I. Call to Order/Roll Call

MEMBERS PRESENT:
Richard Montgomery, BPharm, MBA, Chair
Jonathan Hickman, PharmD, Vice – Chair
David Wright, BPharm
Mark Mikhael, PharmD
Jeffrey J. Mesaros, PharmD, JD
Jeenu Philip, BPharm
Blanca R. Rivera, PharmD, MBA
Gavin Meshad, Consumer Member

STAFF PRESENT:
Jessica Sapp, Executive Director
Traci Zeh, Program Administrator

BOARD COUNSEL:
David Flynn, Senior Assistant Attorney General
Christopher Dierlam, Assistant Attorney General

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

II. DISCUSSION ITEMS
A. Emergency Rule Addressing Consultant Pharmacist Obligations Under 64B16-28, F.A.C.

III. ADJOURNMENT
NOTICE OF EMERGENCY RULE

DEPARTMENT OF HEALTH

Board of Pharmacy

RULE TITLE: Consultant Pharmacist of Record; Initial Designation; Change.

RULE NO.: 64B16ER20-22

SPECKIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: The Board of Pharmacy (hereinafter the “Board”) is statutorily mandated to promulgate rules necessary to regulate the practice of consultant pharmacists. Pursuant to this authority, the Board has promulgated rules setting forth the practice requirements for consultant pharmacists in the State of Florida. Pursuant to Rule 64B16-28.501, Florida Administrative Code, the consultant pharmacist of record for a Class I, Class II, Modified Class II, or Class III Institutional permit shall inspect the facility and prepare a written report to be filed at the permitted facility at least monthly. Rules 64B16-28.702(2)(b), (c), and (d) F.A.C., require consultant pharmacists to “provide on-site consultations not less than once every month, unless otherwise directed by the Board after review of the policy and procedure manual” for the Modified Class II Institutional Pharmacies that are under their supervision and control. Rule 64B16-28.850(16), F.A.C., also requires consultant pharmacists to inspect permitted ESRD\textsuperscript{1} pharmacies under their supervision on a monthly basis. Further, Rules 64B16-28.870(3)(c) and (d), F.A.C., require consultant pharmacists of Special Assisted Living Facilities (“ALF”) permits to “inspect the facility and prepare a written report to be filed at the permitted facility at least monthly”.

On March 1, 2020, Florida Governor Ron DeSantis issued Executive Order Number 20-51 which directed the State Health Officer and Surgeon General, Dr. Scott Rivkees, to declare a public health emergency pursuant to the spread of the Coronavirus Disease 2019 (“COVID-19”). On March 9, 2020, Governor DeSantis issued Executive Order Number 20-52 (Emergency Management - COVID-19 Public Health Emergency) and officially declared that a state of emergency exists in the State of Florida. On March 16, 2020, Dr. Rivkees issued Emergency Order DOH 20-002 in order to prepare for, respond to, and mitigate any effect of COVID-19 in the State of Florida.

COVID-19 is a severe acute respiratory illness that can spread among humans through respiratory transmission.

\textsuperscript{1} An ESRD pharmacy is a type of special pharmacy which is limited in scope of pharmacy practice to the provision of dialysis products supplied to persons with chronic kidney failure.
and presents with symptoms similar to those of influenza. As of March 19, 2020, there are ??? confirmed cases of COVID-19 in the State of Florida. The Center for Disease Control (“CDC”) recommends mitigation measures to combat the spread of COVID-19 such as staying home when sick, keeping away from others who are sick, and staying home when a household member is sick with respiratory disease symptoms. The CDC also recommends those who are at a higher risk, such as older adults and those who have serious chronic medical conditions, should avoid non-essential air travel and avoid crowds as much as possible.

Due to the concerns surrounding the spread of COVID-19, several consultant pharmacists have reached out to the Board staff with concerns regarding the performance of in-person inspections and consultations pursuant to the aforementioned rules. At least one pharmacist was not allowed to enter an ALF permit holder where he was serving as the consultant pharmacist due to COVID-19 concerns. Other practitioners have expressed concerns regarding the potential unintentional spread of the virus to facilities housing high risk individuals if they were to comply with the provisions requiring in-person duties.

Ensuring that Florida’s consultant pharmacists are not unnecessarily put at risk is essential during this healthcare emergency. Further, ensuring facilities that house large portions of high-risk individuals are not exposed to COVID-19 is of utmost concern. Healthcare providers such as consultant pharmacists have an increased likelihood of being exposed to COVID-19 due to the number of health care facilities they visit during the performance of duties. Considering the spread of COVID-19, requiring consultant pharmacists to perform in-person inspections and consultations at permitted institutional pharmacies increases the risk of exposure of the medical providers and the facilities’ patients to COVID-19.

Accordingly, the Board, by emergency rule, hereby waives the requirement that off-site consultant pharmacists conduct monthly inspections and on-site consultations as required by Rule 64B16-28.501, F.A.C.; Rules 64B16-28.702(2)(b), (c), and (d) F.A.C.; Rule 64B16-28.850(16), F.A.C., and Rules 64B16-28.870(3)(c) and (d), F.A.C. The Board finds that these actions are a measured regulatory approach that helps protect the patients of consultant pharmacists and the pharmacists themselves from exposure to COVID-19. This emergency rule shall not be interpreted in any way that would alleviate the obligations to perform drug regimen reviews pursuant to State and Federal law.

REASONS FOR CONCLUDING THAT THE PROCEDURE USED IS FAIR UNDER THE CIRCUMSTANCES:
Given the recently declared emergency in the State of Florida and the recent guidance from the CDC, the Board finds that requiring off-site consultant pharmacists to conduct in person inspections and on-site consultations at permitted institutional pharmacies under their supervision would constitute an immediate danger to the public health, safety, or welfare and necessitates immediate action regarding this issue. Notice of this emergency meeting was published in the Florida Administrative Register on March 18, 2020. Further, notice of the Board’s emergency meeting and an agenda outlining the topic for the meeting was posted on the Board’s official website on March 17, 2020.

SUMMARY: The proposed emergency rule waives the requirement that off-site consultant pharmacists conduct in-person inspections and on-site consultations pursuant to Rule 64B16-28.501, F.A.C.; Rules 64B16-28.702(2)(b), (c), and (d) F.A.C.; Rule 64B16-28.850(16), F.A.C., and Rules 64B16-28.870(3)(c) and (d), F.A.C.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Jessica L. Sapp, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin # C-08, Tallahassee, Florida 32399-1708.

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B16ER20-?? (64B16-28.501) Consultant Pharmacist of Record; Initial Designation; Change.

(1) through (4) No change.

(5) Off-site consultant pharmacists of record shall not be required to perform inspections and on-site consultations at permitted institutional pharmacies as referenced in Rules 64B16-28.501, F.A.C.; Rules 64B16-28.702(2)(b), (c), and (d) F.A.C.; Rule 64B16-28.850(16), F.A.C., and Rules 64B16-28.870(3)(c) and (d), F.A.C., when the consultant pharmacist of record is not regularly present at the location. This rule shall in no way modify any obligations stemming from State or Federal laws requiring drug regimen reviews.


THIS RULE TAKES EFFECT IMMEDIATELY UPON BEING FILED WITH THE DEPARTMENT OF STATE UNLESS A LATER TIME AND DATE IS SPECIFIED IN THE RULE.
64B16-28.501 Consultant Pharmacist of Record; Initial Designation; Change.

(1) Designation as Consultant Pharmacist of Record.

(a) Initial Designation. Pursuant to sections 465.019 and 465.022, F.S., a permit for an Institutional pharmacy may not be issued unless a licensed pharmacist is designated as the consultant pharmacist of record. In addition, pursuant to rule 64B16-28.870, F.A.C., an application for a Special Assisted Living Facility pharmacy permit requires the supervising licensed pharmacist be designated as the consultant pharmacist of record. Finally, applications for Special Sterile Compounding Permits associated with an Institutional pharmacy require the pharmacist-in-charge be designated as the consultant pharmacist of record. Initial designations are accomplished as part of the application process using the appropriate application form incorporated in rule 64B16-28.100, F.A.C.

(b) Change of Consultant Pharmacist of Record.

No later than ten (10) days after a change of designated consultant pharmacist for an Institutional, or Special Assisted Living Facility pharmacy, or a Special Sterile Compounding Permittee, both the pharmacy permittee and the newly designated consultant pharmacist of record shall notify the Board of the change and the identity of the newly designated consultant pharmacist. Notification shall be accomplished by completing Form DH-MQA 1184 (01/18), Consultant Pharmacist of Record (COR) Designation and Privacy Statement Acknowledgement, which is hereby incorporated by reference and which can be obtained from http://www.flrules.org/Gateway/reference.asp?No=Ref-09437 or the Board’s website at http://floridaspharmacy.gov/Applications/app-change-consultant-pharmacist.pdf. In addition, an outgoing consultant pharmacist of record may choose to notify the Board they will no longer serve as consultant pharmacist of record using this form.

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

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

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

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

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re:
SUSPENSION OF STATUTES, RULES AND ORDERS, MADE NECESSARY BY COVID-19.

EMERGENCY ORDER

Pursuant to the authority granted by Executive Order No. 20-52, I find that strict compliance with the provisions of certain regulatory statutes and rules prescribing the procedures for conduct of state business by the Florida Department of Health will prevent, hinder, or delay necessary action in coping with the emergency caused by COVID-19. In order to effectively respond to the threat posed by COVID-19 it is necessary to promulgate the following:

For purposes of preparing for, responding to, and mitigating any effect of COVID-19, health care professionals, advanced life support professionals, and basic life support professionals holding a valid, unrestricted, and unencumbered license in any state, territory, and/or district may render such services in Florida during a period not to exceed thirty days unless extended by order of the State Surgeon General, if such health care practitioner does not represent or hold themselves out as a health care practitioner licensed to practice in Florida. The permitted provision of health care services and treatment by such persons is limited to those licensees as defined in section 456.001(4), part III of chapter 401, and part IV of chapter 468, Florida Statutes, or licensees whose licenses are of a type that is commensurate with such Florida licenses. Any statute and/or rule to the contrary is hereby suspended for a period of thirty days, unless extended.
For purposes of preparing for, responding to, and mitigating any effect of COVID-19, health care professionals not licensed in this state may provide health care services to a patient licensed in this state using telehealth, notwithstanding the requirements of section 456.47(4)(a) through (c), (h), and (i), Florida Statutes, for a period not to exceed 30 days unless extended by order of the State Surgeon General. This exemption shall apply only to the following out of state health care professionals holding a valid, clear, and unrestricted license in another state or territory in the United States who are not currently under investigation or prosecution in any disciplinary proceeding in any of the states in which they hold a license: physicians, osteopathic physicians, physician assistants, and advanced practice registered nurses. All other requirements in section 456.47(4) remain in effect, including the requirement that the health care professional provide health care services within the applicable scope of practice established by Florida law or rule. Any statute and/or rule to the contrary is hereby suspended for a period of thirty days, unless extended.

For purposes of preparing for, responding to, and mitigating any effect of COVID-19, emergency medical services training programs may, with the approval of the training program medical director, substitute supervised remote live videoconferencing or simulation for one-half of the supervised clinical instruction hours and one-half of the supervised field internship hours required by section 401.2701, Florida Statutes, and applicable rules. Any statute and/or rule to the contrary is hereby suspended for a period of thirty days, unless extended.

For purposes of preparing for, responding to, and mitigating any effect of COVID-19, qualified physicians under section 381.986, Florida Statutes, may issue a physician certification only for an existing qualified patient with an existing certification that was issued by that qualified physician without the need to conduct a physical examination while physically present in the same room as the patient. These qualified physicians may only substitute telehealth services for the physical examination while physically present in the same room as the patient. Telehealth shall have the same meaning as section 456.47(1)(a). All other minimum practice
requirements and standards of care shall still apply to recertifications issued under this exception. This exception to section 381.986(4)(a)1., Florida Statutes, only applies for a period not to exceed thirty days unless extended by order of the State Surgeon General. Any statute and/or rule to the contrary is hereby suspended for a period of thirty days, unless extended.

For purposes of preparing for, responding to, and mitigating any effect of COVID-19, physicians, osteopathic physicians, physician assistants, and advanced practice registered nurses licensed in Florida that have designated themselves as a controlled substance prescribing practitioner pursuant to section 456.44, may issue a renewal prescription for a controlled substance listed as Schedule II, Schedule III, or Schedule IV under chapter 893 only for an existing patient for the purpose of treating chronic nonmalignant pain without the need to conduct a physical examination of the patient. These practitioners may only substitute telehealth services for the physical examination. Telehealth shall have the same meaning as section 456.47(1)(a). All other minimum practice requirements and standards of care shall still apply to renewal prescriptions issued under this exception. This exception shall only apply for a period not to exceed thirty days unless extended by order of the State Surgeon General. Any statute and/or rule to the contrary is hereby suspended for a period of thirty days, unless extended.

For the purposes of preparing for, responding to, and mitigating any effect of COVID-19, the provisions of chapters 499 and 465, Florida Statutes, and rules promulgated thereunder, that if applied, would operate to limit distribution, dispensing, or administration of otherwise legitimate prescription drugs in a manner that could hinder, prevent, or delay mitigation of any health-related condition are suspended for a period of thirty days, unless extended. This paragraph does not affect any law governing distribution, dispensation, or administration of any controlled substance as that term is defined in chapter 893, Florida Statutes.

Because section 252.36(5)(a), Florida Statutes, allows the Governor to suspend the provisions of "any regulatory statute prescribing the procedures for [the] conduct of state
business,” and because Section 4. B. of Executive Order No. 20-52 provides the State Surgeon General with the authority to issue this Emergency Order, the requirements of sections 252.46 and 120.54(4), Florida Statutes, do not apply to this Order. The effective dates of this Order shall correspond with the effective dates of Executive Order No. 20-52, unless otherwise specified above.

Executed this 16th day of March 2020, in Department of Health Offices, Tallahassee, Leon County, Florida.

[Signature]

Scott A. Rivkees, M.D.
State Surgeon General
WHEREAS, Novel Coronavirus Disease 2019 (COVID-19) is a severe acute respiratory illness that can spread among humans through respiratory transmission and presents with symptoms similar to those of influenza; and

WHEREAS, in late 2019, a new and significant outbreak of COVID-19 emerged in China; and

WHEREAS, the World Health Organization previously declared COVID-19 a Public Health Emergency of International Concern; and

WHEREAS, in response to the recent COVID-19 outbreak in China, Iran, Italy, Japan and South Korea, the Centers for Disease Control and Prevention ("CDC") has deemed it necessary to prohibit or restrict non-essential travel to or from those countries; and

WHEREAS, on March 1, 2020, I issued Executive Order number 20-51 directing the Florida Department of Health to issue a Public Health Emergency; and

WHEREAS, on March 1, 2020, the State Surgeon General and State Health Officer declared a Public Health Emergency exists in the State of Florida as a result of COVID-19; and

WHEREAS, on March 7, 2020, I directed the Director of the Division of Emergency Management to activate the State Emergency Operations Center to Level 2 to provide coordination and response to the COVID-19 emergency; and

WHEREAS, as of March 9, 2020, eight counties in Florida have positive cases for COVID-19, and COVID-19 poses a risk to the entire state of Florida; and
WHEREAS, the CDC currently recommends community preparedness and everyday prevention measures be taken by all individuals and families in the United States, including voluntary home isolation when individuals are sick with respiratory symptoms, covering coughs and sneezes with a tissue and disposal of the tissue immediately thereafter, washing hands often with soap and water for at least 20 seconds, using of alcohol-based hand sanitizers with 60%-95% alcohol if soap and water are not readily available and routinely cleaning frequently touched surfaces and objects to increase community resilience and readiness for responding to an outbreak; and

WHEREAS, the CDC currently recommends mitigation measures for communities experiencing an outbreak including staying at home when sick, keeping away from others who are sick, limiting face-to-face contact with others as much as possible, consulting with your healthcare provider if individuals or members of a household are at high risk for COVID-19 complications, wearing a facemask if advised to do so by a healthcare provider or by a public health official, staying home when a household member is sick with respiratory disease symptoms if instructed to do so by public health officials or a health care provider; and

WHEREAS, as Governor, I am responsible for meeting the dangers presented to this state and its people by this emergency.

NOW, THEREFORE, I, RON DESANTIS, as Governor of Florida, by virtue of the authority vested in me by Article IV, Section (1)(a) of the Florida Constitution, Chapter 252, Florida Statutes, and all other applicable laws, promulgate the following Executive Order to take immediate effect:

Section 1. Because of the foregoing conditions, I declare a state of emergency exists in the State of Florida.
Section 2. I designate the Director of the Division of Emergency Management ("Director") as the State Coordinating Officer for the duration of this emergency and direct him to execute the State’s Comprehensive Emergency Management Plan and other response, recovery, and mitigation plans necessary to cope with the emergency. Additionally, I designate the State Health Officer and Surgeon General as a Deputy State Coordinating Officer and State Incident Commander.

Pursuant to section 252.36(1)(a), Florida Statutes, I delegate to the State Coordinating Officer the authority to exercise those powers delineated in sections 252.36(5)-(10), Florida Statutes, which he shall exercise as needed to meet this emergency, subject to the limitations of section 252.33, Florida Statutes. In exercising the powers delegated by this Order, the State Coordinating Officer shall confer with the Governor to the fullest extent practicable. The State Coordinating Officer shall also have the authority to:

A. Seek direct assistance and enter into agreements with any and all agencies of the United States Government as may be needed to meet the emergency.

B. Designate additional Deputy State Coordinating Officers, as necessary.

C. Suspend the effect of any statute, rule, or order that would in any way prevent, hinder, or delay any mitigation, response, or recovery action necessary to cope with this emergency.

D. Enter orders as may be needed to implement any of the foregoing powers; however, the requirements of sections 252.46 and 120.54(4), Florida Statutes, do not apply to any such orders issued by the State Coordinating Officer; however, no such order shall remain in effect beyond the expiration of this Executive Order, to include any extension.

Section 3. I order the Adjutant General to activate the Florida National Guard, as needed, to deal with this emergency.
Section 4. I find that the special duties and responsibilities resting upon some State, regional, and local agencies and other governmental bodies in responding to the emergency may require them to suspend the application of the statutes, rules, ordinances, and orders they administer. Therefore, I issue the following authorizations:

A. Pursuant to section 252.36(1)(a), Florida Statutes, the Executive Office of the Governor may suspend all statutes and rules affecting budgeting to the extent necessary to provide budget authority for state agencies to cope with this emergency. The requirements of sections 252.46 and 120.54(4), Florida Statutes, do not apply to any such suspension issued by the Executive Office of the Governor; however, no such suspension shall remain in effect beyond the expiration of this Executive Order, to include any extension.

B. Each State agency may suspend the provisions of any regulatory statute prescribing the procedures for conduct of state business or the orders or rules of that agency, if strict compliance with the provisions of any such statute, order, or rule would in any way prevent, hinder, or delay necessary action in coping with the emergency. This includes, but is not limited to, the authority to suspend any and all statutes, rules, ordinances, or orders which affect leasing, printing, purchasing, travel, and the condition of employment and the compensation of employees. For the purposes of this Executive Order, “necessary action in coping with the emergency” means any emergency mitigation, response, or recovery action: (1) prescribed in the State Comprehensive Emergency Management Plan (“CEMP”); or (2) ordered by the State Coordinating Officer. The requirements of sections 252.46 and 120.54, Florida Statutes, shall not apply to any such suspension issued by a State agency; however, no such suspension shall remain in effect beyond the expiration of this Executive Order, to include any extensions.
C. In accordance with section 465.0275, Florida Statutes, pharmacists may dispense up to a 30-day emergency prescription refill of maintenance medication to persons who reside in an area or county covered under this Executive Order and to emergency personnel who have been activated by their state and local agency but who do not reside in an area or county covered by this Executive Order.

D. In accordance with section 252.38, Florida Statutes, each political subdivision within the State of Florida may waive the procedures and formalities otherwise required of the political subdivision by law pertaining to:

1) Performance of public work and taking whatever prudent action is necessary to ensure the health, safety, and welfare of the community;

2) Entering into contracts; however, political subdivisions are cautioned against entering into time and materials contracts without ceiling as defined by 2 CFR 200.318(j) or cost plus percentage contracts as defined by 2 CFR 200.323(d);

3) Incurring obligations;

4) Employment of permanent and temporary workers;

5) Utilization of volunteer workers;

6) Rental of equipment;

7) Acquisition and distribution, with or without compensation, of supplies, materials, and facilities; and,

8) Appropriation and expenditure of public funds.

E. All State agencies responsible for the use of State buildings and facilities may close such buildings and facilities in those portions of the State affected by this emergency, to the extent necessary to meet this emergency. I direct each State agency to report the closure of any State
building or facility to the Secretary of the Department of Management Services. Under the authority contained in section 252.36, Florida Statutes, I direct each County to report the closure of any building or facility operated or maintained by the County or any political subdivision therein to the Secretary of the Department of Management Services. Furthermore, I direct the Secretary of the Department of Management Services to:

1) Maintain an accurate and up-to-date list of all such closures; and,

2) Provide that list daily to the State Coordinating Officer.

Section 5. I find that the demands placed upon the funds appropriated to the agencies of the State of Florida and to local agencies are unreasonably great and the funds currently available may be inadequate to pay the costs of coping with this emergency. In accordance with section 252.37(2), Florida Statutes, I direct that sufficient funds be made available, as needed, by transferring and expending moneys appropriated for other purposes, moneys from unappropriated surplus funds, or from the Budget Stabilization Fund.

Section 6. All State agencies entering emergency final orders or other final actions in response to this emergency shall advise the State Coordinating Officer contemporaneously or as soon as practicable.

Section 7. Medical professionals and workers, social workers, and counselors with good and valid professional licenses issued by states other than the State of Florida may render such services in Florida during this emergency for persons affected by this emergency with the condition that such services be rendered to such persons free of charge, and with the further condition that such services be rendered under the auspices of the American Red Cross or the Florida Department of Health.
Section 8. All activities taken by the Director of the Division of Emergency Management and the State Health Officer and Surgeon General with respect to this emergency before the issuance of this Executive Order are ratified. This Executive Order shall expire sixty days from this date unless extended.

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the Great Seal of the State of Florida to be affixed, at Tallahassee, this 9th day of March, 2020.

RON DESANTIS, GOVERNOR

ATTEST:

SECRETARY OF STATE