



Via Electronic Submission to: www.regulations.gov

February 2, 2021

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

Re: RIN 1117–AB45/Docket No. DEA–469

Dear Sir or Madam:

The American Pharmacists Association (APhA) is pleased to submit our comments to the Drug Enforcement Administration (DEA) on the [Partial Filling of Prescriptions for Schedule II Controlled Substances proposed rule](#), published in the Federal Register on December 4, 2020 (85 FR 78282). Founded in 1852, APhA represents pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

As DEA is aware, policies allowing pharmacists to dispense less than prescribed amounts of opioids serve to reduce opportunities for opioid misuse and abuse. APhA appreciates the proposed rule’s recognition of pharmacists’ authority under the Comprehensive Addiction and Recovery Act of 2016 (CARA)¹ to dispense less than prescribed amounts of opioids in situations where a prescriber or patient requests a partial fill. **In addition to these situations, APhA urges DEA to clarify that pharmacists -- using their medication expertise and clinical judgment -- also have the authority to recommend partial fills to prescribers and patients and document and dispense partial fills accordingly.**

We offer our specific comments on the proposed rule below:

How a Practitioner May Request That a Prescription Be Partially Filled

The proposed rule states that the prescribing practitioner must specify the quantity to be dispensed in the partial filling:

¹ Public Law 114–198

- on the face of the written prescription;
- in the written record of the emergency oral prescription; or
- in the electronic prescription record.

APhA Comments

APhA supports this proposed approach for a prescribing practitioner to make a partial fill request because it provides clarity to the pharmacist. **In addition, APhA recommends that DEA clarify that prescribing practitioners have the authority to amend an original Schedule II prescription to request a partial fill following consultation with a pharmacist.**

How a Pharmacy Would Be Required To Record the Partial Filling of a Prescription for a Schedule II Controlled Substance When Requested By the Prescribing Practitioner

The proposed rule specifies that upon each such partial filling requested by a prescribing practitioner, the dispensing pharmacist must 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.

Furthermore, for electronic prescriptions, there must be an electronic prescription record, and the record must be permanently attached to the electronic prescription. Also, for each such partial filling, the pharmacy must maintain a record with the date of each dispensing, the name or initials of the individual who dispensed the substance, and all other information required by 21 CFR 1306.22(c) for schedule III and IV prescription refills. For electronic prescriptions specifically, pharmacy applications must allow required information pertaining to the quantity, date, and the dispenser to be linked to each electronic controlled substance prescription record (as currently required by 21 CFR 1311.205(b)(10)).

APhA Comments

APhA appreciates DEA's clear communication of the requirements in proposed § 1306.13(b) for recording the partial filling of a prescription for a Schedule II controlled substance when requested by the prescriber or the patient. APhA agrees with DEA that the most common scenario would be that the pharmacist enters the partial fill information into a computerized system in an existing data field.

How a Patient May Request the Partial Filling of a Schedule II Prescription

The proposed rule specifies that a patient may request the partial filling of a Schedule II prescription in person, in writing if signed by the patient, or by a phone call from the patient to the pharmacist.

APhA Comments

APhA appreciates the ability of patients to make partial fill requests in writing or by phone to account for situations in which the patient is not able to visit the pharmacy in person. To reduce the number of opioids in the home, APhA believes that family members and caregivers should also be authorized to request partial filling of Schedule II prescriptions on behalf of the patient. **In addition, APhA urges DEA to clarify that pharmacists -- using their medication expertise and clinical judgment -- also have the authority to recommend partial fills of Schedule II prescriptions to prescribers and patients, and document and dispense accordingly.** For example, knowing that the patient just had a tooth pulled, the pharmacist might explain to the patient that he/she will likely not need the full amount of the prescription and recommend a partial fill instead. By exercising their clinical judgment in this way, the pharmacist is helping to reduce the opportunity for opioid misuse and abuse.

How a Pharmacy Must Record the Partial Filling of a Prescription for a Schedule II Controlled Substance When Requested By the Patient

Under the proposed rule, when partially filling a prescription for a Schedule II controlled substance at the request of the patient, the pharmacist must make the same notation on the prescription as when partially filling a prescription at the request of the prescribing practitioner. Specifically, the pharmacist must make a notation:

- on the face of the written prescription;
- in the written record of the emergency oral prescription, or
- in the electronic prescription record.

For uniformity and clarity, DEA is proposing that the pharmacy record on all such prescriptions:

- 1) “patient requested partial fill on [date such request was made],” and
- 2) the quantity dispensed.

In addition, for each such partial filling, the pharmacy must maintain a record of dispensing that includes the date of each dispensing, the name or initials of the individual who dispensed the substance, and all other information required by 21 CFR 1306.22(c) for schedule III and IV prescriptions. For electronic prescriptions specifically, such required information pertaining to the quantity dispensed, date dispensed, and the dispenser must be linked to each electronic controlled substance prescription record.

APhA Comments

APhA appreciates DEA’s clear communication of the requirements in proposed § 1306.13(b) for recording the partial filling of a prescription for a Schedule II controlled substance when requested by the prescriber or the patient. In addition, APhA appreciates the clarification that in the event the prescribing practitioner already made the request to partially fill the prescription, the pharmacy will not be required to make any notation on the prescription indicating that the patient requested a partial fill, unless the patient requested a smaller amount. However, where a

practitioner has requested the partial filling of a prescription, the patient may not request a partial filling in an amount greater than that specified by the practitioner.

Alternative 3: Dispense Partial Fill as Requested Without Consent of, or Notification to, the Prescribing Practitioner

APhA Comments

APhA supports DEA's choice of Alternative 3 -- dispense partial fill as requested by the patient without the consent of, or notification to, the prescribing practitioner -- because it is the least burdensome of the three options considered by DEA for pharmacists, prescribing practitioners, and patients. This option would not threaten patient safety and does not preclude the eventual dispensing by the pharmacist of the full amount prescribed.

Burden/Cost Estimates

In the proposed rule, DEA estimates that it may require 10 additional seconds (\$0.24/prescription) for a pharmacist to record a partial fill. This equates to an annual cost to pharmacies of \$4,365,034 to record 18,187,640 partial fill prescription requests per year.²

APhA Comments

APhA is concerned that the 10 second time estimate is too low, and recommends that DEA conduct a time and motion study in order to get a more accurate determination of the time involved in recording partial fill requests. In addition to the time to record the partial fill, a much larger time, cost, and administrative burden falls upon pharmacists to fill requests for the remaining amount of the original prescription. For example, DEA states that if filling the remainder of the partial fill required 10 additional minutes, based on the estimated loaded median hourly rate of \$86.53 for a pharmacist, that additional time would equate to a cost of \$14.42.³ Filling the remainder of a partial fill Schedule II prescription requires the pharmacist to make another trip to the safe/storage container, use additional supplies, make an additional notation in the prescription record, and conduct an additional controlled substances count. **It is critical for pharmacists to be adequately reimbursed for the time and costs associated with filling remaining amounts of partial fill requests for Schedule II prescriptions.**

Specific Questions asked by DEA

8. Questions for industry including private and public plans and entitlements:

- c. Would there be a copay when a patient returns for filling the remainder of a partially filled prescription (full amount or reduced amount)?
- d. Would a patient likely spend less on a partial fill than on a full prescription?

² See 85 Fed. Reg. 78282, p. 78289

³ Id.

e. If so, would requesting two or more partial fills likely cost the patient more than filling the full prescription initially?

APhA Comments

While this is a question for payers, APhA would be concerned if partial fills resulted in additional costs to patients, such as double co-pays.

Guidance on other Partial Fill Scenarios

In addition to the proposed method of recording partial filling of prescriptions for Schedule II controlled substances when requested by prescribers and patients, APhA also respectfully requests that DEA provide clarification and written guidance on cases in which the pharmacist is unable to supply the full quantity called for in the prescription, as well as 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.

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. Further clarification and written guidance for all dispensing limitation situations will help to ensure standardization in execution and the intended patient safety outcomes.

With regard to situation (1), there are cases wherein patients opt to receive the full prescribed amount 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. APhA requests that DEA clarify through written guidance that a pharmacist may comply with the patient's request and fill the prescription for the full quantity despite the health plan coverage limitation.

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. APhA requests that DEA clarify through written guidance that a pharmacy may assign two (or more) different prescription numbers to one prescription where necessitated by health plan coverage limitations.

Conclusion

Thank you for the opportunity to submit comments on the Partial Filling of Prescriptions for Schedule II Controlled Substances proposed rule. Pharmacists have an important role to play in recommending partial fills, documenting partial fill requests, and dispensing Schedule II prescriptions. As stated above, APhA also respectfully requests that DEA provide clarification and written guidance addressing the following issues:

- Documentation of a partial fill pursuant to situations in which the pharmacist is unable to supply the full quantity called for in the prescription;
- 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;
- 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;
- Clarify that 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; and
- Whether pharmacies may assign two (or more) different prescription numbers in their pharmacy system to a single prescription to address situations where the patient opts to pay out-of-pocket for the portion not covered by their health plan.

Thank you for your consideration of our comments on the proposed rule and requests for guidance on additional partial fill scenarios. If you have any questions or require additional information, please contact Karin Bolte, JD, Director, Health Policy, at kbolte@aphanet.org or by phone at (202) 558-2727.

Sincerely,



Ilisa BG Bernstein, PharmD, JD, FAPhA
Senior Vice President, Pharmacy Practice and Government Affairs