February 2, 2021

Drug Enforcement Administration
Attn: DEA Federal Register Representative
DPW, 8701 Morrissette Drive
Springfield, VA 22152

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

Dear Sir or Madam:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments in response to the Drug Enforcement Administration (DEA) proposed rule on *Partial Filling of Prescriptions for Schedule II Controlled Substances* (proposed rule).

NCPA represents America's community pharmacists, including over 21,000 independent community pharmacies. Almost half of all community pharmacies provide long-term care services (LTC) and play a critical role in ensuring patients have immediate access to medications in both community and LTC settings.[1] Together, our members represent a $74 billion healthcare marketplace, employ approximately 250,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

NCPA fully acknowledges and supports DEA's legal authority to implement regulations designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for a sufficient supply of controlled substances and listed chemicals for legitimate medical purposes. The proposed rule would allow a pharmacist to partially fill a C-II controlled drug prescription if requested by the patient or prescriber. To be lawful under the Comprehensive Addiction and Recovery Act (CARA), the partial filling must: 1) not be prohibited by State law; 2) must be written and filled in accordance with the Controlled Substances Act (CSA), DEA regulations and State law; and 3) the total quantity dispensed in all partial fillings cannot exceed the total quantity prescribed.[2] In addition, after the first partial fill, any additional partial fill(s) must occur within 30 days after the date on which the prescription is written (unless the prescription is issued as an emergency oral prescription, in which case the

[1] National Community Pharmacists Association (2019). *2019 NCPA Digest*: *A Roadmap for Independent Community Pharmacists.*

[2] 85 Fed. Reg. at 78,285.

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remaining portion must be filled no later than 72 hours after it was issued).[3] NCPA commends DEA for moving forward with this rulemaking to align its regulations with recent statutory changes that further encourage partial filling practices for Schedule II (C-II) prescriptions and that clarify additional issues related to the partial filling of these medications. To that end, NCPA submits these comments on behalf of both community and LTC independent pharmacies.

Prescriber- and Patient-Initiated Partial Fills for Schedule II Prescriptions

NCPA agrees with DEA in that the pharmacy's actions are straightforward when the prescriber requests the partial fill by writing such terms on the face of the prescription at the time that it is completed, or in the case of an emergency oral prescription, directly stating to the pharmacist when such prescription is communicated to the pharmacist. In the event of a prescriber-requested partial fill, the pharmacist must record the amount partially filled, the date, name/initials of the filling pharmacist and all other information required by 21 C.F.R. § 1306.22(c) for Schedule III and IV prescription refills. However, as noted in the previous section, prescribers generally authorize a partial fill for a C-II prescription after consultation with the dispensing pharmacist, rather than request that a C-II prescription be partially filled when the prescription is first issued. Therefore, NCPA recommends DEA revise the proposed rule to recognize that the prescriber may also authorize a partial fill at a later date, after the original prescription is issued.

NCPA supports DEA's proposal regarding the required notifications to dispense the partial fill as requested without any notification or consent when the partial fill is at the request of the patient. NCPA agrees that this regulatory alternative—as opposed to either 1) notifying the prescribing practitioner or the prescribing practitioner's agent of the patient's request to partially fill the prescription and obtain the prescribing practitioner's consent for the quantity or 2) notifying the prescribing practitioner or the prescribing practitioner's agent of the patient's partial fill request but not require the prescribing practitioner's consent—is the least burdensome to the pharmacy, prescribing practitioner, and the patient and results in no notification-related cost to either the pharmacy or prescriber**.** NCPA appreciates that the proposed rule takes into consideration that patients may have difficulty visiting a pharmacy in person to request a partial fill (e.g., post-surgery), and would allow alternative pathways for the patient to make such a request and specify the amount to be filled.

Prescriptions Issued by Prescribers that may Exceed State-Mandated Day Supply Limits

As noted by DEA in the proposed rule, many states have enacted laws placing varying limits on the prescribing of controlled substances, most of which are applicable to first-time prescriptions issued for acute pain. In the proposed rule, DEA states that because "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 exceed the limits of State law to be invalid, and therefore,

[3] 85 Fed. Reg. at 78,285.

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."[4] **NCPA urges DEA to reconsider this position as it is inconsistent with existing DEA policy and state laws that address prescribing and dispensing of controlled substances.** Most, if not all states, allow a pharmacist to make changes to a C-II prescription after consulting with a prescriber. Moreover, current DEA policy states that "DEA expects that when information is missing from or needs to be changed on a Schedule II controlled substances 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."[5] **NCPA recommends that where controlled substance prescriptions may have been modified following consultation between a pharmacist and prescriber, 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, pharmacist should be able to notate on the prescription or in their recordkeeping system that the quantity prescribed was modified following discussion with the prescriber and a lesser quantity was filled.

Recent state laws that establish prescribing limits on certain initial controlled substance prescriptions for acute pain were carefully written 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 made clear that pharmacists are not required to enforce that prescriptions that are received in excess of the limits applicable to only certain acute pain prescriptions. In states such as 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)."

[4] 85 Fed. Reg. at 78,284.

[5] 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.

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."[6]
- 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."[7]

It is critical that DEA clarify and align its policy with state laws and policies, exemplified above, that have already been implemented at the state level 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.

Uncertainties in Analysis of Benefits and Costs

NCPA agrees that the proposed rule has the potential to reduce the amount of unused C-II medication and the risk of diversion and abuse. However, we question whether this will result in significant cost savings; most patients receiving a C-II prescription pay a copay and do not pay out-of-pocket for the full cost of the drug, and the drug copay does not necessarily decrease based upon small changes in drug quantity. Therefore, it is unclear whether copays for a C-II prescription will be reduced if only partially filled; if copays for partial fills are not reduced, then a patient may ultimately pay multiple copays and more money out-of-pocket than they would otherwise. In addition, as DEA states in the proposed rule that it does not have the basis to estimate the impact of this proposed rule on payments to pharmacies, in terms of price per dosage units, copays, insurance reimbursements, etc., or who would realize the cost savings, **NCPA requests that DEA indicate what kind of information it needs to undertake such an analysis and how we may be helpful in any undertaking to address these uncertainties**.

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[6] State of Ohio Board of Pharmacy. (2017). Pharmacist FAQ: new limits on prescription opioids for acute pain. Retrieved from https://www.pharmacy.ohio.gov/Documents/Pubs/Special/ControlledSubstances/For%20Pharmacists%20-%20New%20Limits%20on%20Prescription%20Opioids%20for%20Acute%20Pain.pdf

[7] National Association of Boards of Pharmacy Foundation. (2018). South Carolina Board of Pharmacy News, 39(3). Retrieved from https://nabp.pharmacy/wp-content/uploads/2016/06/South-Carolina-Newsletter-August-2018.pdf

NCPA greatly appreciates the opportunity to share with you our comments and suggestions on DEA's proposed rule on *Partial Filling of Prescriptions for Schedule II Controlled Substances*. Please feel free to contact me with any further questions at ronna.hauser@ncpa.org.

Sincerely,

Ronna B. Hauser, PharmD
Vice President, Policy & Government Affairs Operations