing of the following diabetes testing supplies for self-care purposes in quantities sufficient to provide adequate testing based upon patient history, including refills for up to 12 months.

- Glucometer
- Glucometer test strips
- Lancet devices
- Lancets
- Blood glucose control solutions
- Alcohol wipes

### **PROCEDURES FOR INITIATING DISPENSING OF DIABETES TESTING SUPPLIES**

Diabetes testing supply initiation will be individualized based on the diagnosis and pharmacologic treatment of diabetes as defined by the ADA Standards of Medical Care in Diabetes and individual preferences:

- Intensive insulin therapy: 4-10 tests per day
- Basal insulin and/or oral antidiabetic agents: 1-3 tests per day
- Non-pharmacologically managed diabetes: 1-4 tests per day

### **PROCEDURES FOR MONITORING AND CONTINUATION OF DISPENSING DIABETES TESTING SUPPLIES**

Follow-up monitoring and evaluation shall occur at a minimum of every 90 days to determine:

- Changes in pharmacologic treatment for diabetes
- How the individual is utilizing testing supplies and efficacy of performing self-monitoring of blood glucose (SMBG)

If pharmacist(s) believes that SMBG is being performed incorrectly, education is to be provided to the individual in regard to proper use of diabetic testing supplies, as well as education on interpretation of blood glucose levels. If pharmacist(s) suspects an individual is consistently hyperglycemic or periodically hypoglycemic, the primary care provider of the individual is to be contacted. If the individual does not have primary care provider, other healthcare provider with prescribing privilege shall be contacted.

#### Resources

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Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S13-S27. Web. 27 Dec. 2017.

Glycemic Targets: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S55-S64. Web. 27 Dec. 2017.

Should follow-up evaluation and monitoring indicate an adjustment in therapy is warranted, all procedures as outlined for initiation of therapies, including education, documentation and notification, will be followed.

### **EDUCATION REQUIREMENTS**

Individuals, or their parent/guardian/caregiver, receiving diabetes testing supplies under the protocol will receive education regarding:

- Monitoring technique both initially and at regular intervals, using dispensed test strips, lancets, and meter
- Proper review and interpretation of the data provided by the blood glucose meter
- Signs and symptoms of hypoglycemia and instructions on steps to take if blood glucose level is 70 mg/dL or less

### **DOCUMENTATION**

Pharmacist(s) shall document via prescription record each person who receives any diabetes testing supplies under this protocol, including:

- Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication
- Documentation that the individual receiving the diabetes testing supplies was provided with the required education pursuant to this protocol
- Documentation of the diagnosis and pharmacologic treatment of diabetes, the plan of care implemented, and follow-up monitoring and evaluation

### **NOTIFICATION**

Pharmacist(s) shall ask all individuals receiving diabetes testing supplies under this protocol for the name and contact information of the individual's primary care provider and shall provide notification of the diabetes testing supplies dispensed under the protocol to the identified primary care provider within two (2) business days. Any individual affirmatively stating that the individual does not have a primary care provider may still receive diabetes testing supplies under this protocol provided all other applicable requirements of the protocol are met.

[If directed by the authorizing prescriber, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber of persons receiving diabetes testing supplies under this protocol within 7 days of initiating dispensing.]

### **TERMS**

This protocol is effective as of the date parties execute this document. It shall remain in effect for a period of one year and shall automatically renew for successive one year periods unless

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Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2018." Diabetes Care 41.

Supplement 1 (2018): S13-S27. Web. 27 Dec. 2017.

Glycemic Targets: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S55-S64. Web. 27 Dec. 2017.

otherwise terminated by any party, with or without cause. Any termination without cause shall require prior notice to all parties of no less than sixty (60) days.

Resources

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Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S13-S27. Web. 27 Dec. 2017.

Glycemic Targets: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S55-S64. Web. 27 Dec. 2017.

## SIGNATURES

_____	_____	_____
Prescriber Name	Prescriber Signature	Date
_____	_____	_____
Pharmacist Name	Pharmacist Signature	Date

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Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S13-S27. Web. 27 Dec. 2017.

Glycemic Targets: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S55-S64. Web. 27 Dec. 2017.

## Resources

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Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2018." *Diabetes Care* 41. Supplement 1 (2018): S13-S27. Web. 27 Dec. 2017.

Glycemic Targets: Standards of Medical Care in Diabetes—2018." *Diabetes Care* 41. Supplement 1 (2018): S55-S64. Web. 27 Dec. 2017.

Physician-Pharmacist Collaborative Practice Agreements (CPA) Overview  
This legislation has passed.

**What would Physicians like pharmacists to do for their patients?**

- **Physician reimbursement opportunities can be created** through *Collaborative Practice Agreements (CPA)* with pharmacists by *optimizing physician practice time*, to allow physicians more time for patients to be seen, diagnosed, and prescribed.
  - By referring medication therapy management for complex chronic patients to the **pharmacist of the physician's choosing, through a physician pre-approved protocol**, physicians can replace those medication therapy appointments with new patients.
  - The use of a Collaborative Practice Agreement allows for improved patient medication outcomes and higher value-based payment for Physicians.
- A Collaborative Practice Agreement is a formal agreement established **voluntarily** between a Florida licensed physician and a Florida licensed pharmacist to perform **physician pre-approved** patient care functions for the physician's patients.
  - A physician pre-approved protocol agreement with the pharmacist *specifies what patient care functions may be provided for the patients of the collaborating physician.*
- **Pharmacists are not trained to perform a differential diagnosis.** Collaborative practice agreements **DO NOT** allow a pharmacist to perform a differential diagnosis.
- Encouraged by the AMA Steps Forward Programming, most physicians in the United States already have established collaborative practice legislation.
  - The American Medical Association (AMA), Centers for Disease Control, American College of Physicians and CMS support Physician directed pharmacist CPAs.
  - The AMAs Steps Forward program encourages implementing “*Embedding Pharmacists into the Practice – Collaborating with Pharmacists to Improve Patient Outcomes*” as physician continuing education programs.

General comments: I listened to the BOOM conference call on 6-9-29 and agree with the comments and discussion. My two general suggestions are:

1. The BOP should adopt rules that mirror and are limited to the legislation wording and examples only at this time. Expansion to diseases not listed as examples can occur later via a process that allows for proposals from pharmacists followed by input from the BOM/BOOM. Formulary should be limited to FDA approved first line treatment for these diseases and specified in the CPA.
2. The BOP should provide a sample blank CPA that contains each of the elements required by the legislation. I also suggest this process become fully electronic online and updated in real time with reporting that can be used to fulfill the legislative requirements.

Comments to sections identified by BOP for consultation with BOM

1. CPC Initial Certification Course -20 hrs
  - a. Performance of patient assessments – I recommend in-person with human simulator no less than 3 hours of content for this portion
  - b. Testing, evaluation and management portions should include content specific to the diseases requested to be covered in the Collaborative practice agreement.
2. Collaborative practice agreement

I suggest providing a sample blank agreement. I also suggest this process become fully electronic online and updated in real time with reporting that can be used to fulfill the legislative requirements
3. Chronic health condition
  - a. I would limit the conditions initially to those examples listed in the legislation.
  - b. I would limit formulary to medications considered to be first line or initial treatments most commonly used in treatment of the listed chronic conditions consistent with the FDA labeling of the medications
  - c. Very important that the formulary be limited to medications that are considered initial treatments of the illnesses and not secondary or tertiary treatments without a consultation with the collaborating physician.
4. Test and treat certification
  - a. I would limit the conditions initially to those examples listed in the legislation.
  - b. I would limit formulary to medications considered to be first line or initial treatments most commonly used in treatment of the listed minor illnesses consistent with the FDA labeling of the medications
  - c. Very important that the formulary be limited to medications that are considered initial treatments of the illnesses and not secondary or tertiary treatments without a consultation with primary care physician.

5. Test and treat an initial certification course must cover the specific disease and treatments specified by the rule with examples of diseases that are similar clinically and often misdiagnosed and mistreated.

June 9, 2020

RE; CS/HB 389

Dear Ed and Claudia,

Below are some thoughts offered for further elaboration, clarification, discussion and consideration.

Respectfully Submitted.

Robert London MD

1. Standards of Care: Clarify that participating pharmacists, their practice, employees and agents held to the same standards as physicians with regards to:
  - a. Existing Florida Statutes and Administrative Rules (Ex. See Appendix A for medical record documentation)
  - b. HIPAA compliance
  - c. Medicare/Medicaid compliance
  - d. Requirements for electronic medical record keeping
  
2. Practice Model: The intent of the law is to expand the current pharmacy-based scope of practice. Are the following models of practice permissible?
  - a. Pharmacist independently practices in an office setting indistinguishable to that of a physician or ARNP.
  - b. Pharmacist owns the medical practice, and employs physicians, who enter into a collaborative agreement with the pharmacist.
  - c. The pharmacist restricts their professional activity solely/exclusively to the expanded scope of practice established by the law.
  - d. Pharmacist is hired by a participating physician as a physician-extender to work in their office.
  
3. Collaborative Agreements:
  - a. Standardization/simplification: Creation of individualized agreements for each patient, potentially by multiple providers and pharmacists, invites the risk of error, where a pharmacist inadvertently treats a patient outside of their particular agreement, or duplication or contrary managements are put in place.
  - b. Creating a small number of standardized agreements based on the specific disease, severity of disease, or existence of patient co-morbidities may mitigate risk. An example of a risk stratification method based on disease states and comorbidity is the American Society of Anesthesiologists (ASA) Risk Classes (ASA I, II, III, IV, V) (See Appendix B)

- c. Implementation of a process whereby overlapping CPAs (more than one Collaborative Practice Agreement for a single patient) can be identified and reviewed or eliminated if needed.
  - d. Patient centric/control:
    - i. Consider documentation of patient's informed consent to allow the pharmacist's provision of care and physician/pharmacist sharing of protected health information.
    - ii. Consider patient acknowledgement, and approval of expanded role of pharmacist in their personal care
    - iii. Consider the patient's signature on the collaborative agreement
  - e. Clarification of physician/pharmacist liability in such arrangements
    - i. If pharmacist treats the patient outside of the terms of the collaborative agreement,
    - ii. If changes to the patient's care/treatment are not reported back to the physician in a timely fashion,
    - iii. Delays in diagnosis due to a patient not feeling the need to follow-up with a physician.
    - iv. If patient follows pharmacist care against the medical advice of the physician?
  - f. If patient leaves physician's practice?
  - g. Clarification of the number of times or the duration of time a pharmacist can manage a patient for a particular condition without improvement or resolution before having to refer the patient to a physician.
  - h. Clarification of the number of supervising physicians and pharmacists who can be involved with CPAs with regard to a specific patient. Example, any prohibition on an internist, family physician, and pulmonologist each having a CPA with their preferred pharmacist (multiple) regarding the same patient.
4. Continuing Medical Education:
- a. The 20-hour CME is one time. Are continuing medical education requirements to be included to assist the pharmacist in maintaining competency over time?
  - b. Objective assessment of competency? Testing? Evaluations? Auditing? Other?
5. Are BOM and BOOM able to create standards for rules applying to physicians for entering into a collaborative practice agreement with a pharmacist?
- a. Establishment of clear communication protocols
  - b. Avoid the confusion of multiple physicians and pharmacists managing the same patient for the same condition
  - c. Standards of care
  - d. Liability
  - e.

## Appendix A: Documentation requirements for medical record keeping

### Example FS 458.331(1)(m):

(m) Failing to keep legible, as defined by department rule in consultation with the board, medical records that identify the licensed physician or the physician extender and supervising physician by name and professional title who is or are responsible for rendering, ordering, supervising, or billing for each diagnostic or treatment procedure and that justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.

## Appendix B: ASA Risk Classes

### Current Definitions and ASA-Approved Examples

ASA PS Classification	Definition	Adult Examples, Including, but not Limited to:
<b>ASA I</b>	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
<b>ASA II</b>	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30 < BMI < 40), well-controlled DM/HTN, mild lung disease
<b>ASA III</b>	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant PCA < 60 weeks, history (>3 months) of MI, CVA, TIA, or CAD/stents.
<b>ASA IV</b>	A patient with severe systemic disease that is a constant threat to life	Examples include (but not limited to): recent (< 3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis
<b>ASA V</b>	A moribund patient who is not expected to survive without the operation	Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
<b>ASA VI</b>	A declared brain-dead patient whose organs are being removed for donor purposes	

\*The addition of "E" denotes Emergency surgery: (An emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part)

### References

For more information on the ASA Physical Status Classification system and the use of examples, the following publications are helpful. Additionally, in the reference section of each of the articles, one can find additional publications on this topic.

1. Abouleish AE, Leib ML, Cohen NH. ASA provides examples to each ASA physical status class. *ASA Monitor* 2015; 79:38-9 <http://monitor.pubs.asahq.org/article.aspx?articleid=2434536>
2. Hurwitz EE, Simon M, Vinta SR, et al. Adding examples to the ASA-Physical Status classification improves correct assignments to patients. *Anesthesiology* 2017; 126:614-22
3. Mayhew D, Mendonca V, Murthy BVS. A review of ASA physical status – historical perspectives and modern developments. *Anaesthesia* 2019; 74:373-9





**Florida Board of Medicine  
Rules/Legislative Committee Meeting**

**Meet-Me-Number: 888-585-9008  
Conference Room Number: 432-162-565  
(Please login and mute your phone)**

**Wednesday, June 3, 2020**

**MINUTES**

Roll call 1:00 pm

**Members Present:**

Shailesh Gupta, MD, Vice Chair  
Kevin Cairns, MD  
Hector Vila, MD  
Zachariah P. Zachariah, MD  
Eleonor Pimentel, MD

**Members Absent:**

Sarvam TerKonda, MD, Chair  
Nicholas Romanello, Consumer Member

**Staff Present:**

Claudia Kemp, JD, Executive Director  
Edward Tellechea, Board Counsel  
Donna McNulty, Board Counsel  
Nancy Murphy, Certified Paralegal  
Crystal Sanford, Program Operations Administrator (850) 222-5491  
Shaila Washington, Regulatory Supervisor  
Rebecca Hewett, Regulatory Specialist III

**Others Present:**

For the Record Court Reporting  
Lindsey Sampson  
1500 Mahan Drive, Suite 140  
Tallahassee, FL 32308

**Legislative Discussion**

**Legislative Summary ..... 1**

Ms. Kemp addressed the Committee and provided a brief summary of the bills. She said the Governor signed HB 389 (Practice of Pharmacy) and HB 607 (Direct Care Workers). She added that HB 743 (Nonopioid Alternatives) has been presented to the Governor but is pending his signature. She said the rest of the bills have not yet been presented to the Governor.

**No action necessary**

**May 2020 Rules Report ..... 3**

The Rules Report, prepared by Ms. Murphy, provided updates on rules currently in development.

**No action necessary.**

**House Bill 389 .....2 and Addendum V3**

Ms. Kemp presented the bill and the draft work completed by the Board of Pharmacy on the rule language. She explained she sent updated information to the members that morning from the Board of Pharmacy (attached). She said they plan to meet on the rule again on June 25, 2020.

Dr. Vila expressed concerns over the process because there were issues to talk about like the timing, the items for consultation in the rule, and how the Board of Medicine can provide consultation to the Board of Pharmacy.

Ms. Kemp suggested a couple of ways to proceed, such as having a medical doctor on the call with the Board of Osteopathic Medicine when they consider the rule at their June 9, 2020 conference call. She also suggested presenting this to the entire Board at Friday's meeting.

Dr. Vila felt full Board participation was necessary.

Mr. Tellechea said he has spoken with counsel to the Board of Pharmacy, David Flynn. He said the language being presented today was preliminary language and they would be solidifying the language at their June 25<sup>th</sup> meeting. He said the Pharmacy Board wanted to hear the Board's input and concerns including meeting with a member and are waiting to hear from us and the Osteopathic Board before their June 25<sup>th</sup> meeting.

Ms. Kemp confirmed Mr. Tellechea's statement and said she has been in direct contact with the Executive Director of the Board of Pharmacy, Jessica Sapp, and in other conversations about the rule and the Board's input.

Dr. Zachariah said he was happy to hear the Pharmacy Board wanted to their input. He suggested conducting a joint committee meeting.

Mr. Tellechea suggested the members write down their comments and concerns and send those to Ms. Kemp. Ms. Kemp could then provide that information to Ms. Sapp to include in the agenda materials for the June 25<sup>th</sup> meeting. He explained the Pharmacy Board is being asked to have this rule in place by August 1, 2020 so Florida is ready for the Fall when COVID-19 is expected to flare again.

Dr. Vila said this was a big change and going slow and deliberate equals success. He suggested starting with a few conditions, see how that goes, then expand to other conditions. He said he was willing to meet at any time and would send his comments to Mr. Tellechea.

Ms. Kemp suggested taking this discussion to the full Board during Friday's meeting.

Dr. Gupta said the Board should offer to meet and work with the Pharmacy Board.

Mr. Tellechea reminded the members about the Sunshine Law. He suggested the members send their comments. He said there is no action yet and today was a good discussion.

Dr. Zachariah advised for members to send their comments to Ms. Kemp and Mr. Tellechea.

**Action taken:** members to submit comments to Ms. Kemp and Mr. Tellechea; discuss at Friday's Board Meeting



Florida Board of Medicine  
Board Meeting

**Meet-Me Number:**  
Toll Free Number: 1-888-585-9008  
Conference Room Number: 432 162 565

June 5, 2020

**Meeting Minutes**

8:00 a.m. Roll call

**Members Present:**

Zachariah P. Zachariah, MD, Chair  
Hector Vila, MD, Vice Chair  
Eleonor Pimentel, MD  
Scot Ackerman, MD  
Sarvam TerKonda, MD  
Kevin Cairns, MD  
Jorge Lopez, MD  
Robert London, MD  
Nicholas Romanello, Consumer Member  
(was present for initial roll call, but not present for the second roll call)  
Andre Perez, Consumer Member  
David Diamond, MD  
Shailesh Gupta, MD  
Luz Pages, MD

**Members Absent:**

Barbara Fonte, Consumer Member

**Staff Present:**

Claudia Kemp, JD, Executive Director  
Edward Tellechea, Board Counsel  
Donna McNulty, Board Counsel  
Nancy Murphy, Certified Paralegal  
Crystal Sanford, CPM, Program Operations Administrator (850) 222-5491  
Wendy All, Program Operations Administrator  
Shaila Washington, Regulatory Supervisor  
Rebecca Hewett, Regulatory Specialist III

**Others Present:**

For the Record Court Reporting  
Lindsey Sampson  
1500 Mahan Drive, Suite 140  
Tallahassee, Florida 32308

**Department Prosecutors Present:**

Allison Dudley, Esquire  
Jamal Burk, Esquire  
Geoffrey Christian, Esquire  
Sarah Corrigan, Esquire  
Cynthia Nash-Early, Esquire  
Corynn Alberto, Esquire  
Michael Williams, Esquire  
Andrew Perrin, Esquire  
Major Thompson, Esquire

**Rules/Legislative Committee ..... No tab**

Dr. Gupta provided the report for the meeting held June 3, 2020. He explained the Committee discussed HB 389 and the best way to consult with the Board of Pharmacy on their rule. He

encouraged all members to send their comments to Mr. Tellechea and Ms. Kemp who would share the comments with the Board of Pharmacy members.

Ms. Kemp reminded the members the rule language is still being drafted. She said the Board of Pharmacy's Rules Committee will be conducting another meeting on June 25, 2020 and encouraged members to listen in to the call.

Dr. Pages asked if the law differentiates between adults and pediatric patients.

Mr. Tellechea said the law did not differentiate between them.

Dr. Zachariah said the process should be methodical, thoughtful and should not be rushed. He suggested asking for members of the Boards of Medicine, Osteopathic Medicine and Pharmacy hold a joint meeting to work on the rule language.

Dr. Pimentel asked if there was a similar law in other states.

Mr. Tellechea said he was not aware of other states.

Ms. Kemp said she could find out and let the members know.

Dr. Gupta asked how the Board asks for a joint meeting.

Ms. Kemp said she and Mr. Tellechea could talk to their Executive Director and Board Counsel.

Dr. TerKonda said there are a lot of questions and the members need a better understanding. He said he would be on the call on June 25<sup>th</sup>.

Dr. London said this is a significant increase in scope of practice.

Dr. Vila said he had concerns but glad to have the opportunity to work with the Board of Pharmacy so patients have more access to care.

Dr. Gupta brought up the next topic from the meeting which concerned Telehealth by Electrologists doing Laser Hair Removal.

Dr. Zachariah called speakers to address the Board.

Jolynn Greenhalgh, DNP, ARNP, Electrology Council Chair, addressed the Board in support of their rule.

Judy Adams, Legislative Liaison with the Electrolysis Society of Florida, addressed the Board in support of the rule language.

Tali Arviv was called but was not on the call.

Christopher Nuland, Esquire, representing the Florida Society of Dermatology and Dermatologic Surgeons and the Florida Society of Plastic Surgeons, addressed the Board in opposition to the rule language. He said Chapters 456 and 458, F.S. define direct supervision requiring the onsite presence of the physicians. He said the Legislature specifically put supervision in the law.

Lawrence Gonzalez, Counsel to the Electrolysis Society of Florida and the Electrolysis Association of Florida, addressed the Board in support of the language. He said the language

would allow supervision under telehealth and direct supervision and responsibility was within the Board's scope to define. He reminded the Board the profession has a superior safety record.

A motion was made and seconded to accept the report.

Mr. Tellechea read the language into the record.

Dr. Vila asked if the rule would now go into rule making.

Mr. Tellechea confirmed.

The motion passed unanimously.

**Action taken:** report accepted; send comments to Ms. Kemp and Mr. Tellechea regarding the Pharmacy rule, members encouraged to attend June 25<sup>th</sup> Pharmacy meeting, Mr. Tellechea and Ms. Kemp to discuss a joint meeting with Pharmacy's Executive Director and Board Council, Electrology telehealth rule language approved

# FLORIDA | Board of Osteopathic Medicine

June 9, 2020



**DRAFT MEETING MINUTES**  
**Board of Osteopathic Medicine**  
**Teleconference Business Meeting**  
**June 9, 2020**  
**1:00 p.m.**

The meeting was called to order by Dr. Joel Rose, Chair, at approximately 1:00 p.m.

Those present for all or part of the meeting included the following:

**MEMBERS PRESENT:**

Joel B. Rose, DO, Chair  
Sandra Schwemmer, DO, Vice-Chair  
Anna Hayden, DO  
Michelle R. Mendez, DO  
Bridget Bellinger, DO.

**MEMBERS ABSENT**

Valerie Jackson, Consumer Member

**COURT REPORTER:**

For the Record Reporting  
(850) 222-5491  
Julie Pulver

**OTHERS PRESENT:**

Jessica Sapp, Board of Pharmacy Executive Director  
Claudia Kemp, Board of Medicine Executive Director  
Ed Tellachea, Board of Medicine Board Counsel  
David Fynn, Board of Pharmacy Board Counsel  
Dr. Terkonda, Board of Medicine  
Dr. Gupta, Board of Medicine  
Dr. London, Board of Medicine  
Dr. Mesaros, Board of Pharmacy

**BOARD STAFF PRESENT:**

Kama Monroe, Executive Director  
Carol Taylor, Program Administrator

**BOARD COUNSEL**

Donna McNulty, Board Counsel  
Nancy Murphy, Paralegal

*Please note that the meeting minutes reflect the actual order that agenda items were discussed during the meeting and may differ from the agenda outline*

## **TAB 1: Discussion of Board of Pharmacy's Draft Rules Related to HB389 Informational Materials for Review for Discussion**

Board Chair, Dr. Joel Rose, called the meeting to order and welcomed all attendees.

Program Administrator, Carol Taylor, noted that the purpose of the meeting was to discuss House Bill 389 (HB 389). Dr. Rose provided a brief overview of HB 389 and the items the board would discuss.

Dr. Rose asked for volunteers from the Osteopathic board who would be interested in serving as the board's second member of the joint committee with the Board of Pharmacy and the Board of Medicine. He also stated that he would serve as the first member. The first Joint Committee meeting is scheduled for June 25, 2020.

Dr. Bellinger nominated Dr. Mendez to serve as the second member of the Joint Committee. Dr. Hayden seconded the nomination. The nomination passed.

Direction was given to the board to provide any comments or questions they might have, following the meeting, to the Board of Osteopathic Medicine board office.

Discussion ensued with input from the board and meeting attendees. Discussion included the desire from an attendee, that there be a single standard of care that is no less than the standard currently in place. There was a further desire that the term "interactive computer based" when discussing a course, be better defined. Several questions and comments arose during discussion of Rule 64B16-0035. A desire to see in rule something that specifies what modification entails was conveyed. Discussion regarding the Collaborative Agreement resulted in much input from all present, including concerns with HIPAA compliance. Board of Pharmacy board counsel noted HIPAA concerns would be further discussed at the June 25<sup>th</sup> joint meeting. In discussion of test and treat, there was concern that movement forward should be in a safe and responsible manner. Much discussion entailed regarding concerns with sharing of information, records, and a failure to specify which board when referencing the board. This discussion generated much input and many concerns.

Direction was again provided for osteopathic physicians to provide comments or questions to Board of Osteopathic Medicine board office and for medical physicians to provide comments or questions to Board of Medicine board staff.

A Joint Committee Meeting with representation from the Board of Osteopathic Medicine, Board of Pharmacy and Board of Medicine is scheduled for June 25, 2020.

### **ADJOURN**

Motion: by Dr. Hayden, to adjourn the meeting.  
Meeting adjourned at 2:00 pm.

### **ADJOURN**

**Next Meeting: June 22, 2020  
Teleconference**

**64B16-26.XXXX Collaborative Pharmacy Practice Certification.**

(1) An application for certification to provide services under a collaborative pharmacy practice agreement shall be made on Board approved form DH-MQA XXXX, "Board of Pharmacy Collaborative Pharmacy Practice Certification Application," dated XX/20, which is hereby incorporated by reference. To obtain an application go to XXXXXX, or contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254 or (850)488-0595, or download the application from the web at <http://www.doh.state.fl.us/mqa/pharmacy>.

(2) The Board shall approve a 20-hour education course offered by an Accreditation Council of Pharmacy Education (ACPE) accredited provider for initial certification to provide services under a collaborative pharmacy practice agreement. The course shall cover all of the following:

- (a) Performance of patient assessments;
- (b) Ordering, performing, and interpreting clinical and laboratory tests related to collaborative pharmacy practice;
- (c) Evaluating and managing diseases and health conditions in collaboration with other health care practitioners; and
- (d) Review of applicable state and federal laws and rules.

(3) The 20-hours of education for initial certification may be applied to the 30 hours of continuing education required under section 465.009, F.S.

(4) The Board shall approve an 8-hour continuing education course offered by an ACPE accredited provider to be completed by a pharmacist who practices under a collaborative pharmacy practice each biennial license renewal period. The course shall provide a review of the material covered in the initial certification course and any applicable updated information.

**64B16-27.XXXX Collaborative Pharmacy Practice for Chronic Health Conditions.**

In addition to the chronic health conditions listed in section 465.1865, F.S., “chronic health condition” means any chronic condition to be collaboratively managed by a pharmacist and a collaborating physician under a collaborative pharmacy practice agreement that meets the requirements of 465.1865(3), F.S.

**64B16-26.XXXX Certification for Testing or Screening for and Treating Minor, Nonchronic Health Conditions.**

(1) An application for certification to test or screen for and treat minor, nonchronic health conditions shall be made on Board approved form DH-MQA XXXX, "Board of Pharmacy Test and Treat Certification Application," dated XX/20, which is hereby incorporated by reference. To obtain an application go to XXXXXX, or contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254 or (850)488-0595, or download the application from the web at <http://www.doh.state.fl.us/mqa/pharmacy>.

(2) The Board shall approve a 20-hour education course offered by an Accreditation Council of Pharmacy Education (ACPE) accredited provider for initial certification to test or screen for and treat minor, nonchronic health conditions. The course, at a minimum, shall cover all of the following:

- (a) Patient assessments;
- (b) Point-of-care testing procedures;
- (c) Safe and effective treatment of minor, nonchronic health conditions;
- (d) Identification of contraindications;
- (e) Applicable state and federal laws and rules.

(3) The 20-hours of education for initial certification may be applied to the 30 hours of continuing education required under section 465.009, F.S.

(4) The Board shall approve a 3-hour continuing education course offered by an ACPE accredited provider to be completed by a pharmacist providing services under section 465.1895, F.S., each biennial license renewal period. The course shall provide a review of the material covered in the initial certification course and any applicable updated information.

**64B16-27.XXXX Formulary of Drugs for Treating Minor, Nonchronic Health Conditions**

A pharmacist certified to treat minor, nonchronic health conditions in accordance with section 465.1895, F.S., may prescribe any medicinal drug for the treatment of a minor, nonchronic health condition that is:

- (1) Not a controlled substance as described in section 893.03, F.S., or 21 U.S.C. section 812;
- (2) Approved by the United States Food and Drug Administration; and
- (3) Indicated for treatment of the minor, nonchronic health condition.

**64B16-27.XXXX Guidelines for Providing Patients with Written Information Advising Patients to Seek Followup Care**

A pharmacist who tests or screens for and treats minor, nonchronic health conditions in accordance with section 465.1895, F.S., must provide a patient with written information advising the patient to followup with his or her primary care provider when:

- (1) The written protocol between the pharmacist and the supervising physician requires the pharmacist to advise the patient to followup with his or her primary care provider.
- (2) The pharmacist determines in his or her professional judgment that the patient should followup with his or her primary care provider.

# FLORIDA BOARD OF PHARMACY

June 8, 2020



Dear Dr. Zachariah,

On March 11, 2020, CS/HB 389 Practice of Pharmacy was approved by the Governor and is effective July 1, 2020. This bill authorizes a pharmacist, who meets certain qualifications, to enter into a collaborative pharmacy practice agreement with a physician to manage chronic health conditions. It also authorizes a pharmacist, who meets certain qualifications, to test or screen for and treat minor, non-chronic health conditions within the framework of a written protocol with a supervising physician.

The Board of Pharmacy must consult with the Boards of Medicine and Osteopathic Medicine to develop rules to implement certain provisions of the bill. The first draft of the proposed rules has been provided to your Board identifying the sections in which consultation is required. The Board of Pharmacy will hold a Rules Committee meeting on June 25, 2020 at 1:00 p.m. ET wherein we invite two representatives from the Board of Medicine to participate in rulemaking discussion. Multi-board collaboration will ensure quality rules are produced. Please inform the Board of Pharmacy, through your Executive Director, of your chosen representatives so that we may provide them with the meeting materials.

The Board of Pharmacy looks forward to working with the Board of Medicine to implement this bill. Together, we will continue to protect, promote, and improve the health of all people in Florida.

Sincerely,

Jessica Sapp, Executive Director  
*on behalf of*

Jeffrey Mesaros, PharmD, J.D., Rules Committee Chair

**Richard Montgomery, BPharm, MBA,**  
Chair  
Orlando, FL

**Jonathan Hickman, PharmD,**  
Vice-Chair  
Tallahassee, FL

**Mark Mikhael, PharmD**  
Orlando, FL

**Blanca R. Rivera, PharmD, MBA**  
Miami, FL

**Jeffrey J. Mesaros, PharmD, JD**  
Orlando, FL

**Jeenu Philip, BPharm**  
Jacksonville, FL

**David Wright, BPharm**  
Fort Pierce, FL

**Gavin Meshad**  
Consumer Member  
Jacksonville, FL

# FLORIDA BOARD OF PHARMACY



June 8, 2020

Dear Dr. Rose,

On March 11, 2020, CS/HB 389 Practice of Pharmacy was approved by the Governor and is effective July 1, 2020. This bill authorizes a pharmacist, who meets certain qualifications, to enter into a collaborative pharmacy practice agreement with a physician to manage chronic health conditions. It also authorizes a pharmacist, who meets certain qualifications, to test or screen for and treat minor, non-chronic health conditions within the framework of a written protocol with a supervising physician.

The Board of Pharmacy must consult with the Boards of Medicine and Osteopathic Medicine to develop rules to implement certain provisions of the bill. The first draft of the proposed rules has been provided to your Board identifying the sections in which consultation is required. The Board of Pharmacy will hold a Rules Committee meeting on June 25, 2020 at 1:00 p.m. ET wherein we invite two representatives from the Board of Osteopathic Medicine to participate in rulemaking discussion. Multi-board collaboration will ensure quality rules are produced. Please inform the Board of Pharmacy, through your Executive Director, of your chosen representatives so that we may provide them with the meeting materials.

The Board of Pharmacy looks forward to working with the Board of Osteopathic Medicine to implement this bill. Together, we will continue to protect, promote, and improve the health of all people in Florida.

Sincerely,

Jessica Sapp, Executive Director  
*on behalf of*

Jeffrey Mesaros, PharmD, J.D., Rules Committee Chair

**Richard Montgomery, BPharm, MBA,**  
Chair  
Orlando, FL

**Jonathan Hickman, PharmD,**  
Vice-Chair  
Tallahassee, FL

**Mark Mikhael, PharmD**  
Orlando, FL

**Blanca R. Rivera, PharmD, MBA**  
Miami, FL

**Jeffrey J. Mesaros, PharmD, JD**  
Orlando, FL

**Jeenu Philip, BPharm**  
Jacksonville, FL

**David Wright, BPharm**  
Fort Pierce, FL

**Gavin Meshad**  
Consumer Member  
Jacksonville, FL

**From:** [Sapp, Jessica](#)  
**To:** [Monroe, Kama](#); [Taylor, Carol](#)  
**Cc:** [Kemp, Claudia J](#)  
**Subject:** BOOM Representatives  
**Date:** Tuesday, June 9, 2020 2:26:20 PM

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Hi Kama and Carol,

From your call today, I understand that Dr. Mendez and Dr. Schwemmer were selected as your Board's representatives. Please let them know, as well as the rest of your Board, that our June 25 meeting begins at 9:00 a.m., not 1:00 p.m. We discussed two different times and I did not amend the letter when 9:00 a.m. was finalized so I apologize for the typo.

Claudia- Will you also let your Board know as you all are still deciding on your representatives?

Thank you!

**Jessica Sapp**

**Executive Director**

Department of Health | Division of Medical Quality Assurance

Bureau of Health Care Practitioner Regulation

4052 Bald Cypress Way Bin C-04

Tallahassee, FL 32399-1708

Phone 850/245-4463

[www.FloridasDentistry.gov](http://www.FloridasDentistry.gov)

[www.FloridasPharmacy.gov](http://www.FloridasPharmacy.gov)



**Mission:** To protect, promote and improve the health of all people in Florida through integrated state, county and community efforts.

**Note:** Florida has a very broad public records law. Most written communications to or from state officials regarding state business are public records available to the public and media upon request. Your email communication may therefore be subject to public disclosure.



March 30, 2020

Richard Montgomery, BPharm, MBA  
Chair  
Florida Board of Pharmacy  
4052 Bald Cypress Way Bin C-04  
Tallahassee FL, 32399-3258

***Re: HB 389 - Boards of Pharmacy, Medicine and Osteopathic Medicine Joint Committee***

Dear Mr. Montgomery,

On March 11, 2020, Governor Ron DeSantis signed into law House Bill 389 which greatly expands the role pharmacists play in Florida's healthcare system. HB 389 is best characterized as having two major pieces of legislation wrapped up in one. First, it creates a collaborative pharmacy practice agreement between a physician and pharmacist for the management of chronic conditions and second, establishes a protocol for pharmacists that may test and treat for minor, nonchronic conditions.

HB 389 calls for the promulgation of several rules by the Board of Pharmacy in consultation with the Boards of Medicine and Osteopathic Medicine. It is the role of all three boards to protect the public and to assure competency and safety to practice in their respective service for the people of Florida. In order for that mission to be accomplished in regard to HB 389, it is imperative that all three boards have a seat at the table so that the proper expertise can be shared. Rules that must be developed in consultation include the following:

Chronic conditions under a collaborative pharmacy practice agreement –

- **Chronic conditions** – HB 389 defines “chronic health conditions” as arthritis, asthma, COPD, type 2 diabetes, HIV/AIDS, obesity, or any other chronic condition adopted in rule by the Board of Pharmacy (BOP), in consultation with the Board of Medicine (BOM) and Board of Osteopathic Medicine (BOOM).
- **Certification Criteria** – In order to provide services under a collaborative pharmacy practice agreement, the BOP must certify the pharmacist according to rules adopted in consultation with the BOM and BOOM.
- **Educational Requirements** – In order to be certified to provide services under a collaborative pharmacy practice agreement, the pharmacist must complete an initial 20-hour course approved by the BOP in consultation with the BOM and BOOM.
- **Implementation** – all other rules required to implement this section shall be done in consultation with the BOM and BOOM.

Minor, non-chronic conditions under a protocol –



- **Certification Criteria** – In order to provide services under a protocol agreement to test and treat for minor, non-chronic conditions, the BOP must certify the pharmacist in accordance to requirements established by rule in consultation with the BOM and BOOM.
- **Educational Requirements** – In order to be certified to test and treat for minor, nonchronic health conditions, the pharmacist must complete an initial 20-hour course approved by the BOP in consultation with the BOM and BOOM.
- **Protocol Requirements** – HB 389 sets the minimum requirements for what a protocol must contain and allows for other requirements as established by rule in consultation with the BOM and BOOM.

While HB 389 does not mandate the Board of Pharmacy adopt rules in consultation in other areas of the legislation, such as establishing the drug formulary and guidelines for providing medical record information to patients for physician follow-up, it would be best practice for the three boards to continue to collaborate. The FMA believes that the BOP would benefit from the presence of BOM and BOOM members throughout the rulemaking process.

The Florida Medical Association hereby respectfully requests that the Board of Pharmacy create a Joint Committee with the Boards of Medicine and Osteopathic Medicine in order to collaborate and streamline the rulemaking process.

Thank you for your consideration in this matter. If you have any questions, please do not hesitate to contact me via email at [MThomas@flmedical.org](mailto:MThomas@flmedical.org) or by telephone at 850-224-6496.

Sincerely,

Mary Thomas, Esq.  
Assistant General Counsel  
Florida Medical Association

Cc: Zachariah Zachariah, M.D., Chair, Board of Medicine  
Joel Rose, D.O., Chair, Board of Osteopathic Medicine

# WINN LAW

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and Governmental Law*

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850.222.1562(f)

April 7, 2020

Richard Montgomery, BPharm, MBA  
Chair Florida Board of Pharmacy  
4052 Bald Cypress Way, Bin C-04  
Tallahassee, FL 32399-3258

Re: HB 389 – Board of Pharmacy, Medicine and Osteopathic Medicine Joint Committee

Dear Mr. Montgomery,

As General Counsel to the Florida Osteopathic Medical Association (FOMA), please accept this letter on behalf of the FOMA requesting the Board of Pharmacy create a Joint Committee with the Boards of Medicine and Osteopathic Medicine for rulemaking regarding HB389.

As you are aware, HB389 passed during the 2020 Legislative Session, and Governor DeSantis signed the bill into law on March 11, 2020, expanding the role of pharmacists in Florida. There are two major components to this new law: creating a collaborative pharmacy practice agreement between a physician and pharmacist for the management of chronic conditions; and, establishing a protocol for pharmacists that may test and treat for minor, non-chronic conditions.

## **CHRONIC HEALTH CONDITIONS**

HB389 defines **chronic health conditions** as: Arthritis, Asthma, Chronic obstructive pulmonary diseases, type 2 diabetes, human immunodeficiency virus or acquired immune deficiency syndrome, obesity, or any other chronic condition adopted in rule by the board, in consultation with the Boards of Medicine and Board of Osteopathic Medicine. (465.1865(1)(b), (FS)).

Also, HB389 requires the Board of Pharmacy to collaborate with the Boards of Medicine and Osteopathic Medicine to: 1. certify pharmacists under a collaborative agreement; 2. Provide an approved 20-hour course; and, 3. Any other rules required to implement HB389.

## **NON-CHRONIC & MINOR CONDITIONS**

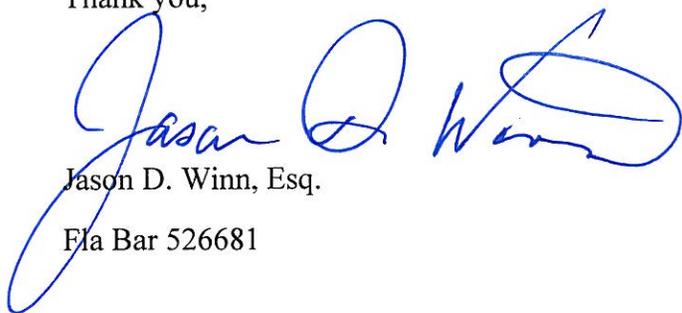
HB389 defines non-chronic & minor conditions as: Influenza, Streptococcus, lice, skin conditions such as ringworm and athlete's foot, and minor uncomplicated infections. Again, this new law requires consultation by this Board with the Boards of Medicine and Osteopathic Medicine to: 1. Set requirements for certification of pharmacists to test and treat for non-chronic and minor conditions; 2. Provide an approved 20-hour course; 3.

Set the minimum requirements for what a protocol must contain; and, 4. Any other requirements established by rule.

The FOMA supports the FMA's letter dated March 30, 2020 in requesting the Board of Pharmacy create a Joint Committee with the Boards of Medicine and Osteopathic Medicine in order to collaborate during the rulemaking process. The FOMA supports the position that the Board of Pharmacy would benefit from the inclusion of members from the Board of Medicine and Board of Osteopathic Medicine.

Thank you for your time in this matter, and please contact me via email at [jwinn@jwinnlaw.com](mailto:jwinn@jwinnlaw.com) or by phone at 850/519-5876.

Thank you,

A handwritten signature in blue ink, appearing to read "Jason D. Winn". The signature is fluid and cursive, with a large initial "J" and "W".

Jason D. Winn, Esq.  
Fla Bar 526681

CC: Zachariah Zachariah, MD, Chair of Board of Medicine

Joel Rose, DO, Chair of Board of Osteopathic Medicine