

June 17, 2022

Fellow Patient Care Stakeholder:

Re: DEA Policy Reversal on Allowed Prescription Annotations for Schedule II Prescriptions

The National Association of Chain Drug Stores (NACDS) writes to share information regarding recent communications NACDS has had with the federal Drug Enforcement Administration (DEA) concerning DEA's policy reversal on the annotations that a pharmacist may make to a prescription for a Schedule II controlled substance.

During a May 2, 2022 telephone discussion among DEA officials and NACDS staff, DEA officials indicated that, despite its historical guidance permitting pharmacist annotations to Schedule II controlled substance prescriptions and established state law permitting the same, Schedule II controlled substance prescriptions now must arrive at the pharmacy with all elements required by 21 C.F.R. 1306.05(a)¹ in final form.

The implication of this DEA policy reversal is that if any of the elements required by 21 C.F.R. 1306.05(a) are missing or in need of alteration (such as the current address of the patient) then a pharmacist cannot add or change any of them, and the prescriber must instead issue a new prescription.

Considering the likely negative impact of this DEA policy reversal on patients' ability to receive timely their critical medications, in response to hearing this information from DEA, NACDS requested from DEA the following:

- 1. That DEA reconsider its policy reversal on annotation of controlled substance prescriptions without delay; or,
- In the alternative, that DEA consider temporarily suspending that reversal pending formal rulemaking on the issue.
- Absent either of the above, NACDS asked for DEA's prompt written confirmation of this long-standing policy reversal.

Since, as of the time of this writing, DEA has failed to respond to the above-mentioned requests, NACDS feels compelled to share this information with you because it appears to NACDS that DEA has not publicly announced this policy reversal. For additional information, we would suggest that you contact the DEA Office of Diversion Control, Liaison and Policy Section, at 571-362-3260 or ODLP@dea.gov.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM President and Chief Executive Officer National Association of Chain Drug Stores

Stan P. Allen

¹ "All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner." 21 C.F.R. 1306.05(a)