



Department of Health

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Executive Deputy Commissioner

November 10, 2016

Dear Colleague:

This letter is in follow-up to the November 4, 2016 communication regarding the Teleflex Medical recall of specific lots of the MAD300 mucosal atomization device. This device is used by opioid overdose prevention programs in New York State.

As advised by Teleflex, the affected devices do not consistently provide an atomized spray, but may instead produce a straight stream. This defect may compromise absorption of naloxone resulting in possible under-dosing. Unfortunately, Teleflex Medical has indicated that it has a manufacturer's backorder on the new devices and it is unclear how long it will take to provide them. The New York State Department of Health (Department) will continue to provide information about available sources of naloxone, as information becomes available.

Affected devices that have not yet been distributed to responders should be handled as directed by the pharmaceutical distributors that shipped the devices. The Department continues to work to determine the number of recalled devices in stock at the Department's registered Overdose Prevention Programs. If you represent a registered program and have not already responded to a survey link distributed by the Department to registered programs, please do so immediately. The survey can be found here: <https://www.surveymonkey.com/r/69XNKDS>.

This letter is intended to provide additional guidance on how your program should address devices already in the community among trained responders. Registered programs should communicate with responders who have received devices since January 2016 to advise them of this recall and the risk of under dosing. Responders should be advised to examine the clear plastic bag in which the white, cone-shaped devices are packaged, and identify the lot number which appears on the bag. If the device does not have a number corresponding to one on the recall list, the device is not subject to the recall. For ease of reference, the recall notification is attached along with a listing of the affected lot numbers.

If your registered program or facility does identify MAD300 devices subject to the recall, your registered program or facility's clinical director should assess how best to proceed. The clinical director may make a determination for specific responders, or sets of responders, that naloxone immediately needs to be in place even if the only available supply are kits subject to the recall. For example, individuals who have previously administered naloxone are at elevated risk of encountering a subsequent overdose situation. Also, persons who are known to use opioids need continuous access to naloxone. In these circumstances, responders should be aware of the potential for under-dosing if a MAD300 device is used. Programs can consider training responders on intramuscular (IM) naloxone administration.

Over 2,000 pharmacies in NYS have non-patient specific prescriptions (standing orders) in place to dispense naloxone. This means that the responder does not need a health care practitioner's prescription to get naloxone at these pharmacies. In addition, all pharmacies can dispense naloxone with an order from an individual's health care practitioner. Medicaid and many private insurance plans are now covering naloxone and naloxone kits can be purchased by individuals. The directory of pharmacies with standing medical orders to dispense naloxone can be found at: www.health.ny.gov/overdose. There are various formulations of naloxone that may be available at these pharmacies, including the generic intramuscular, the Evzio[®] auto-injector, and the Narcan[®] nasal spray.

Thank you for your commitment to naloxone distribution to save lives through overdose prevention. The Department is working to restore naloxone nasal spray availability for registered programs and will make information known as it becomes available. If you have any clinical questions please contact Sharon Stancliff, MD at stancliff@harmreduction.org. For non-clinical questions, please contact Mark Hammer, Director of the Opioid Overdose Prevention Program at the AIDS Institute at mark.hammer@health.ny.gov.

Thank you for your patience.

Sincerely,

Joanne Morne

Johanne Morne, MS
Director
AIDS Institute

Sharon Stancliff

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Harm Reduction Coalition