December 19, 2022

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Office of Diversion Control Policy
Diversion Control Division
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

Submitted via email: thomas.w.prevoznik@usdoj.gov

Re: Application of Retail Sales Limit to Scheduled Listed Chemical Products Dispensed Pursuant to a Prescription

Dear Mr. Prevoznik:

The American Pharmacists Association (APhA), the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) write to the Drug Enforcement Administration (DEA) regarding the 2022 version of the DEA *Pharmacist's Manual,* which indicates on page 88 that the federal daily sales quantity limit of 3.6 grams applies when a pharmacist dispenses pursuant to a prescription a scheduled listed chemical product (SLCP) (for practical purposes, hereinafter "pseudoephedrine") that federally does not require a prescription.[1] It has been our understanding since the *Combat Methamphetamine Epidemic Act (CMEA)* passed into law over 15 years ago that the federal daily sales quantity limit does not apply when dispensing pseudoephedrine products pursuant to a prescription.

Applying Sales Limit to SLCP Prescriptions will Harm Patients to no Additional Policy Benefit

Based on discussions among our different associations and DEA officials contemporary with the passing of the *CMEA* and DEA's promulgation and finalizing of implementing regulations, it has been our understanding that any SLCP that is dispensed pursuant to a prescription order is not subject to any of the requirements of the *CMEA*, irrespective of whether the product is a legend drug under federal law. We believe that DEA's apparent policy reversal, seemingly announced in 2022 version of the *Pharmacist's Manual,* will cause great harm to patients that rely on pseudoephedrine products to treat chronic medical conditions. These patients would now have to make additional office visits to their prescribers for much more frequent prescriptions and much more frequent visits to their pharmacies to receive their pseudoephedrine medications. Notably, this apparent policy change would likely provide little to no additional benefit, as we are not aware that patients taking pseudoephedrine products pursuant to a prescription, without a federal sales limit for the past 15 years, have been even a minor contributor to the problems of methamphetamine abuse, production, or diversion.[2]

[1] *See* https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-046R1)(EO-DEA154R1)_Pharmacist%27s_Manual_DEA.pdf .

[2] Considering the implications of this policy change, NACDS questions whether DEA can make this change without proper public notice-and-comment rulemaking.

DEA's Policy Change is Not Supported by the *CMEA*

The *CMEA* and DEA regulations of SLCPs (21 CFR 1314.01. et seq.) contemplate the sale of these products through "retail transactions" by "regulated sellers." The *CMEA* defines a "regulated seller" as "a retail distributor (including a pharmacy or a mobile retail vendor), except that the term does not include an employee or agent of the distributor."[3] The *CMEA*'s definition of "retail distributor" is as follows:

> ... a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, **either directly to walk-in customers or in face-to-face transactions by direct sales**. (emphasis added)[4]

Considering that sales of SLCPs pursuant to a prescription result from a professional evaluation and through a learned intermediary, we do not believe that these types of transactions could be construed as being with a "walk-in customer or in face-to-face transactions by direct sales." When a patient presents a prescription to a pharmacy for a SLCP, such as pseudoephedrine, they are not merely walking into the pharmacy to conduct a transaction upon their own accord. Rather, they are presenting to the pharmacist an order given to them from a prescriber that has conducted a medical examination and evaluation. Consequently, we do not believe that *CMEA* sales limits would apply in these circumstances.

In addition, the *CMEA* exempts from the reporting requirement under 21 USC 830(b)(3)(B) distributions of drug products, including all SLCPs, distributed pursuant to a prescription. This means that mail order distributions of SLCPs pursuant to a valid prescription do not have to be reported. By requiring retail distributors to adhere to the sales limit even when distributing pursuant to a prescription, DEA seems to be indicating that such sale would also be subject to logbook recordkeeping requirements of 21 USC 830(e). This leads to the perverse outcome in which a sale pursuant to a prescription at retail, the information regarding which would already be maintained in the patient's prescription record, would now be subject to a redundant, duplicative recordkeeping requirement under 21 USC 830(e), while the same prescription sale by way of mail order would be completely exempt from the same 21 USC 830(e) recordkeeping requirements.

The Same Protections Apply when SLCPs Are Dispensed Pursuant to a Prescription Irrespective of Legend Status

Since the *CMEA* does not apply to legend drugs, we believe that it should also not apply to non-legend drugs that are dispensed under the same procedures as a legend drug, which are more stringent than the requirements of the *CMEA*. To obtain a SLCP pursuant to a prescription order, a consumer has to be under the care of a practitioner, and may receive the SLCP only as prescribed by the practitioner, and can receive the SLCP only from a pharmacy/ pharmacist. The recordkeeping requirements are more stringent, as the pharmacy will have to maintain a prescription record for the dispensed SLCP.

DEA's Policy Change is Without Precedent

By imposing the *CMEA* sales limits on non-prescription SLCPs, DEA would be regulating how a practitioner may prescribe non-prescription products. Specifically, DEA is attempting to assert its authority over the quantity of non-prescription products that may be prescribed. Such assertion of authority has no precedent, as DEA does not even regulate the quantity of controlled substances that may be prescribed. We urge DEA to avoid the perverse result of

[3] 21 USC 802(46).
[4] 21 USC 802(49).

regulating the quantity of non-prescription products that may be prescribed despite the fact that DEA does not regulate the quantity of controlled substances that may be prescribed.

Conclusion

APhA, NACDS and NCPA thank DEA for the consideration of our concerns about its apparent policy change announced in the 2022 version of its *Pharmacist's Manual.* We urge DEA to issue official guidance clarifying that the federal sales limits of the *CMEA*, including the federal daily sales quantity limit of 3.6 grams, does not apply when a pharmacist dispenses pursuant to a prescription a SLCP. For any questions, please contact APhA's Heather Boyd, Director, Health Policy, at hboyd@aphanet.org or 202-429-7517; NACDS' Sara Roszak, Senior Vice President, Health and Wellness Strategy and Policy, at sroszak@nacds.org or 703-837-4251; and NCPA's Ronna Hauser, Senior Vice President, Policy and Pharmacy Affairs at ronna.hauser@ncpa.org or 703-838-2691. We thank you for consideration of our concerns and requests.

Sincerely,

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APhA is the only organization advancing the entire pharmacy profession. Our expert staff and strong volunteer leadership, including many experienced pharmacists, allow us to deliver vital leadership to help pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians find success and satisfaction in their work while advocating for changes that benefit them, their patients, and their communities.

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.

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a $67 billion healthcare

marketplace, employ 215,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.