

U. S. Department of Justice Drug Enforcement Administration 8701 Morrissette Drive Springfield, Virginia 22152

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OCT 0 6 2017

Kevin N. Nicholson, R.Ph., J.D. Vice President Public Policy and Regulatory Affairs National Association of Chain Drug Stores 1776 Wilson Boulevard, Suite 200 Arlington, Virginia 22209

Dear Mr. Nicholson:

This is in response to your letter dated May 26, 2017, to the Drug Enforcement Administration (DEA) regarding information that DEA provided at the April 6, 2017, Controlled Substance Stakeholder Coalition meeting about transferring unfilled prescriptions. Please accept DEA's apology for the delay in providing a written response to your inquiry.

You requested guidance on how a pharmacy should handle unfilled prescriptions for controlled substances in schedules II-V that cannot be filled for any reason. Whether a prescription can be transferred from one pharmacy to another depends on the form of the prescription (paper (including facsimile), oral (call-in), or electronic) and the schedule of the controlled substance prescribed. For purposes of this letter, we refer to prescriptions for controlled substances that conform with all DEA regulations relating to electronic prescriptions (21 C.F.R. Part 1311, Subpart C) as "EPCS." Additionally, please note that while you referred to "forwarding" and "forward" in your letter, we have used "transfer" and "transferring" as those are the terms in the relevant DEA regulation (21 C.F.R. § 1306.25).

• Transferring unfilled schedule II-V EPCS :

DEA understands the interest in being able to transfer from one pharmacy to another an unfilled EPCS for a schedule II-V controlled substance. DEA regulations do not specifically allow for the transfer of unfilled schedule II prescriptions in any form, and only specifically allow for the transfer of original information from schedule III-V prescriptions in any form for purposes of refill only. However, it is DEA's current policy that any **unfilled** EPCS for a schedule II-V controlled substance may be transferred to another pharmacy.

• Transferring unfilled schedule III-V prescriptions received in the form of paper (including fax) and oral (call-in):

In your letter, you indicated that various State Boards of Pharmacy have different interpretations of 21 C.F.R. § 1306.25(a). That regulation states, "The transfer of original prescription information for a controlled substance listed in Schedule III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization." This regulation accurately states DEA's position -- that it is not permissible to transfer any original

unfilled prescription received in <u>paper (including fax) or oral form</u> to another pharmacy; however, <u>after</u> the original prescription is filled, the <u>refills</u> may be transferred, subject to the conditions of 21 C.F.R. § 1306.25.

In your letter you also asked for guidance regarding "the transfer of unfilled paper, fax, and oral prescriptions in Schedules III-V that have been entered into an electronic database." Entering an unfilled paper (including fax) or oral prescription into an electronic database does not change the prescription into an EPCS. Such a prescription remains subject to all the regulations applicable to paper, fax, or oral prescriptions. Therefore, pharmacies may not transfer such an unfilled prescription to another pharmacy.

DEA appreciates your concern regarding the possible diversion of unfilled original paper and oral prescriptions for schedule III-V controlled substances that a pharmacy is not allowed to transfer. However, please bear in mind that DEA regulations do not prohibit a pharmacy from returning a paper controlled substance prescription to the ultimate user, mailing the prescription back to the issuing prescriber, or calling the issuing prescriber. As to your concern of there being two "active" prescriptions, 21 C.F.R. § 1306.25(b)(1) requires that the transfer of prescription information for schedule III-V controlled substances for refill purposes be communicated directly between two licensed pharmacists. In addition, both the transferring pharmacist and the receiving pharmacist are required to provide and record specific information regarding the transfer, including, but not limited to, writing the word "VOID" on the face of the invalidated prescription, which serves to prevent the existence of two "active" prescriptions. 21 C.F.R. § 1306.25(b)(2)-(5).

We trust this letter adequately addresses your inquiry. If you have additional questions on this issue, please contact the Diversion Control Division Liaison and Policy Section at (202) 307-7297.

Sincerely,

James Arnold, Chief Viaison and Policy Section

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