



Via Electronic Submission to: www.regulations.gov

September 28, 2020

Drug Enforcement Administration
Attn: DEA Federal Register Representative/DPW
8701 Morrissette Drive
Springfield, VA 22152

Re: RIN 1117-AB57/Docket No. DEA-547

Dear Sir or Madam:

The American Pharmacists Association (APhA) is pleased to submit our comments to the Drug Enforcement Administration (DEA) on the *Reporting of Theft or Significant Loss of Controlled Substances* proposed rule, published in the Federal Register on July 29, 2020 (85 FR 45547). Founded in 1852, APhA represents 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, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

APhA appreciates DEA's efforts to prevent the diversion of controlled substances, and supports DEA's proposal to require DEA Form 106 to be submitted electronically. **However, we strongly oppose the proposed 15-day deadline to file a complete and accurate DEA Form 106 following theft or significant loss of controlled substances, because we believe that this time frame is unreasonable and would place an undue burden on registrants.**

Currently, DEA's regulations require that registrants notify the DEA Field Division Office in their area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such theft or loss, to be followed by the filing of DEA Form 106 with the same field division office once the facts and circumstances of the theft or significant loss are determined.¹ The regulations are silent as to the DEA Form 106 filing deadline.

APhA is concerned that a 15-day deadline to file DEA Form 106 is an insufficient time frame for registrants to complete a thorough investigation into the theft or significant loss of controlled substances. If the registrant cannot complete the investigation within the 15-day period, then that

¹ See 21 CFR 1301.74(c) and 1301.76(b).

submission would not be “complete and accurate” as DEA is proposing to require. APhA notes that in response to a 2005 proposal that a 30-day deadline be established for filing DEA Form 106, DEA declined to designate a particular timeframe. Rather, DEA recognized that it may be “difficult to comply with in some cases, so [DEA] prefers to retain the registrant flexibility provided..., i.e., DEA Form 106 should be submitted once the circumstances surrounding the theft or significant loss are clear, but updates should be provided to DEA if the investigation takes more than two months.”² **APhA agrees with DEA’s previous decision and rationale, and opposes DEA’s current 15-day filing proposal. Instead, APhA recommends that DEA establish a more reasonable 60-day filing deadline in order to allow registrants adequate time to conduct thorough investigations and submit complete and accurate DEA Form 106’s.**

Should DEA choose to move forward with a filing deadline for DEA Form 106 shorter than 60 days, APhA urges the agency to delay the effective date of the filing requirement until after the COVID-19 public health emergency has ended. Delaying implementation of the new timeframe will allow pharmacist registrants to continue to focus their attention and efforts on COVID-19 testing, vaccination, and continued care of their patients.

Furthermore, if DEA chooses to establish a 15-day or shorter than 60-day filing period, APhA respectfully requests that DEA clarify in its regulations that the agency will accept supplemental Form 106’s after the initial filing period has expired. DEA should also allow registrants to supplement their initial Form 106’s to correct any “inaccurate” or “incomplete” information based on the later discovery of additional facts or upon completion of an investigation.

APhA appreciates the opportunity to provide comments on this important issue, and urges DEA not to move forward with its 15-day filing proposal. If you have any questions or require additional information, please contact Karin Bolte, Director, Health Policy, at kbolte@aphanet.org or by phone at (301) 648-0673.

Sincerely,



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

² Reports by Registrants of Theft or Significant Loss of Controlled Substances, 70 Fed. Reg. 155 (August 12, 2005), Pages 47094-47097.