

May 2, 2022

Anthony Rubinaccio
Executive Director
New Jersey State Board of Pharmacy
PO Box 45013
Newark, NJ 07101
Submitted via RubinaccioA@dca.lps.state.nj.us

Re: Clarification Needed Regarding the Expiration of Schedule III-V Prescriptions

Dear Mr. Rubinaccio,

On behalf of our members operating pharmacies throughout New Jersey, the National Association of Chain Drug Stores (NACDS) is writing to the New Jersey State Board of Pharmacy (Board) regarding a matter of confusion related to the expiration of Schedule III-V "controlled dangerous substance prescriptions" (as that term is defined in N.J.S.A. 24:21-2.) Specifically, some NACDS members operating pharmacies in New Jersey have received direction from representatives of the New Jersey Medicaid program that are seemingly in direct conflict with both federal and state laws and regulations regarding the timeframe in which Schedule III-V prescriptions expire. As the regulatory body responsible for enforcement of state laws and regulations applicable to pharmacies in New Jersey, we ask the Board to provide clarification on this matter.

As the Board is already aware, both federal and state laws and rules for controlled dangerous substances specify that prescriptions for Schedule III and IV must be filled within six months from the date of issuance and are silent with respect to this issue for Schedule V prescriptions. See 21 C.F.R. 1306.22(a); N.J. Stat. Ann. § 24:21-15(b); N.J. Admin. Code § 13:45H-7.14(b). Additionally, state rules for controlled dangerous substances expressly state that that "[a]II prescriptions for controlled substances, regardless of schedules, shall be presented to the pharmacist for filling within 30 days after the date when issued..." See N.J. Admin. Code § 13:45H-7.5 (emphasis added). Read together, the requirements of N.J. Admin. Code § 13:45H-7.5 and § 13:45H-7.14(b) convey, as their plain meaning, a requirement that Schedule III-IV controlled substance prescriptions must be presented to the pharmacist within 30 days from the date of issuance but that thereafter the pharmacist may fill those prescriptions for up to six months from the date of issuance. Schedule V prescriptions are subject to the same requirement to be presented to the pharmacist by day 30 after the date of issuance but are not subject to the six-month limitation on filling thereafter.

Some NACDS members have become aware of a contrary interpretation put forward by New Jersey Medicaid and others suggesting that the requirement under N.J. Admin. Code § 13:45H-7.5's for all controlled substances to be "presented to the pharmacist for filling within 30 days" means that no prescription for controlled substances in New Jersey can be filled beyond 30 days from date of issuance, regardless of when the prescription was presented to the pharmacist. This interpretation of the rule ignores the plain meaning of N.J. Admin. Code § 13:45H-7.5 and the contrary language in the same regulation, found in N.J. Admin. Code § 13:45H-7.14(b).

To avoid any further confusion on this issue, NACDS respectfully requests that the Board provide clarification that Schedule III-V prescriptions timely "presented to the pharmacist" within 30 days after date of issuance may thereafter be filled in conformance with the time limitations specified in N.J. Admin. Code § 13:45H-7.14(b) and

federal law. If it is the Board's intent that all controlled substance prescriptions expire 30 days after date of issuance, then we respectfully propose that the Board initiate proper rulemaking efforts to amend N.J. Admin. Code §§ 13:45H-7.5 and 7.14(b) to effectuate that intent.

Thank you for attention to this matter. For questions or further discussion, please contact NACDS' Anne Fellows, Director, State Government Affairs at afellows@nacds.org or 978-456-9235.

Sincerely,

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

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NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' over 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. Please visit NACDS.org.