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Board of Registration in Pharmacy

Advisory: Compounded Ketamine

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") became aware that several pharmacies in the Commonwealth were engaging in the practice of compounding ketamine nasal spray, as well as other formulations including oral formulations. 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 undertook 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.

In February 2022, the FDA 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.

In October 2023, the FDA issued a further alert to health care professionals regarding ***all*** compounded ketamine products, including oral formulations, for the treatment of psychiatric disorders. Once again, the FDA took no action to prevent the compounding of ketamine products.

Similarly, this Board will take *no* action to prevent the continued compounding and dispensing of ketamine products.

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

1. Evaluate each prescription for compounded ketamine 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 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, the compounding of ketamine 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 products including for patients who have been maintained on compounded ketamine, dose adjustments and/or changes, and for patients being newly started.

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