The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure
250 Washington Street, Boston, MA 02108-4619

Tel: 617-973-0800
TTY : 617-973-0988
www.mass.gov/dph/boards

Board of Registration in Pharmacy

Advisory: Compounded Ketamine Nasal Spray

Spravato® (esketamine) is an FDA approved, commercially available nasal spray that is only available through a restricted distribution system and is subject to a Risk Evaluation and Mitigation Strategy ("REMS") program due to the risks for sedation, dissociation, and abuse and misuse. The REMS program, which requires enrollment by the health care facility, pharmacy, and patient, specifies that the medication must be self-administered by the patient in a certified medical office or clinic where the health care provider can monitor the patient during and after each use. The REMS also prohibits the medication from being dispensed directly to, or taken home by, the patient.

The Massachusetts Board of Registration in Pharmacy ("Board") has recently become aware that several pharmacies in the Commonwealth have been compounding ketamine nasal spray. Unlike Spravato®, which contains only the S isomer of ketamine, the compounded formulations are made from racemic ketamine and therefore contain both the R and S isomers. These compounded formulations are not FDA approved, nor are they compliant with any REMS program or related requirements.

The Board has undertaken investigative efforts to consider whether the practice of compounding ketamine nasal spray should be allowed to continue, either unrestricted or subject to some restrictions and/or guidance by the Board, or if the practice should be discontinued in the Commonwealth.

The Board felt it necessary to undertake these steps to balance patient access to necessary treatment with that of patient safety.

The FDA previously issued an alert to health care professionals regarding the potential risks associated with compounded ketamine nasal spray, however, FDA took no action to prevent the compounding of ketamine nasal spray. **Similarly, this Board will take *no* action to prevent the continued compounding and dispensing of ketamine nasal spray.**

The Board endorses the FDA alert on compounded ketamine nasal spray and recommends pharmacies and/or pharmacists engaging in the compounding and dispensing of compounded ketamine nasal spray adhere to the following:

1. Evaluate each prescription for compounded ketamine nasal spray in accordance with best practices and the pharmacist's corresponding responsibility as outlined in MGL c. 94C.

2. Adhere to all applicable federal and state laws, statutes, and regulations including but not limited to M.G.L. c. 94C § 21A (*Prescriptions: prospective drug review and counseling by pharmacist*) and 105 CMR 700.012 (*Prescription Monitoring Program*).

3. Evaluate each prescription for compounded ketamine nasal spray for adherence with evidence-based practice utilizing sound medical judgment and ensure that the compounding and dispensing are done in accordance with the acceptable standards of care.

4. As with all compounded prescriptions, compounding of ketamine nasal spray must be done in accordance with all applicable federal and state laws, statutes, and regulations including but not limited to USP <795>, M.G.L. c. 112 § 39D, and Section 503A of the Federal Food, Drug, and Cosmetic Act.

5. Maintain documentation evidencing compliance with the above.

Please note, these recommendations are for ***all*** compounded ketamine nasal spray prescriptions including for patients who have been maintained on compounded ketamine nasal spray, dose adjustments and/or changes, and for patients being newly started.

Please direct any questions to: **Pharmacy.Admin@mass.gov**