



**U. S. Department of Justice**  
Drug Enforcement Administration  
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*www.dea.gov*

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Janssen Pharmaceuticals, Inc.  
1125 Trenton-Harbourton Road  
Titusville, New Jersey 08560  
[REDACTED]

This is in response to your letter dated October 8, 2018, to the Drug Enforcement Administration (DEA) in which you requested DEA's permission for specialty pharmacies, selected by Janssen Pharmaceuticals, Inc., to deliver patient-specific esketamine nasal spray directly to prescribing practitioners who do not have co-located pharmacies. The DEA appreciates the opportunity to address your request.

As you know, as a general matter, the DEA cannot provide individuals with definitive, private legal opinions about whether their particular activities relating to controlled substances comply with the requirements of the Controlled Substances Act (CSA) and DEA regulations. Among the reasons for this is that such letters cannot establish a rule that is legally binding on the recipient or the agency. At the same time, the DEA recognizes the importance of working with regulated entities to help guide them toward compliance with the law and regulations. In that vein, we can provide the following general information.

For purposes of this letter, we will address the following hypothetical scenario:

- A DEA-registered practitioner, acting in the usual course of his/her professional practice, issues a prescription for a controlled substance for a legitimate medical purpose, and the prescription complies in all other respects with DEA regulations found in 21 C.F.R. Part 1306.
- The practitioner determines, in the exercise of his/her sound medical discretion, that it is appropriate for the patient to self-administer the controlled substance while under the direct supervision of the practitioner at the practitioner's registered location.
- The prescription is for a single dose of the controlled substance for a particular patient - not a take-home supply for that patient and not for the practitioner's office stock.
- The practitioner indicates on the prescription that the controlled substance should be delivered by the pharmacy to the practitioner, at his/her registered location, for administration to the patient.
- The above activity is carried out in compliance with applicable State law and regulations.

- The controlled substance is to be administered only to the patient named on the prescription not later than 14 days after the date of receipt of the controlled substance by the practitioner.

Neither the CSA nor DEA regulations specifically address the foregoing scenario. Nonetheless, assuming all the foregoing facts apply, the DEA would consider it permissible under the CSA and DEA regulations for the pharmacy to deliver the controlled substance to the practitioner, at his/her registered location, provided the following conditions are met:

- The pharmacy treats its actions as a dispensing for purposes of the CSA and DEA regulations and complies with all applicable requirements thereunder. This includes, but is not limited to, keeping records pursuant to 21 C.F.R. Part 1304 indicating that the controlled substance was delivered to the practitioner and including the practitioner's name and address of the registered location to which it was delivered.
- The supervising practitioner treats his/her actions as administering for purposes of the CSA and DEA regulations and complies with all applicable requirements thereunder. This includes, but is not limited to, keeping records, to the extent required for the administering of controlled substances under 21 C.F.R. Part 1304, and maintaining security as required by the regulations in 21 C.F.R. §§ 1301.71(a) and 1301.75(b).

Finally, please be advised that while this letter represents the current view of the DEA, it is not a binding rule. The DEA is continuing to evaluate the issues related to your inquiry to determine whether it would be appropriate for the agency to propose an amendment to its regulations to specifically address this topic.

For further information regarding the DEA Diversion Control Division, please visit [www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov). If you have any additional questions on this issue, please contact the Diversion Control Division Policy Section at (202) 307-7297.

Sincerely,



Keith Brown  
Deputy Assistant Administrator  
Diversion Control Division