U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

Ilisa Bernstein, PharmD, JD, FAPhA
Interim Executive Vice President and CEO
American Pharmacists Association
2215 Constitution Avenue, N.W.
Washington, DC 20037

Dear Ms. Bernstein:

This is in response your letter dated December 19, 2022, to the Drug Enforcement Administration (DEA) in which you, along with Steven C. Anderson, President and CEO of the National Association of Chain Drug Stores and B. Douglas Hoey, CEO of the National Community Pharmacists Association, expressed your concern and disagreement with a segment of the DEA Pharmacist's Manual, revised 2022. Specifically, your disagreement concerns a statement on page 88 in the Pharmacist's Manual concerning the daily sales limit of scheduled listed chemical products (SLCP) which indicates that this limit applies even if state law mandates that a prescription be issued for these products. DEA appreciates the opportunity to address your inquiry and apologizes for the delay in response. We are sending an identical response to both Steven C. Anderson and B. Douglas Hoey.

You state in your letter that it is your understanding that any SLCP that is dispensed pursuant to a prescription order is not subject to any of the requirements of the Combat Methamphetamine Epidemic Act (CMEA) of 2005, irrespective of whether the product is a legend drug under federal law. You further stated that you urge DEA to issue official guidance clarifying that the federal sales limits of the CMEA, including federal daily sales quantity limit of 3.6 grams, do not apply when a pharmacist dispenses an SLCP pursuant to a prescription.

The Controlled Substances Act (CSA), as amended by the CMEA, defines an SLCP as a product that contains ephedrine, pseudoephedrine, or phenylpropanolamine and may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act as a non-prescription drug. 21 U.S.C. 802(45)(A). As you alluded to in your letter, the CMEA mandates a 3.6-gram daily sales limit for SLCPs. In addition, regulated sellers of SLCPs must maintain a written or electronic logbook of each SLCP sale that identifies the products by name, the quantity sold, the names and addresses of the purchasers, and the dates and times of the sales. Even though a state may enact legislation that requires the purchase or dispensing of these products be made only pursuant to a prescription, if the products in question are categorized as non-prescription drugs under the Federal Food, Drug, and Cosmetic Act, they are, for the purposes of the CMEA, considered to be SLCPs.

The CMEA clearly contemplates that a pharmacy filling a prescription for SLCPs is acting as a "retail seller" as defined at 21 U.S.C. 802(46). First, that definition expressly includes pharmacies. Second, the definition of retail distributor at 21 U.S.C. 802(49) expressly includes "drug stores" as

defined by reference to Standard Industrial Classification (SIC) code 5912. SIC code 5912 covers "[e]stablishments engaged in the retail sale of prescription drugs, proprietary drugs, and non-prescription medicines, and which may also carry a number of related lines…." SIC Manual, Division G, Major Group 59, Industry Group 591 at https://www.osha.gov/sic-manual/5912. A pharmacy filling prescriptions (which by definition are for personal use) for SLCPs is therefore a drug store "whose activities as a distributor relating to ephedrine, pseudoephedrine, or phenylpropanolamine products are limited almost exclusively to sales for personal use, both in number of sales and volume of sales." 21 U.S.C. 802(49)(A). Therefore, pharmacies that dispense these products in any manner are regulated sellers that must comply with CMEA requirements for the sale of SLCPs.

These requirements include, but are not limited to, the aforementioned 3.6-gram daily sales limit and logbook requirements (see 21 U.S.C. 830(d)(1) and 21 U.S.C 830(e)(1)(A)(iii) respectively). The DEA Pharmacist's Manual, revised 2022, which you referred to in your letter, as well as the DEA Chemical Handler's Manual, revised 2022, accurately reflect the fact that state-imposed prescription requirements for products that contain ephedrine, pseudoephedrine, or phenylpropanolamine do not negate CMEA mandates.

Please note that nothing in DEA's regulations shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other federal laws, or under the laws of the state in which he or she desires to do such act; nor shall compliance with DEA's regulations be construed as compliance with other federal or state laws unless expressly provided in such other laws. *See* 21 U.S.C. 903; 21 CFR 1307.02. Specifically, where the CMEA is less stringent than a State law (for example, limiting of sales to licensed pharmacists), the State requirements continue to be in force. If there are State requirements that are less stringent than the CMEA provisions (for example, higher daily limits), CMEA supersedes the provisions. 71 FR 56008, 56015.

I trust this letter adequately addresses your inquiry. For information regarding the DEA Diversion Control Division, please visit www.DEAdiversion.usdoj.gov. If you have any additional questions on this issue, please contact the Diversion Control Division Policy Section at (571) 362-3260.

Sincerely,

CLAIRE BRENNAN

Digitally signed by CLAIRE BRENNAN
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Claire M. Brennan
Acting Deputy Assistant Administrator
Diversion Control Division

Cc: Steven C. Anderson
B. Douglas Hoey