APhA
2215 Constitution Avenue, NW • Washington, DC 20037-2985

April 22, 2019

Re: Docket No. DEA 453; Proposed Rule: New Single-Sheet Format for U.S. Official Order Form for Schedule I and II Controlled Substances

Dear Sir/Madam:

The American Pharmacists Association ("APhA") welcomes the opportunity to respond to the Drug Enforcement Agency's proposed rule, "New Single-Sheet Format for U.S. Official Order Form for Schedule I and II Controlled Substances" (hereinafter, "Proposed Rule"). APhA, founded in 1852 as the American Pharmaceutical Association represents 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.

APhA appreciates efforts to modernize and improve workplace and administrative efficiencies for DEA registrants using DEA Form 222 to order schedule I and/or Schedule II controlled substances. Generally, APhA supports modifying the single-sheet form to enhance security features to both ensure the identity of the original and make copying for counterfeit purposes more difficult. However, APhA does have concerns regarding the shift to the new single-sheet form and seeks clarity from DEA.

I. Transition from Current to New Order Form

The Proposed Rule indicates DEA registrants will be allowed to exhaust their supply of the current triplicate order forms as part of the transition period and that two years after the final rule becomes effective, use of the triplicate forms would not be allowed. However, the Proposed Rule does not indicate if registrants' handling and recordkeeping practices when using the triplicate Form 222 will remain the same or if any of the changes indicated in the Proposed Rule will apply.

II. National Drug Code

Currently, Form 222 provides space for inclusion of the National Drug Code (NDC). The Food and Drug Administration has indicated that the format of the NDC is expected to change when FDA runs out of 5-digit labeler codes.[1] As DEA considers developing and implementing the new Single-Sheet Format, we encourage the agency to coordinate efforts with the Food and Drug Administration to ensure the new Single-Sheet Format does not conflict with or can be adapted to the future format of the NDC.

[1] *See* Food and Drug Administration, (November 2018), Public Hearing: Future Format of the National Drug Code, available at: https://www.fda.gov/Drugs/NewsEvents/ucm574488.htm, last accessed: April 9, 2019.

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III. Copy Retention

The Proposed Rule requires "purchasers" (e.g., pharmacies, practitioners, hospitals and clinics), registrants who execute DEA Form 222 to order Schedules I and II controlled substances, to "make a copy (photocopy or scan) prior to submission to a supplier." For "dispensing suppliers" (e.g., physicians, pharmacies, hospitals, clinics, etc.), the Proposed Rule provides similar flexibility by allowing them to submit by fax or email their copy of the order form to DEA. APhA notes that different devices (e.g., smartphone), other than a photocopier or scanner, could be used to obtain images of DEA Form 222. APhA encourages DEA to provide flexibility to purchasers and dispensing suppliers regarding methods used to obtain a copy and clarify a picture and/or image is an acceptable type of copy. Doing so will provide flexibility and convenience for purchasers and dispensing suppliers in their compliance efforts.

APhA supports DEA's decision to now provide purchasers with flexibility regarding the retention of order completed forms by allowing purchasers to retain the original of the single-sheet form or to make and retain readily retrievable copies of the form. APhA believes such flexibility will improve work flow and administrative efficiencies, and limit expenditures associated with the Proposed Rule once implemented. We strongly encourage DEA to retain this policy as the agency finalizes the Proposed Rule.

APhA supports DEA's efforts to improve DEA Form 222 and appreciates the opportunity to comment on this Proposed Rule. Should you have any questions please contact, Jenna Ventresca, Director, Health Policy, by email jventresca@aphanet.org or phone (202) 558-2727.

Sincerely,

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Mitchel C. Rothholz, RPh, MBA
Chief Strategy Officer