



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

David G. Miller, R. Ph.
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International Academy of Compounding
Pharmacists
4638 Riverstone Boulevard
Missouri City, Texas 77459

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Dear Mr. Miller:

This correspondence is in response to your letter dated August 31, 2011, to the Drug Enforcement Administration (DEA) on behalf of officers and members of the International Academy of Compounding Pharmacists. Please accept DEA's apology for the delay in responding to your inquiry. You asked for clarification and guidance on the appropriate completion of a DEA Form 222. You stated that due to increasing shortages and backorders of FDA-approved products, pharmacists are being asked by hospitals and institutions to prepare and supply compounded versions of those products pursuant to a prescription or medical order. It is your belief that the DEA Form 222 requires the transferring registrant pharmacy to include on the executed DEA Form 222 the National Drug Code (NDC) number of each schedule II product distributed. However, you noted that NDC codes do not exist for the final compounded preparation as each one is unique to the prescription or medical order issued by a DEA registered prescriber. You asked how, given this situation, a pharmacy can complete the NDC section of the DEA Form 222. DEA has concerns regarding your inquiry since it seems that your basic premise regarding what a retail pharmacy can do is based on misinformation. DEA provides the following information regarding these concerns.

A DEA registered retail pharmacy may compound a controlled substance without being required to obtain a separate DEA registration as a manufacturer **only** if the requested compounded product is dispensed to the ultimate user (e.g. patient) pursuant to a valid patient specific prescription. The term *ultimate user* is defined as "a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household. . . ." 21 U.S.C. § 802(27). The term "ultimate user" does not include the practitioner, researcher, or other healthcare provider that ordered the controlled substance be dispensed. Compounding a controlled substance other than pursuant to a valid patient-specific prescription or medical order, is manufacturing, and a pharmacy that wishes to distribute a compounded controlled substance would first need to obtain a DEA registration as a manufacturer. Title 21 U.S.C. § 802(15) defines the term *manufacture* as meaning "the production, preparation, propagation, **compounding** [emphasis added], or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of its container; except that such term does not include the preparation, **compounding** [emphasis added], packaging or labeling of a drug or other

substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice.” The term *distribute* means “to deliver (other than by administering or dispensing) a controlled substance or listed chemical.” 21 U.S.C. § 802(11). The term *dispense* means to “deliver a controlled substance to an ultimate user ...pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or **compounding** [emphasis added] necessary to prepare the substance for such delivery.” 21 U.S.C. § 802(10).

In light of the information you provided in your letter, you asked the following question.

“In order to be fully compliant with the Controlled Substances Act as well as DEA regulations, how should a pharmacy complete the DEA Form 222 to correctly record a transfer of a compounded preparation which includes a schedule II active ingredient to another DEA registrant?”

A retail pharmacy has **no** authority to *distribute* a compounded controlled substance. Consequently, a pharmacy would not be distributing a compounded controlled substance in response to a DEA Form 222. A hospital pharmacy may compound a controlled substance pursuant to a medical order in the hospital setting without being registered as a manufacturer for patients in the hospital. However, a hospital pharmacy has **no** authority to distribute a compounded controlled substance. Consequently, a hospital pharmacy would not be distributing a compounded controlled substance in response to a DEA Form 222. Therefore, the direct answer to your question would be that neither a retail pharmacy, nor a hospital pharmacy, would have need to record a transfer of a compounded controlled substance via a DEA Form 222 to another registrant since they have no authority to carry out such activity.

Manufacturers of compounded controlled substances may, as a coincidental activity of their registration, transfer the controlled substances they “manufacture” via DEA Form 222, or the electronic equivalent, to other requesting DEA registrants. A DEA registration as a manufacturer requires corresponding security, inventories, recordkeeping, and reporting.

You may obtain additional information regarding the Office of Diversion Control at www.DEAdiversion.usdoj.gov. You can also find on this website an electronic copy of the aforementioned statutes, as well as the procedure by which to apply for registration as a manufacturer. If you have further questions, please contact the DEA’s Houston Field Division Office at (713) 693-3670 or the Liaison and Policy Section at (202) 307-4654.

Sincerely,



John W. Partridge, Chief
Liaison and Policy Section
Office of Diversion Control