NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

February 2, 2021

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Regulatory Drafting and Policy Section
Diversion Control Division
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

Submitted via www.regulations.gov

Re: RIN 1117–AB45; Docket No. DEA–469; Partial Filling of Prescriptions for Schedule II Controlled Substances

Dear Mr. Brinks:

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to share our comments with the Drug Enforcement Administration on the notice of proposed rulemaking (NPRM) for partial filling of prescriptions for Schedule II controlled substances. We appreciate the agency considering our feedback on this matter.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 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 900 supplier partners and over 70 international members representing 21 countries.

Given the ongoing opioid epidemic in communities throughout the country – which has only been exacerbated by the COVID-19 public health crisis – the chain pharmacy community is steadfastly committed to policies and practices that serve to curb prescription drug abuse, misuse and diversion. Accordingly, NACDS strongly supports policies that facilitate partial filling of Schedule II prescriptions and those that set quantity or days supply limits for prescribers on opioid prescriptions. Both of these practices can promote careful use of prescription opioids and reduce the quantity of unused controlled substances that might otherwise be diverted or abused.

We commend DEA for moving forward with this rulemaking to align its regulations with recent statutory changes that further encourage partial filling practices for Schedule II prescriptions and that clarify additional issues related to the partial filling of these

medications. However, we have identified a number of issues that warrant further consideration and clarification by DEA before the rule is finalized.

I. PRESCRIPTIONS ISSUED BY PRESCRIBERS THAT MAY EXCEED STATE-MANDATED DAY SUPPLY LIMITS

As noted by DEA in the NPRM preamble, many states have enacted laws placing varying limits on the prescribing of controlled substances, most of which are applicable to first-time opioid prescriptions issued for acute pain. In the rule preamble, DEA states that "CARA provides that partial filling of Schedule II prescriptions is permitted if the prescription is written and filled in accordance with, among other things, State law. 21 U.S.C. 829(f)(1)(B)." DEA interprets a prescription written for a quantity that exceeds the limits of State law to be invalid, and therefore, the prescription may not be filled as written. Because such a prescription is invalid, it also cannot be partially filled as a means of getting around the limits imposed by State law." ***We urge DEA to reconsider this position, as this is inconsistent with existing DEA policy and state laws that address prescribing and dispensing of controlled substances.***

Notably, most if not all states allow a pharmacist to make changes to a Schedule II prescription after consulting with a prescriber. Moreover, DEA current policy states that "DEA expects that when information is missing from or needs to be changed on a Schedule II controlled substance prescription, pharmacists use their professional judgment and knowledge of state and federal laws and policies to decide whether it is appropriate to make changes to that prescription."[1] ***Where controlled substance prescriptions may have been modified following communication between the prescriber and pharmacist, DEA should codify existing DEA policy that aligns with state law and allow for updated prescriptions to be treated as valid authorization to the pharmacist to dispense a lesser quantity in conformance with any state law quantity limits.*** In these instances, pharmacists should be allowed to notate on the prescription or in their recordkeeping system that the quantity prescribed was modified after discussion with the prescriber and a lesser quantity was filled and such notation should be deemed sufficient to comply with DEA regulations.

With respect to recent state laws that establish prescribing limits on certain initial controlled substance prescriptions for acute pain, states took care when enacting these laws to ensure that patients with certain medical conditions would not be subject to the stricter limits applicable to prescriptions issued for acute pain. Moreover, state lawmakers and policymakers further made clear that pharmacists are not required to enforce these

[1] Letter from Joseph T. Rannazzisi to Carmen Catizone; August 24, 2011; available at https://nabp.pharmacy/wp-content/uploads/2016/07/DEA-missing-info-schedule-2.pdf; accessed January 24, 2021.

requirements for prescriptions that are issued in excess of the limits applicable only to certain acute pain prescriptions.

For example, in Arizona and Utah, lawmakers included language in their statutes to make clear pharmacists are not required to enforce the prescribing limits:

- Arizona: Language in 32-3248, Arizona Revised Statutes specifies that "An initial prescription for a Schedule II controlled substance that is an opioid that is written for more than a five-day supply is deemed to meet the requirements of an exemption under this section when the initial prescription is presented to the dispenser. A pharmacist is not required to verify with the prescriber whether the initial prescription complies with this section."
- Utah: U.C.A. 1953 § 58-37-6 specifies that "[a] pharmacist is not required to verify that a prescription is in compliance with [the controlled substance prescribing limits applicable for initial acute pain prescriptions] Subsection (7)(f)(iii)."

Similarly, the Boards of Pharmacy in both Ohio and South Carolina issued policy guidance explicitly indicating that state laws do not require that pharmacists confirm that higher quantity prescriptions were issued in accordance with the statutory exceptions to state prescribing limits:

- Ohio: Board guidance issued on February 22, 2017 specifies that "The responsibility of adhering to the limits is the responsibility of the prescriber. Pharmacists should be aware that there are exceptions to the rules and therefore there is no expectation that pharmacists enforce the limits."[2]

- South Carolina: A policy statement outlined in the August 2018 version of the South Carolina Board of Pharmacy Newsletter specifies that "The Board does not interpret the opioid limitation to impose an obligation upon the pharmacist in question to verify compliance, as the practitioners are expected to comply and may be subject to discipline if they do not. Pharmacies may choose to implement their own verification procedures for prescriptions in accordance with the requirements of the Pharmacy Practice Act."[3]

It is critical that DEA clarify and align its policy with state laws and policies, exemplified above, that have already been implemented in numerous jurisdictions across the country. Otherwise, inconsistencies among DEA policies and state laws and policies will lead to confusion amongst healthcare providers and create harmful delays in the delivery of patient care.

[2]https://www.pharmacy.ohio.gov/Documents/Pubs/Special/ControlledSubstances/For%20Pharmacists%20-%20New%20Limits%20on%20Prescription%20Opioids%20for%20Acute%20Pain.pdf
[3] https://nabp.pharmacy/wp-content/uploads/2016/06/South-Carolina-Newsletter-August-2018.pdf

II. OTHER PROVISIONS IN THE PROPOSED RULE THAT WARRANT FURTHER CLARIFICATION AND/OR REVISIONS BY DEA

a. Partial Fills Requested by a Prescriber

1. How a Practitioner May Request That a Prescription Be Partially Filled ((1306.13 (b)(3))

The NPRM proposes to add language to 21 CFR 1306.13 (b)(3) outlining the process that must be followed when a partial fill is requested by the prescriber upon first issuing the prescription. Generally, it is our members' experience that it is extremely rare for a prescriber to request that a Schedule II prescription be partially filled when the prescription is first issued. More commonly, prescribers authorize a partial fill for a Schedule II prescription after the dispensing pharmacist has presented this option to the prescriber. ***Thus, we urge DEA to further revise the rule language to explicitly recognize that the prescriber may also authorize a partial fill at a later date - after the original prescription is issued.***

2. Requirements for Pharmacies to Record Partial Filling of Schedule II Prescriptions When Requested by the Prescriber (1306.13) (b)(5)(i))

Proposed revisions to 21 CFR 1306.13) (b)(5)(i) outline the various recordkeeping requirements for pharmacists that partially fill a Schedule II prescription pursuant to prescriber direction. Among the required records, the proposed rule would require that the dispensing pharmacist make a notation of the quantity dispensed on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record. ***As an alternative to this potentially redundant requirement, we ask that DEA revise the rule language to allow pharmacists to satisfy the recordkeeping requirement by making an annotation in the electronic dispensing record.***

b. Partial Fills Requested by a Patient

1. How a Patient May Request Partial Fill of a Schedule II Prescription

Although not explicitly specified in the proposed rule language, DEA notes in the NPRM preamble that the agency has determined that "CARA did not authorize members of the patient's household to request the partial filling of a prescription on behalf of the patient," thus a request to fill remaining portions of a partially filled Schedule II prescriptions must be initiated by the patient. We are concerned that DEA's overly narrow interpretation of CARA may in fact undermine the intent of the recent law change to reduce access to any unused quantities from larger prescriptions by encouraging more frequent partial filling of Schedule II medications.

Moreover, DEA's interpretation directly conflicts with federal HIPAA privacy regulations at 45 CFR 164.510(b)(3), which state that a "covered entity may use **professional judgment and its experience with common practice to make reasonable inferences of the individual's best interest in allowing a person to act on behalf of the individual to pick up filled prescriptions,** medical supplies, X-rays, **or other similar forms of protected health information**" (emphasis added). HHS arrived at this conclusion because patients commonly request their representatives (e.g., friends, neighbors, family members, etc.) to drop off prescription orders and/or pick up filled prescriptions on their behalf. HHS has stated that "the personal representative stands in the shoes of the individual and has the ability to act for the individual and exercise the individual's rights."[4] Especially for the homebound, elderly, and/or patients who have had recent surgeries or other health events, a family member, caretaker or other person acting as the patients' representative is likely to drop off a prescription order and/or pick up the filled prescription from the pharmacy. Moreover, given that patients do not regularly initiate a request for a partially filled prescription (absent health plan coverage incentives that encourage partial filling at the point of sale), patients are unlikely to send their representative to the pharmacy with written and signed instructions requesting a partial fill, nor are they likely to call the pharmacy ahead of time and request that only a partial amount be dispensed. Thus, unless DEA recognizes the ability of patients' representative to act on a patient's behalf, this policy interpretation is likely to lead to increased and unnecessary dispensing of the full amount prescribed on any original Schedule II prescription. ***It is therefore imperative that DEA revise the rule language to recognize and accommodate scenarios in which a partial fill can be initiated by the patient's representative.***

With respect to the manner in which a patient may request a partial fill, proposed rule language under 21 CFR 1306.13 (b)(4) only recognizes the following as allowed means of communicating a patient's partial fill request: "[i]n person, in writing if signed by the patient, or by a phone call from the patient to the pharmacist." In addition to these types of communications, patients commonly use many other mediums allowed by state boards of pharmacy to communicate requests that partial fills be dispensed, including (but not limited to) text messages, online portals (i.e. pharmacy websites). Moreover, DEA's proposed language does not consider additional communication options that may be available in the future. ***Accordingly, we ask that DEA further clarify in the final rule that a patient may request a partial fill in any manner allowed per the laws of the state.***

[4] *See* https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/personal-representatives/index.html; accessed January 25, 2021.

2. Requirements for Pharmacies to Record Partial Filling of Schedule II Prescriptions When Requested by Patient:

Similar to the proposed recordkeeping requirement for prescriber-initiated partial fills of Schedule II prescriptions, DEA has proposed under 21 CFR 1306.13) (b)(5)(ii) various recordkeeping requirements for pharmacists to follow with patient-initiated partial fills for Schedule II prescriptions that include making a notation of the quantity dispensed on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record. ***As an alternative to this potentially redundant requirement, we ask that DEA revise the rule language to allow pharmacists to satisfy the recordkeeping requirement by making an annotation in the electronic dispensing record.***

With respect to instances when the prescriber has already requested that a Schedule II prescription be partially filled, but the patient requests an even lesser quantity (likely due to an insurance coverage issue at the point of sale,) DEA has proposed to require that the pharmacy make an additional notation to the record indicating that the patient requested the lesser quantity. Altogether, these numerous steps create obstacles to partial filling practices, whereas it's in the interest of public health to encourage these practices. ***Thus, we urge DEA to eliminate these types of redundant recordkeeping requirements given that the total quantity dispensed compared to the total quantity prescribed will be obvious based on the dispensing record.***

c. <u>Adequate Time Needed to Update Pharmacy Systems, Policies and Procedures Before the Rule Takes Effect</u>

As noted in the NPRM, DEA has proposed to establish certain requirements for the partial filling of Schedule II prescriptions that "fill in any gaps in the regulatory scheme not addressed by […] CARA." Consequently, pharmacies need adequate time to update pharmacy systems, policies and procedures to conform with these new requirements outlined in the NPRM. ***Thus, we ask DEA to set the effective date of the rule changes as six months after the final rule is published in the Federal Register.***

II. IN CONCLUSION

NACDS thanks DEA for considering our comments and perspectives on this critical matter. Subsequently, in Appendix 1 (attached to this letter,) we have provided responses to some of the questions posed by DEA in the NPRM to stakeholders that we hope the agency finds useful as it further deliberates on this rulemaking. NACDS welcomes the opportunity to work with policymakers at DEA and other government and private stakeholders to help curb prescription opioid abuse. Please do not hesitate to contact Michelle Cope for any further information at 703-837-4200 or at mcope@nacds.org.

Sincerely,

Steven C. Anderson, FASAE, IOM, CAE
President and Chief Executive Officer

Attachment (1)

Attachment 1

Compilation of NACDS Chain Member Responses to Certain Questions Posed by DEA in the NPRM Federal Register Notice Pertaining to Partial Fill of Schedule II Prescriptions

DEA Question: Why do so many prescriptions for Schedule II controlled substances result in unused dosages?

Response(s):

- There are numerous circumstances wherein patients may be issued a prescription that inadvertently results in unused dosages.
    - Prescriptions issued to patients receiving end-of-life care who expire may have unused pain medication at the time of their death.
    - Prescriptions issued by pain specialists to patients who are in the process having their medication therapy carefully titrated to a different dosage, quantity and/or the directions for use may no longer need the original prescribed amount.
    - For patients prescribed Schedule II medications for acute pain episodes, the majority take them sparingly and as needed. Once a patient's acute pain is resolved, most will commit the remaining doses to the cabinet for possible future use if there is recurrent pain.
    - At times, prescribers may also issue a prescription for a larger quantity Schedule II medications because of their inability to provide refills for the original prescription and because they are uninformed about state laws and their ability to recommend partial fills of Schedule II medications.

DEA Question: How likely are patients to request partial filling at the pharmacy when the prescriber has not given instructions for a partial fill on the prescription?

Response(s):

- Except where patients may be limited by coverage policies, patients do not otherwise commonly or regularly request that their pharmacist only partially fill their Schedule II prescriptions. This is unlikely to change, as patients are even less informed than prescribers regarding their ability to request a partial fill that can be fully filled at a later date if needed. Patients largely rely on the healthcare professionals for guidance in these matters.

DEA Question: Is it reasonable to assume that a patient interested in a partial filling of a Schedule II controlled substance would request the prescriber to provide instructions on the prescription?

Response(s):

- No, it is very unlikely that a patient is going to ask their healthcare practitioner to issue a prescription directing that their prescription be partially filled initially.

DEA Question: Is it reasonable to assume that when prescribers do not request a partial fill, patients will generally not request a partial fill?

Response(s):

- Except where patients may be limited by coverage policies, patients do not otherwise commonly or regularly request that their pharmacist only partially fill their Schedule II prescriptions.

DEA Question: Questions for industry including private and public plans and entitlements.

Response(s):

- Unfortunately, due to differing policies among prescription drug plans and pharmacy benefit managers, it is impossible for NACDS to opine on this series of questions.