



April 16, 2020

William T. McDermott, Assistant Administrator
Diversion Control Division
U.S. Drug Enforcement Administration (DEA)

Subject: Signature Requirement for OTC Pseudoephedrine Products During COVID-19 National Emergency

[Transmitted via email]

Dear Mr. McDermott:

The American Pharmacists Association (APhA) appreciates the efforts the Drug Enforcement Agency (DEA) has taken within its authorities to further the public health response to COVID-19. I am writing to urge the DEA to exercise its enforcement discretion and not require a signature for the over-the-counter (OTC) purchase of pseudoephedrine (PSE) products during the COVID-19 pandemic.

APhA, founded in 1852 as the American Pharmaceutical Association represents nearly 60,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians' offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

Annually, over 18 million Americans use cold, allergy, and sinus medications containing pseudoephedrine.¹ While APhA appreciates the importance of the Combat Methamphetamine Epidemic Act (CMEA) signature requirement for OTC PSE products to help prevent the illegal manufacture of methamphetamine², APhA is concerned that requiring a signature for these products during the COVID-19 pandemic poses risks to patients by exposing them to potentially coronavirus-contaminated stylus/pens.

While DEA notes in its COVID-19 FAQ document that “gloves or a sterilized stylus/pen could be offered for the customer to use,”³ pharmacists are finding that this is very difficult to implement in practice. We have heard from our members that the signature unit is on the other side of the Plexiglas now in place in many community pharmacies, making it difficult and

¹ Consumer Healthcare Products Association. Pseudoephedrine. Last Accessed: April 15, 2020, available at: <https://www.chpa.org/Meth.aspx>

² Combat Methamphetamine Epidemic Act of 2005. See 21 U.S.C. 830(e)(1)(A), available at: <https://codes.findlaw.com/us/title-21-food-and-drugs/21-usc-sect-830.html>

³ DEA. COVID-19 FAQ. Last accessed: April 15, 2020, available at: https://www.deadiversion.usdoj.gov/faq/coronavirus_faq.htm#PSEUDO

impractical to clean after every use. Pharmacists and pharmacy personnel are under significant stress from staff shortages and excessive demands during COVID-19 and it significantly disrupts operations and workflow to leave the pharmacy area to clean the stylus/pen on the other side of the Plexiglas. Furthermore, there is a glove shortage and it is impractical to offer gloves to patients. When disinfectant and hand sanitizer is left on the pharmacy counter, it is often stolen or misused. Recent pharmacy specific guidance by the Centers and Disease Control and Prevention⁴ and the Occupational Safety and Health Administration⁵ acknowledge the heightened level of concern and need for controls in pharmacies to minimize pharmacy personnel risk of exposure to the virus and reduce the risk for customers during the COVID-19 pandemic.

Given the risks of transmission of COVID-19 from the pen/stylus, APhA believes that requiring the review and recordation of the patient's driver's license number in order to purchase OTC PSE products should be deemed to be a sufficient form of identification and documentation for the duration of the pandemic.

In order to protect patient health and ensure access to OTC PSE products, APhA urges DEA to expeditiously revise the FAQ document to indicate that DEA will exercise its enforcement discretion and not require a signature for the purchase of these products during the COVID-19 pandemic.

Thank you for your attention to this issue. We look forward to DEA's response to our request. Please contact Karin Bolte, JD, Director, Health Policy, at kbolte@aphanet.org if you have any questions.

Sincerely,



Ilisa BG Bernstein, PharmD, JD
Senior Vice President, Pharmacy Practice and Government Affairs

⁴ Centers for Disease Control and Prevention. Considerations for Pharmacies During the COVID-19 Pandemic. Last accessed April 16, 2020 at www.cdc.gov/coronavirus/2019-ncov/hcp/pharmacies.html

⁵ OSHA. COVID-19 Guidance for Retail Workers. Last accessed April 16, 2020 at www.osha.gov/Publications/OSHA3996.pdf.