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ADVISORY

DCP Regulations and Over-The-Counter Naloxone

This Advisory is directed to persons wishing to purchase, store or otherwise work with Naloxone, to clarify how the regulations of the Drug Control Program apply to such activities. **The regulations of the Drug Control Program do not apply to activities regarding Over-the-Counter (OTC) Naloxone. The regulations of the Drug Control Program do apply to activities regarding Prescription Naloxone.**¹

The Food and Drug Administration (FDA) has approved OTC Naloxone to be sold over the counter (OTC).² Naloxone also continues to be available by prescription. Therefore, Naloxone is currently available both as an OTC medication (OTC Naloxone), and as a medication which cannot be dispensed without a prescription or standing order (Prescription Naloxone).

OTC Naloxone and Prescription Naloxone are separate and distinct products, and different laws and regulations apply to each. These products can be identified by reference to their packaging.

- OTC Naloxone is sold in FDA approved packaging for OTC medications.³
- Prescription Naloxone is sold in FDA approved packaging which states that federal law prohibits dispensing without prescription.⁴

A Massachusetts Controlled Substance Registration (MCSR) is not required for activities regarding OTC Naloxone.

Questions regarding this Advisory should be emailed to the Drug Control Program at: dcp.dph@mass.gov.

¹ The regulations of the Drug Control Program are: 105 CMR 700.000 *Implementation of M.G.L. c. 94C*; 105 CMR 721.000: *Standards For Prescription Format And Security In Massachusetts*; 105 CMR 722: *Dispensing Procedures For Clinic And Hospital Pharmacies*; and 105 CMR 970.000: *Pharmaceutical And Medical Device Manufacturer Conduct*.

² On March 29th, 2023, the FDA approved a 4-mg intranasal naloxone formulation (Narcan, Emergent Biosolutions) for over the counter (OTC) sale. A generic version of the 4-mg product (Padagis, Padagis) and a 3-mg intranasal branded formulation of naloxone (RiVive, Harm Reduction Therapeutics) were both approved in July 2023. OTC Naloxone has been available for retailers to sell since September 2023.

³ See, e.g., FDA circular re OTC packaging:
<https://web.archive.org/web/20150511183425/http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/UCM285993.pdf>

⁴ 105 CMR 700.001 (Definitions)