

May 26, 2017

Ms. Demetra Ashley  
Deputy Assistant Administrator  
Diversion Control Division  
U.S. Drug Enforcement Administration  
8701 Morrissette Drive  
Springfield, VA 22152

Dear Ms. Ashley:

We are writing to follow up from your presentation at the April 6, 2017 Controlled Substance Stakeholder Coalition hosted by the National Association of Boards of Pharmacy in Chicago. At the meeting, you announced new guidance that a pharmacy may transfer electronically to another pharmacy an unfilled, electronic, Schedule II prescription that the pharmacy is not able to fill for any reason. You further stated that this guidance does not apply to situations in which a paper or oral prescription has been entered into a pharmacy computer system and that a pharmacy may only transfer refills of paper or oral controlled substance prescriptions—not original, unfilled prescriptions. Finally, you mentioned that DEA will follow up with written information concerning this guidance so that NABP may disseminate it to state boards of pharmacy.

The National Association of Chain Drug Stores (NACDS) represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate 40,000 pharmacies, and NACDS' more than 100 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.2 million individuals, including 178,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 850 supplier partners and over 60 international members representing 21 countries. Please visit [nacds.org](http://nacds.org).

We very much appreciate DEA's willingness to provide guidance on the issue of how a pharmacy should handle unfilled prescriptions for controlled substances in schedules II, III, IV & V that they are unable to fill for any reason. We would like to share our perspectives as DEA drafts written guidance on these matters. We provide more specific details below, addressing our concerns for both electronic and non-electronic prescriptions.

#### **Forwarding Unfilled Electronic Schedule II Prescriptions**

DEA first provided guidance that a pharmacy may *forward* an unfilled prescription in an email to NACDS dated May 20, 2015. DEA reiterated this policy in subsequent

emails dated on May 27, 2015 and March 28, 2016. We believe that DEA provided the most rational solution in these emails that stated the policy that a pharmacy may *forward* an unfilled prescription for a Schedule II controlled substance to another pharmacy, as opposed to “transfer,” as current DEA and state regulations only speak to “transfers” in the context of a Schedule III-V prescription.

### **Transferring Unfilled Paper, Fax and Oral Schedule III-V Prescriptions**

Due to varying regulations and conflicting advice from State Boards of Pharmacy, we believe the policy guidance should also address the transfer of unfilled paper, fax and oral prescriptions in Schedules III-V that have been entered into an electronic database. Some State Boards of Pharmacy currently interpret 21 C.F.R. 1306.25(a) to mean that a Schedule III-V prescription can only be transferred after it has been filled one time, and that an unfilled prescription cannot be transferred. However, in the 2010 *Federal Register* notice that addressed changes in regulations for electronic prescriptions, one commenter requested guidance on the transfer of original Schedule III-V prescriptions that had not been filled.<sup>1</sup> DEA’s response to this commenter was that “existing requirements for transfers . . . remain unchanged,” and that it “currently permits the transfer of original prescription information for a prescription in Schedules III, IV, and V on a one time basis.”<sup>2</sup> Presumably, DEA was referring to “existing requirements” for transfers that were in place prior to the addition of requirements addressing electronic prescriptions or, in other words, requirements that applied to paper, fax, and oral Schedule III-V prescriptions.

Our reading of 21 C.F.R. 1306.25(a) and the corresponding comments in the *Federal Register* is that a pharmacy is allowed to transfer a paper, fax, or oral schedule III-V prescription for a controlled substance that has not been filled to another pharmacy in accordance with existing transfer requirements. If a pharmacy is not allowed to transfer a prescription for a schedule III-V controlled substance unless it has been filled once, a patient would then need to request a second prescription from the prescriber. From a diversion control perspective, it seems that not allowing transfers of unfilled prescriptions for schedule III-V controlled substances would foster diversion and abuse as the patient would have two active prescriptions—one still unfilled at the first pharmacy and one filled at the second pharmacy. Therefore, we ask that DEA provide guidance to clarify its interpretation of this regulation.

### **Prescription Transfer Regulations**

DEA has provided statements in *Federal Register* notices regarding whether a pharmacy may transfer original unfilled electronic prescriptions to another pharmacy.<sup>3</sup> We support DEA’s intent of allowing a pharmacy to address patient needs in a timely manner in these *Federal Register* statements. However, we believe

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<sup>1</sup> *Federal Register*, Vol. 75, No. 61, March 31, 2010, at 16268.

<sup>2</sup> *Id.*

<sup>3</sup> *Federal Register*, Vol. 73, No. 125, June 27, 2008, at 36750; and Vol. 75, No. 61, March 31, 2010, at 16268.

that relying on DEA transfer regulations may leave unresolved problems. For example, the regulations require the recording of “date of original dispensing,” which would not exist for unfilled prescriptions. Therefore, we ask DEA to clarify that the “date of original dispensing” is required only if the prescription has been filled one time.

**Conclusion**

In conclusion, we urge DEA to issue new written guidance, similar to the guidance provided at the Controlled Substance Stakeholder Coalition, concerning situations in which a pharmacy is not able to fill a controlled substance prescription. However, we ask that DEA provide pursuant to the guidance that a pharmacy may *forward* an unfilled Schedule II prescription as opposed to “transfer.”

Moreover, we ask that DEA confirm that a pharmacy is allowed to transfer a paper, fax, or oral schedule III-V prescription for a controlled substance that has been entered into an electronic database, but has not yet been filled, to another pharmacy in accordance with existing transfer requirements. This solution would allow for the timely delivery of patient care in a manner that best minimizes opportunities for diversion and abuse.

Sincerely,



Kevin N. Nicholson, R.Ph., J.D.  
Vice President  
Public Policy and Regulatory Affairs