



April 18, 2018

Cheranne McCracken, R.Ph.
Executive Director/Chief Drug Inspector
New Mexico Board of Pharmacy
5500 San Antonio Dr. NE, Suite C
Albuquerque, New Mexico 87109

Via email: cheranne.mccracken@state.nm.us

Re: Proposed Rule Changes under 16.19.20.46 NMAC and 16.19.29.8 NMAC

Dear Ms. McCracken:

On behalf of our members operating chain pharmacies in the state of New Mexico, the National Association of Chain Drug Stores (NACDS) thanks the Board of Pharmacy ("Board") for the ongoing opportunity to provide input on the proposed rule changes under 16.19.20.46 NMAC pertaining to the partial filling of controlled substance prescriptions, as well as the opportunity to comment on 16.19.29.8 NMAC regarding mandatory reporting of prescription information to the prescription monitoring program. We appreciate the Board considering our input on these proposed rule changes.

16.19.20.46 NMAC – Partial Filling of Controlled Substances Prescriptions

We support the Board's general effort to update the requirements for the partial filling of schedule II prescriptions under the existing partial fill rule, especially in light of recent updates to federal law enacted under the Comprehensive Addiction and Recovery Act of 2016. However, we are concerned that the latest version of the proposed changes to 16.19.20.46 NMAC is inconsistent with (and in some cases directly contradicts) the requirements of federal law and regulations. To address these inconsistencies, we urge the Board to further revise the proposed rule language to address the following issues:

- *Federal law requires that remaining portions of a partially filled schedule II prescription be filled no later than 30 days after the date on which the prescription is written.*
 - Under 21 U.S.C. 829 (f)(2)(A), federal law specifies that the "remaining portions of a partially filled prescription for a controlled substance in schedule II... *shall be filled not later than 30 days after the date on which the prescription is written* [emphasis added]."
 - The proposed language under 16.19.20.46 (B) directly contradicts this provision in federal law in specifying that "[a] prescription for a controlled substance in Schedule II *initially filled later than 30 days after the date written* [emphasis added] may be partially filled..."

- *Federal law allows for a schedule II prescription to be partially filled when requested by the patient or prescriber.* Notably, language accommodating the partial filling of schedule II prescriptions in these circumstances was enacted into law by Congress as a way to reduce the quantity of schedule II medications dispensed that ultimately go unused when some patients' acute pain conditions resolve.
 - Under 21 U.S.C. 829 (f)(1)(C), federal law specifies that “[a] prescription for a controlled substance in schedule II may be partially filled if... the partial fill is requested by the patient or the practitioner that wrote the prescription.”
 - By comparison, the proposed rule changes to 16.19.20.46 NMAC omits language that would accommodate the partial filling of controlled substances in these situations.

- *Federal rules allow for pharmacies to maintain the required records of partially filled prescription either by making a notation on the face of the written prescription, making a written record, or maintaining this information in the electronic prescription record.*
 - Under 21 CFR §1306.13 (a), federal rules specify that pharmacists that partially fill a controlled substance prescription shall “make a notation of the quantity supplied on the face of the written prescription, written record of the emergency oral prescription, or in the electronic prescription record.”
 - By comparison, language under 16.19.20.46 (B)(2) would require that “the partial fill amount is recorded on the prescription,” but does not accommodate the other recordkeeping formats allowed under the federal rules.

- *Under federal rules, only pharmacists that initiate a partially filled schedule II prescription because the pharmacy does not have the full amount of the prescribed medication in stock are required to notify prescribers when the remaining portion of a partially filled schedule II prescription is not filled.* Requiring pharmacists to notify prescribers in situations beyond that would be redundant since prescribers are able to review the quantity of medications dispensed to patients by running and reviewing a prescription monitoring program report.
 - Federal rules under 21 CFR §1306.13 (a) specify that pharmacists may initiate a partial fill when “unable to supply the full quantity called for in a written or emergency oral prescription.... [and] the remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescribing individual practitioner.”
 - By comparison, the proposed rule changes under 16.19.20.46 (B)(4) would require pharmacists filling the remaining portion of partially filled prescriptions to “notify[y] the prescribing physician if remaining portion cannot be filled within the 72 hour period.” This provision appears to provide to all partially filled schedule II prescriptions and is therefore broader than the federal requirement.

16.19.29.8 NMAC – Prescription Monitoring Program Reporting Requirements

Under 16.19.29.8 (D), the Board has proposed to update the timeframe for submitting corrections to dispensing information previously provided to the prescription monitoring program (PMP). On occasions, technology glitches on the vendor side can prevent pharmacies from correcting an incorrect submission in a timely manner. Depending on how long it takes the vendor to correct the issue, the proposed new timeframe of 3 days for data corrections may not be adequate, despite pharmacies' best efforts to comply. To reflect that pharmacies are not responsible for PMP vendor technology failures, we urge the Board to revise 16.19.29.8 (D) to clarify that pharmacists must submit data for correction within the 3-day timeframe:

- D.** Corrections to information submitted to the PMP must be addressed including:
- (1)** file upload or “outstanding uncorrected errors” as defined in the PMP data reporting manual;
 - (2)** prescriptions that were not dispensed to the patient must be voided from the PMP;
 - (3)** incorrect information in prescriptions records submitted to the PMP must be **submitted for correction corrected** ~~as soon as possible and reflected within the PMP database within three (3) business days~~ after the dispenser has been notified or becomes aware of the incorrect information.

NACDS thanks the Board for considering our input on the proposed changes under 16.19.20.46 NMAC and 16.19.29.8 NMAC. Please do not hesitate to contact me with any questions or for further assistance. I can be reached at: 817-442-1155 or mstaples@nacds.org.

Sincerely,



Mary Staples
Regional Director, State Government Affairs

Enclosure: 1

cc: R. Dale Tinker, NMPHA
Liz MacMenamin, NMRA

ENCLOSURE 1

CARA Partial Fill Language

*SEC. 702. PARTIAL FILLS OF SCHEDULE II CONTROLLED SUBSTANCES.
21 U.S.C. 829 (f)*

(a) In General.--Section 309 of the Controlled Substances Act (21 U.S.C. 829) is amended by adding at the end the following:

- “(f) Partial Fills of Schedule II Controlled Substances.--
 - “(1) Partial fills.--A prescription for a controlled substance in schedule II may be partially filled if--
 - “(A) it is not prohibited by State law;
 - “(B) the prescription is written and filled in accordance with this title, regulations prescribed by the Attorney General, and State law;
 - “(C) the partial fill is requested by the patient or the practitioner that wrote the prescription; and
 - “(D) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.
 - “(2) Remaining portions.--
 - “(A) In general.--Except as provided in subparagraph (B), remaining portions of a partially filled prescription for a controlled substance in schedule II--
 - “(i) may be filled; and
 - “(ii) shall be filled not later than 30 days after the date on which the prescription is written.
 - “(B) Emergency situations.--In emergency situations, as described in subsection (a), the remaining portions of a partially filled prescription for a controlled substance in schedule II--
 - “(i) may be filled; and
 - “(ii) shall be filled not later than 72 hours after the prescription is issued.
 - “(3) Currently lawful partial fills.--Notwithstanding paragraph (1) or (2), in any circumstance in which, as of the day before the date of enactment of this subsection, a prescription for a controlled substance in schedule II may be lawfully partially filled, the Attorney General may allow such a prescription to be partially filled.”.

(b) Rule of Construction.--Nothing in this section shall be construed to affect the authority of the Attorney General to allow a prescription for a controlled substance in schedule III, IV, or V of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) to be partially filled.

DEA Rules Addressing Partial Fill

21 CFR §1306.13 Partial filling of prescriptions.

[note: these provisions were in effect before CARA was enacted and they still apply]

(a) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription, written record of the emergency oral prescription, or in the electronic prescription record. The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

(b) A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the Act. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.