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January 24, 2014

VIA US MAIL AND FACSIMILE TRANSMISSION (919-715-4645)

Robin Gary Cummings, MD
Deputy Secretary for Health Services
Acting State Health Director
North Carolina Department of Health and Human Services
2001 Mail Service Center
Raleigh, NC 27699-2001

Dear Dr. Cummings:

Thank you for your recommendation of December 19, 2013 that the Board of Pharmacy approve the addition of naloxone to the permitted formulary of drugs that registered nurses are permitted by G.S. § 90-85.34A to dispense at local health departments.


At the Board's January 21, 2014 meeting, the members unanimously approved your recommendation and took the following actions:

1. To ensure that your recommendation can be implemented in local health departments immediately, the Board agreed (pursuant to 21 N.C.A.C. 46.2510) to partially waive enforcement of 21 N.C.A.C. 46.2401 and .2403 to allow registered nurses to begin dispensing naloxone in a manner consistent with G.S. 96-106.2 (the "Good Samaritan/Naloxone" statute) and a standing order submitted to, and reviewed by, the Board at its meeting. A copy of that waiver order is attached.
2. The Board will initiate a permanent rulemaking proceeding amending 21 N.C.A.C. 46.2401 and .2403 to accommodate the approved change in formulary. I anticipate that the

Board will review a set of proposed rule amendments at its February 18, 2014 meeting and will publish them for notice and comment shortly thereafter.

Please feel free to contact me any time with questions about the Board's actions or plans.

Sincerely yours,

A handwritten signature in blue ink, appearing to be "Jay Campbell", is written over the typed name and title. The signature is fluid and stylized, with a large loop at the end.

Jay Campbell
Executive Director

Enclosure

cc: Scott Proescholdbell (via e-mail, scott.proescholdbell@dhhs.nc.gov)
Joy Reed (via e-mail, joy.reed@dhhs.nc.gov)
Chris Hoke (via e-mail, chris.hoke@dhhs.nc.gov)
Matt Kelm (via e-mail, matthew.kelm@duke.edu)
Steve Dedrick (via e-mail, steve_dedrick@unc.edu)

NORTH CAROLINA BOARD OF PHARMACY

In re:)
)
21 N.C.A.C. 46.2510) **ORDER OF THE BOARD**
Partial Waiver of Enforcement of)
21 N.C.A.C. 46.2401 and)
21 N.C.A.C. 46.2403)
)

Pursuant to authority granted by 21 N.C.A.C. 46.2510, the Board of Pharmacy (“Board”) hereby partially waives enforcement of 21 N.C.A.C. 46.2401 and 21 N.C.A.C. 46.2403 as follows:

1. 21 N.C.A.C. 46.2510, promulgated by the Board pursuant to statutory authority, states that “Board may waive the enforcement of specific rules” under certain circumstances.

2. The North Carolina General Assembly has passed, and the Governor has signed into law, G.S. 96-106.2, which provides statutory authority for authorized practitioners to prescribe naloxone, an opioid antagonist medication, to a person at risk of experiencing an opiate-related overdose or to a family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose.

3. G.S. § 90-85.34A, authorizes registered nurses in a local health department to dispense prescription drugs and devices with certain conditions. Among them, the registered nurse may dispense “[o]nly prescription drugs and devices contained in a formulary recommended by the Department of Health and Human Services and approved by the Board.”

4. Acting State Health Director Robin Gary Cummings, M.D., has recommended that naloxone be added to the formulary from which health department registered nurses may dispense.

5. 21 N.C.A.C. 46.2401(a)(1) provides that a “registered nurse employed by a local health department may dispense prescription drugs or devices under the following conditions: (1) Drugs and devices may be dispensed only to health department patients.”

6. 21 N.C.A.C. 46.2401(a)(4) provides that “[o]nly the general categories of drugs or devices listed in Rule .2403 may be dispensed by a health department registered nurse.” Neither naloxone specifically, nor opioid antagonist medications generally, are among the prescription drugs that may be dispensed pursuant to 21 N.C.A.C. 46.2403.

7. The Board partially waives enforcement of 21 N.C.A.C. 46.2401 to allow registered nurses in local health departments to dispense naloxone to a health department patient or to others as permitted by G.S. 90-106.2.

8. The Board partially waives enforcement of 21 N.C.A.C. 46.2403 to allow registered nurses in local health departments to dispense an opioid antagonist prescribed pursuant to G.S. 90-106.2.

9. The Board has determined that a partial enforcement waiver of 21 N.C.A.C. 46.2401 and .2403 will: (i) positively impact the delivery of pharmaceutical care; and (ii) will not compromise patient health and safety. 21 N.C.A.C. 46.2510(1), (2).

10. Any registered nurse at a local health department who chooses to dispense an opioid antagonist medication pursuant to this partial waiver of enforcement shall conform to the policies and procedures set forth in a naloxone standing order submitted to, and reviewed by, the Board on January 21, 2014. 21 N.C.A.C. 46.2510(3).

11. The partial enforcement waiver of 21 N.C.A.C. 46.2401 and .2403 is subject to continuing study by the Board. 21 N.C.A.C. 46.2510(4). The waiver shall continue until such time as the Board either promulgates amendments to 21 N.C.A.C. 46.2401 and .2403, or Board determines, after appropriate notice and hearing, that continuation of the waiver would no longer meet the standards of 21 N.C.A.C. 46.2510.

This is the 21st day of January, 2014.

NORTH CAROLINA BOARD OF PHARMACY

by:



Jack W. Campbell IV
Executive Director