NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

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NCPA NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

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Dear Messrs. Brown and Miller:

Re: Follow up from June 21 Meeting Regarding Partial Filling of Schedule II Prescriptions

Thank you for the opportunity to meet with you and the DEA Diversion Control team on June 21 to discuss issues of mutual interest and concern. We appreciated the opportunity to receive updates on relevant DEA policy matters and upcoming guidance and regulations.

We wish to follow up from our discussion of DEA policies concerning the partial filling of Schedule II controlled substance prescriptions. DEA advised us at the June 21 meeting that for a situation wherein a health plan insurer has coverage limitations for the quantity or day supply of a Schedule II prescription medication, DEA's interpretation is that patients are initiating the partial fill if they opt to take a lesser quantity or day supply due to the insurance coverage limitations. Moreover, DEA indicated that such a situation would comply with the provision under Section 702 of the *Comprehensive Addiction and Recovery Act (CARA)* that allows for the partial fill of a controlled substance prescription in Schedule II if so requested by the patient.[1] In addition, pharmacists are trying to respond to these requests and restrictions in accordance to relevant state and federal laws and regulations. We appreciate DEA's prompt response to this inquiry and ask for further clarification and written guidance for all dispensing limitation situations to ensure standardization in execution and the intended patient safety outcomes.

[1] Under language enacted in the Comprehensive Addiction and Recovery Act of 2016, 21 USC 829(f) specifies that a pharmacist may "partially fill" a controlled substance prescription "if … the partial fill is requested by the patient or the practitioner that wrote the prescription." Additional language under 21 CFR 1306.13 specifies that a "partial fill" of a schedule II prescription "is permissible if the pharmacist is unable to supply the full quantity called for in a … prescription…"

Specifically, we ask DEA to provide clarification and written guidance addressing the following three situations:

- Situation (1): a partial fill is initiated as a result of a health plan insurer's plan benefit rules;
- Situation (2): a partial fill is initiated as a result of state/local law or regulation limits on the quantity or day supply of a Schedule II controlled substance prescription that may be prescribed; and
- Situation (3): a partial fill is initiated when a patient chooses a pharmacy that has a policy limiting the day supply or quantity of a Schedule II controlled substance that the pharmacy will dispense.

It is important to note that pharmacy providers may not be able to distinguish between a health plan insurer's dispensing limitation initiated by the health plan (situation 1) and a health plan insurer's dispensing limitation initiated by a state/local law or regulation (situation 2).

Please advise whether situations (1), (2), and (3) would be subject to Section 702 of CARA, and if not, whether other federal statute or regulation would be applicable. We ask that DEA provide this guidance in written format to ensure that the policy is clear for all interested parties, including states that are working to update their own laws and regulations.

In addition, we note other proposals (e.g., FDA blister-packaging requirements) may also result in a scenario where the pharmacist may need to dispense an amount different from that amount prescribed. It remains to be seen how DEA will address future partial fill scenarios not contemplated in this letter.

As DEA is aware, policies allowing pharmacists to dispense less than prescribed amounts of opioids serve to reduce opportunities for opioid misuse and abuse. In addition, pharmacies need flexibility to serve their patients' legitimate pain management needs in light of state laws and health plan designs that strictly limit quantities or day supply of opioids in certain situations. Therefore, we urge DEA to update 21 CFR 1306.13 to explicitly recognize a pharmacist's authority to dispense less than prescribed amounts of opioids in situations where a patient or a prescriber requests a partial fill including the situations described herein.[2] However, given that the regulatory process is lengthy and that the need to reduce opioid misuse and abuse is immediate, we ask DEA to provide written guidance in the interim that explicitly clarifies the pharmacist's authority to dispense a partially filled prescription for a schedule II drug in situations described in the above paragraphs.

Related to these matters, there are situations wherein patients opt to receive the full prescribed amount under situation (1) despite the health plan coverage limitation. For example, the patient may opt to pay for the full amount out-of-pocket or may pay out-of-pocket for the portion not covered by the health plan. We ask DEA to clarify through written guidance whether a pharmacist may comply with the patient's request and fill the prescription for the full quantity despite the health plan coverage limitation.

[2] 21 CFR 1306.13 specifically addresses the partial filling of prescriptions.

Moreover, in situations where the patient opts to pay out-of-pocket for the portion not covered by the health plan, pharmacies may need to assign two (or more) different prescription numbers in their pharmacy system to a single prescription. This is because pharmacy and payer systems are designed not to allow refills for Schedule II prescriptions, so when a subsequent (partial) fill is conducted, these systems will assign a new prescription number even though this new prescription number is an incremental fill to the original prescription. The industry has been awaiting an HHS final rule to update technology standards to address this issue. However, until the HHS rule is finalized and can be implemented, which will likely take a few more years, pharmacy seeks guidance from DEA. In regard to this issue, the pharmacy community has received conflicting messages from DEA over the years and is requesting written DEA guidance that a pharmacy may assign two (or more) different prescription numbers to one prescription where necessitated by health plan coverage limitations. We ask DEA to provide written clarification on this issue as well.

Finally, we ask DEA to provide written guidance as to the agency's expectations with respect to the documentation of a partial fill pursuant to situations in which the pharmacist is unable to supply the full quantity called for in the prescription; the documentation of when the partial fill is requested pursuant to the provisions of CARA, that is, when a prescriber or patient request the partial fill; and when a partial fill is the result of situations (1), (2), and (3) above, that is, (1) pursuant to a health plan insurer's plan benefit rules, (2) the result of state/local law or regulation limits on the quantity or day supply of a Schedule II controlled substance prescription that may be prescribed, and (3) when a patient chooses a pharmacy that has a policy limiting the day supply or quantity of a Schedule II controlled substance that the pharmacy will dispense.

In sum, we are requesting written DEA guidance for the following:

- Whether situations (1), (2), and (3) would be subject to Section 702 of CARA, and if not, whether other federal statute or regulation would be applicable;
- Whether a pharmacist may comply with a patient's request to fill a controlled substance prescription for the full quantity despite a health plan coverage limitation;
- Whether pharmacies may assign two (or more) different prescription numbers in their pharmacy system to a single prescription;
- DEA's expectations with respect to the documentation of a partial fill pursuant to situations in which the pharmacist is unable to supply the full quantity called for in the prescription; the documentation of when the partial fill is requested pursuant to the provisions of CARA, that is, when a prescriber or patient request the partial fill; and when a partial fill is the result of situations (1), (2), and (3) above.

Thank you for your attention to these issues. We look forward to DEA's response to these questions and, more generally, partial fill regulations based on patient and prescriber requests.

Sincerely,

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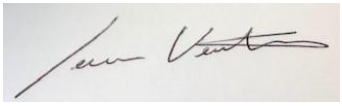

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