

The Commonwealth of MassachusettoExecutive Office of Health and Human ServicMARYLOU SUDDERS
SecretaryDepartment of Public Health
Bureau of Health Professions LicensureMARYLOU SUDDERS
Secretary239 Causeway Street, Suite 500, Boston, MA 02114

CHARLES D. BAKER Governor KARYN E. POLITO Lieutenant Governor Tel: 617-973-0800 TTY : 617-973-0988 www.mass.gov/dph/boards

The Board of Registration in Pharmacy

Policy No. 2018-04: Naloxone Dispensing via Standing Order

On August 9, 2018, Governor Baker signed into law chapter 208 of the acts of 2018, *An Act for Prevention and Access to Appropriate Care and Treatment of Addiction.* The law makes important strides in our work as a state to combat the opioid epidemic, including thorough updates to M.G.L. c. 94C section 19B to expand access to naloxone through a statewide standing order for this life-saving medication. The statewide standing order preserves the ability of pharmacies to dispense the opioid antagonist without a prescription to any person at risk of experiencing an opioid-related overdose, as well as by family members, friends or other persons in a position to assist individuals at risk of experiencing an opioid-related overdose, while lifting the current requirement that each pharmacy in the Commonwealth have its own pharmacy-specific standing order for dispensing naloxone.

In the face of this ongoing opioid crisis, the Board, through collaboration with the Department of Public Health's Bureau of Substance Addiction Services, has determined that, compared to the national average, all areas of Massachusetts experience high incidences of opioid-related overdoses or deaths thereby requiring all pharmacies to stock naloxone in accordance with M.G.L. c. 94C section 19C.

All retail pharmacies located in Massachusetts and licensed by the Board of Pharmacy must maintain a continuous, sufficient supply of naloxone rescue kits, or other approved opioid antagonist medication, to meet the needs of the community. Additionally, as required by M.G.L. c. 94C section 19B, each pharmacy must annually report the number of naloxone doses dispensed.

There is no limit to the amount of naloxone that may be dispensed to an individual. Massachusetts state law specifically allows for an individual to obtain naloxone with the intention to administer it to another person. <u>A pharmacy may dispense naloxone either</u> <u>pursuant to a patient-specific prescription or via the statewide standing order.</u>

A copy of the statewide standing order is attached to this Policy.

Dispensing Naloxone:

Naloxone should be dispensed in accordance with the following protocol:

- Naloxone rescue kits must be labeled with the expiration date of the included naloxone unit.
- In place of the name and address, "Naloxone Rescue Kit," may be used to create a patient profile and prescription label.
- The pharmacy must counsel the individual and distribute an Opioid Antagonist Information Pamphlet such as the ones found here:
 - <u>https://www.getnaloxonenow.org/INFO-ON-HOW-TO-ADMINISTER-</u> <u>NALOXONE.pdf</u>
 - o <u>https://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/responding-to-opioid-overdose/call-for-help/</u>
- In accordance with the Massachusetts Controlled Substances Act, unless the purchaser requests otherwise, the pharmacy must make a reasonable effort to determine if the purchaser's insurance covers naloxone.
- When an individual presents to the pharmacy to obtain naloxone, the order should be processed under the statewide standing order.
- For insurance billing and cost-sharing purposes, the pharmacy must treat the transaction as the dispensing of a prescription to the person purchasing naloxone.
- Annually, by January 15th, each pharmacy must submit a report via email to <u>naloxonestandingorders@MassMail.State.MA.US</u>, including the following information for the previous calendar year:
 - The name and zip code of the pharmacy;
 - The total number of naloxone <u>doses</u> (not prescriptions or manufacturersupplied units) dispensed; and
 - The total number of those doses paid for with insurance.

While not required, the Board encourages pharmacies to also submit information for <u>each dispensing event</u> that includes the following:

- The number of doses dispensed;
- The date dispensed;
- The zip code of residence for the individual to whom the naloxone is dispensed; and
- Whether the naloxone was paid for with insurance.
- The pharmacy should consider advertisements or signage to inform the public that naloxone kits are available.

Standing Order for Dispensing Naloxone Rescue Kits

This standing order is issued pursuant to M.G.L. c. 94C, § 19B, as amended by section 32 of chapter 208 of the acts of 2018, An Act for Prevention and Access to Appropriate Care and Treatment of Addiction, which expands access to naloxone through a statewide standing order, rather than requiring each pharmacy to secure and file one individually. This standing order authorizes licensed pharmacists to dispense naloxone rescue kits to a person at risk of experiencing an opioid-related overdose, family member, friend or other person in a position to assist a person at risk of experiencing an opioid-related overdose.

Chapter 208 protects the physician signing the statewide order, and all practitioners prescribing or dispensing naloxone from criminal or civil liability or any professional disciplinary action. (M.G.L. c. 94C, § 19B(f)) In addition to the immunity established under M.G.L. c. 94C, § 34A, chapter 208 also provides criminal and civil immunity for anyone, acting in good faith, who administers an opioid antagonist to an individual appearing to experience an opioid-related overdose. (M.G.L. c. 94C, § 19B(g))

For intranasal administration:

Naloxone 4mg/0.1mL nasal spray

Dispense 2 doses.

Directions for use: Administer a single spray of naloxone in one nostril. Repeat after 3 minutes if no or minimal response.

OR

Naloxone 2mg/2mL single-dose Luer-Jet prefilled syringe

Dispense 2 doses.

Include one luer-lock mucosal atomization device (MAD 300) per dose dispensed. Directions for use: Spray 1 mL in each nostril. Repeat after 3 minutes if no or minimal response.

For intramuscular injection:

Naloxone 0.4mg/mL in 1mL single dose vials

Dispense 2 doses.

Include one 3cc, 25 gauge, 1" syringe per dose dispensed.

Directions for use: Inject 1 mL IM in shoulder or thigh. Repeat after 3 minutes if no or minimal response.

OR

- Naloxone 2mg/0.4mL auto-injector Dispense 2 doses.
- Directions for use: Follow audio instructions from device. Place on thigh and inject 0.4 mL. Repeat after 3minutes if no or minimal response.

October 4, 2018 Date

Alexander Y. Walley, MD, MSc

MA 221133

Physician's Name and MA License No. (print legibly)