STATE OF NEW JERSEY DEPARTMENT OF LAW AND PUBLIC SAFETY DIVISION OF CONSUMER AFFAIRS

NOTICE OF RULE WAIVER AND MODIFICATION PURSUANT TO P.L. 2020, c. 18

OFFICE OF DRUG CONTROL REGULATIONS EMERGENCY ORAL PRESCRIBING OF SCHEDULE II MEDICATIONS

DCA Administrative Order No. 2020-18 and DCA Waiver No. W-2020-16

Temporary Rule Waivers and Modifications adopted by Paul R. Rodríguez, Acting Director, Division of Consumer Affairs

Date: September 1, 2020

Authority: P.L. 2020, c. 18

Effective Date: September 1, 2020

Expiration Date: Concurrent with the end of the state of emergency and the public health emergency declared pursuant to Executive Order No. 103 (EO 103), whichever is later.

* * *

WHEREAS, on March 9, 2020, through EO 103, the facts and circumstances of which are adopted by reference herein, the Governor declared both a public health emergency and a state of emergency throughout the State due to the public health hazard posed by coronavirus disease 2019 (COVID-19); and

WHEREAS, the public health emergency declared in EO 103 has been extended through Executive Order Nos. 119, 138, 151, 162, and 171 (2020) issued on April 7, May 6, June 4, July 2, and August 1, 2020, respectively, and continues to exist today; and

WHEREAS, on April 14, 2020, Governor Murphy signed into law P.L. 2020, c. 18, which permits the Director to issue an administrative order to suspend temporarily any provision of Title 45 of the Revised Statutes or suspend or modify temporarily any rule adopted pursuant to such authority or to adopt temporarily any rule relating to the practice of any profession licensed by a board in the Division, upon concurrence by the Attorney General, after determining that such order is necessary to promote the public welfare and further such other purposes of the state of emergency or public health emergency declared in EO 103; and

WHEREAS, on March 27, 2020, the federal Drug Enforcement Administration (DEA) issued guidance providing clarification as to when oral prescribing of schedule II controlled dangerous substances (CDS) would be permitted during the public health Emergency Declaration

issued by the Secretary of Health and Human Services on January 31, 2020; and the DEA determined to extend the time for a prescriber to provide a follow-up paper prescription from seven to fifteen days, and to permit satisfaction of the paper prescription requirement through the use of a facsimile or scan of the prescription or a photograph of the prescription; and

WHEREAS, modification to the rules of the Office of Drug Control are warranted to maintain consistency with federal law governing emergency oral prescribing of schedule II CDS, and to enable New Jersey prescribers and pharmacists to comply with current federal guidance without violating Office of Drug Control regulations; and

WHEREAS, under current New Jersey law, a physician may issue a paper or electronic prescription for a schedule II CDS in a quantity that does not exceed a 30-day supply, although a physician may issue multiple prescriptions for up to a 90-day supply if the physician determines there is no undue risk of diversion or abuse, and each separate prescription indicates the earliest date the pharmacy may fill each prescription; and

WHEREAS, although many prescribers continue to conduct patient visits via telemedicine, oral prescribing of schedule II medication is limited to emergency situations, for only a 72-hour supply of medication, with no refills allowed, presenting a potential barrier for patients receiving care by telemedicine who require schedule II CDS prescriptions; and

WHEREAS, many New Jersey prescribers are unable to electronically prescribe CDS, either from their offices or from their homes, such that without modification of existing rules, many patients may be required to go to a physician's office in person to obtain a prescription, or have telemedicine encounters with their physicians every three days to obtain a 72-hour supply; and

WHEREAS, mindful of the current opioid crisis, the Director has determined that any emergency oral authorization for schedule II CDS should be limited to a 30-day supply for the treatment of conditions other than acute pain, and that existing rules should continue to apply for prescribing and dispensing of opioids for treatment of acute pain;

NOW THEREFORE, I, Paul R. Rodríguez, Acting Director of the Division of Consumer Affairs, by virtue of the authority vested in me by P.L. 2020, c. 18, and upon concurrence by the Attorney General, determine that this ORDER is necessary to promote the public welfare and further such other purposes for which the state of emergency and the public health emergency were declared, and hereby ORDER as follows:

1. **N.J.A.C. 13:45H-7.8**, concerning the oral emergency dispensing of schedule II controlled substances, currently allows emergency dispensing of a 72-hour supply upon oral authorization. This provision will be modified so that pharmacists may dispense up to a 30-day supply of a Schedule II controlled substance upon the oral authorization of the prescriber if, in the pharmacist's professional judgment, failure to fill would endanger the health or welfare of the patient. The pharmacist should only dispense the amount adequate to treat the patient during the emergency period. In addition, consistent with waivers issued by the United States Drug Enforcement Administration, follow up paper

prescriptions may be submitted within 15 days, and may be submitted via facsimile. This waiver does NOT apply to "initial" opioid prescriptions for pain; it is only applicable for patients being treated for "chronic" pain. These rules, as modified, (additions indicated in boldface **thus**; deletions indicated in brackets [thus]) shall read:

N.J.A.C. 13:45H-7.8

- a) to c) No change.
- d) In the case of an emergency situation, as defined by the Secretary of the Federal Department of Health and Human Services in 21 CFR 290.10, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:
 - 1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period not to exceed 72 hours <u>for</u> the treatment of acute pain with opioids, or 30 days for treatment of other conditions with controlled substances, to include opioids for the treatment of chronic pain conditions (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner).
 - 2) to 3) No change.
 - 4) Within [seven] **fifteen** days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed (not to exceed the amount for a [72-hour] 30-day period) to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of N.J.A.C. 13:45H-7.4, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the [seven-day] **fifteen-day** period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription, which had earlier been reduced to writing. The pharmacist shall notify the Drug Control Unit and the nearest office of the DEA in his or her district if the prescribing individual practitioner fails to deliver a written prescription to him or her; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense with a written prescription of a prescribing individual practitioner.

e) to g) No change.

This Order shall take effect immediately and shall remain in effect until the end of the state of emergency and the public health emergency declared pursuant to Executive Order No. 103 (EO

Date: September 1, 2020	Paul Rodnigues

Paul R. Rodríguez, Acting Director

103), whichever is later, unless expressly revoked or superseded by a subsequent Administrative Order issued by the Director of the Division of Consumer Affairs.