



Via Electronic Submission to: www.regulations.gov

January 4, 2021

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

Re: RIN 1117-AB47/Docket No. DEA-437

Dear Sir or Madam:

The American Pharmacists Association (APhA) is pleased to submit our comments to the Drug Enforcement Administration (DEA) on the Suspicious Orders of Controlled Substances proposed rule, published in the Federal Register on November 2, 2020 (85 FR 69282). 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. **However, we believe that the proposed rule places unreasonable requirements and an undue burden on dispensers (pharmacies and pharmacists) that distribute controlled substances pursuant to the “five percent rule” and Narcotic Treatment Programs (NTPs) compounding narcotics for treatment programs and other locations.** Our specific concerns with the proposed rule appear below:

Undue Burden on Dispensers

APhA respectfully disagrees with DEA's contention that "there is no added cost associated" with the new two-option framework. Rather, the proposed rule places a significant new burden on NTPs and dispensers covered by the five percent rule by requiring them to design and operate a system to identify suspicious orders of controlled substances in order to address the few times they might distribute controlled substances to other programs or dispensers. The financial impact will be greatest on dispensers in community pharmacies that do not already have an electronic data capture and reporting system in place.

Pharmacies or NTPs may distribute controlled substances to another pharmacy or treatment program in order to meet patient care needs. For example, a pharmacy that serves a hospice might have a need for an additional supply of controlled substances to dispense to the hospice's patients. In that instance, the pharmacy might choose to request the required amount from another pharmacy. Under DEA's proposed rule, the pharmacy receiving the order would need to determine whether it constitutes a "suspicious order," with little to no information to make that determination. Rather than risk running afoul of DEA requirements, pharmacies or NTPs might choose to simply NOT distribute any controlled substances to other pharmacies or programs, thus impacting patient access to needed medications.

In addition to the chilling effect on pharmacies and NTPs working together with other pharmacies and programs to address patient care needs, drug shortages, and cases of either overstocking or understocking of controlled substances, APhA has the following additional concerns about the proposal:

Two Option Framework

In the proposed rule, upon receipt of an order received under suspicious circumstances (ORUSC), registrants authorized to distribute controlled substances will have a choice under the two-option framework to either:

- (1) Immediately file a suspicious order report through the DEA centralized database, decline to distribute pursuant to the suspicious order, and maintain a record of the suspicious order and any due diligence related to the suspicious order, or
- (2) before distributing pursuant to the order, conduct due diligence to investigate each suspicious circumstance surrounding the ORUSC, and maintain a record of its due diligence regarding the ORUSC.

Under the second option, if, through its due diligence, the registrant is able to dispel each suspicious circumstance surrounding the ORUSC within seven calendar days after receipt of the order, it is not a suspicious order. After that determination is made, the registrant may thereafter distribute pursuant to the order. The order need not be reported to the DEA as a suspicious order, but the registrant must maintain a record of its due diligence.

However, if the registrant is unable, through its due diligence, to dispel each suspicious circumstance surrounding the ORUSC within seven calendar days after receiving the order, it is a suspicious order. The registrant must then promptly file a suspicious order report through the DEA centralized database, decline to distribute pursuant to the suspicious order, and maintain a record of its due diligence.

APhA Comments

As stated above, APhA is concerned about the burden on dispensers and NTPs resulting from the requirement for registrants to investigate and dispel *each* suspicious circumstance surrounding an ORUSC within seven calendar days and document due diligence.

APhA believes that seven calendar days is too short a time frame for investigation and reporting. DEA's proposed seven calendar day time frame does not take into account holiday periods, bad weather, computer system breakdowns, or other situations beyond the registrant's control that might interfere with conducting an investigation and submitting the required report.

If DEA chooses to move forward with a specific time frame, APhA recommends that the agency establish at least ten business days as a more reasonable requirement for investigating and reporting an ORUSC. APhA also recommends that DEA allow registrants to request an extension of the time frame in order to provide sufficient time to file the required report and recordkeeping.

Definitions

As discussed below, APhA is very concerned that the definitions included in the proposed rule lack clarity, creating significant uncertainty and confusion among registrants about how to ensure compliance with the suspicious order regulations. Given the substantial impact of these definitions on how registrants handle suspicious orders of controlled substances, APhA urges DEA to carefully consider APhA's and other stakeholders' requests for clarity and any recommendations for revised definitions.

Due Diligence

The proposed rule adds a definition of "Due Diligence" to §1300.01 (b): "Due diligence means a reasonable and documented investigation into persons and orders (coupled with other appropriate investigations, including previous investigations into persons and orders) that includes, but is not limited to, verification that a person (or a person submitting an order) holds the appropriate DEA registration, verification that a person (or a person submitting an order) holds all licenses required by the state(s) in which a person (or a person submitting an order) conducts business with respect to controlled substances, examination of each suspicious circumstance surrounding an order, and examination of all facts and circumstances that may be relevant indicators of diversion in determining whether a person (or a person submitting an order) is engaged in, or is likely to engage in, the diversion of controlled substances."

APhA Comments

APhA is concerned that the proposed definition of due diligence is overly broad and creates too much room for subjectivity. Specifically:

- "...examination of each suspicious circumstance surrounding an order" should be changed to "examination of each *identified* suspicious circumstance surrounding an order" (emphasis added). Adding "identified" will ensure that registrants are only held responsible for suspicious circumstances of which they are actually aware, not those that DEA might later deem to be suspicious.
- "...examination of all *facts and circumstances* that may be relevant indicators of diversion" (emphasis added) is quite broad. The proposed rule does not provide clarity on

the types of information that should be reviewed in order to meet a registrant's obligations. The rule should provide examples of the types of "facts and circumstances" DEA considers relevant indicators of diversion.

- "...in determining whether a person (or a person submitting an order) is engaged in, *or is likely to engage in*, the diversion of controlled substances" (emphasis added). APhA recommends that DEA delete "or is likely to engage in" from the definition, because it is unreasonable to require registrants to intuit future behavior or investigate business practices of the person submitting an order so as to determine what they will likely do with the controlled substances.
- In addition, APhA is concerned that the definition's requirement for registrants to "verif[y] that a person (or a person submitting an order) holds all licenses required by the state(s) in which a person (or a person submitting an order) conducts business with respect to controlled substances" is overly burdensome, especially for busy community pharmacists. This licensing information might be difficult for dispensers to obtain.

Order

"Order means *any communication* by a person to a registrant proposing or requesting a distribution of a controlled substance, regardless of how it is labeled by the person or the registrant, and regardless of whether a distribution is made by the registrant, except that simple price/availability inquiries, standing alone, do not constitute an order" (emphasis added).

APhA Comments

Like the proposed definition of "due diligence," APhA is concerned that the proposed definition of "order" is overly broad, greatly expanding the universe of what could be considered an order. As proposed, "any communication" could include a verbal communication. At the very least, APhA recommends that DEA specify in the definition that order means any written communication (either hardcopy or electronic). APhA agrees that "simple price/availability inquiries, standing alone, do not constitute an order."

Suspicious Order

"Suspicious order includes, *but is not limited to*, an order of unusual size, an order deviating substantially from a normal pattern, or an order of unusual frequency" (emphasis added).

APhA Comments

Again, APhA is concerned that the language "but is not limited to" does not provide clarity or guidance to registrants as to what constitutes a suspicious order, beyond orders of unusual size, frequency, and/or pattern. This leaves ambiguity and uncertainty regarding DEA's compliance and enforcement approach, opening the door for DEA to be arbitrary and capricious in its actions. DEA should provide additional notice and comment rulemaking or guidance that provides clarity for registrants on what constitutes a suspicious order.

Reporting a Suspicious Order

§ 1301.78 adds “Procedures for identifying and reporting suspicious orders of controlled substances.” All suspicious order reports must be made to the DEA centralized database, and must include:

- (i) The DEA registration number of the registrant placing the order for controlled substances;
- (ii) The date the order was received;
- (iii) The DEA registration number of the registrant reporting the suspicious order;
- (iv) The National Drug Code number, unit, dosage strength, and quantity of the controlled substances ordered;
- (v) The order form number for schedule I and schedule II controlled substances;
- (vi) The unique transaction identification number for the suspicious order; and
- (vii) What information and circumstances rendered the order actually suspicious.

APhA Comments

APhA is concerned about the significant expansion and lack of specificity of the proposed new reporting and recordkeeping requirements. With regard to §1301.78 (b)(1)(vii): “What information and circumstances rendered the order *actually* suspicious” (emphasis added), APhA notes that “actually” is not in keeping with the two-option framework, in which the registrant has the option to immediately file a suspicious order report through the DEA centralized database without having conducted an investigation. In this case, it is not known whether the ORUSC is “actually suspicious.” APhA recommends that DEA delete “actually” from clause (vii). In addition, DEA might also consider adding a new clause (viii) requiring reporting of whether the registrant investigated the order.

Recordkeeping for Suspicious Orders and ORUSCs

The proposed rule requires the registrant to maintain a record of every suspicious order and ORUSC, and how the registrant handled the order, for two years. The record must be prepared no later than seven calendar days after the suspicious order or ORUSC was received and must include the following information:

- (1) What information and circumstances rendered the order actually or potentially suspicious;
- (2) What steps, if any, the registrant took to conduct due diligence;
- (3) If the registrant conducted due diligence, what information it obtained during its investigation, and where the registrant concludes that each suspicious circumstance has been dispelled, the specific basis for each such conclusion; and
- (4) Whether or not the registrant distributed controlled substances pursuant to the order.

APhA Comments

As noted above, APhA is concerned about the significant expansion and lack of specificity of the proposed new reporting and recordkeeping requirements. Regarding recordkeeping, the proposed

rule specifies that it would require more than just a “check-the-box” type of documentation, thus greatly expanding the rigor, care, attention, and burden of reporting and recordkeeping. The proposed reporting and recordkeeping requirements are also likely to increase registrants’ cost of compliance, which does not appear to be considered in the economic analysis.

Compliance Date

APhA urges DEA to allow a lead time of at least one year for the development and implementation of suspicious order monitoring systems and compliance with the rule. Especially since we are still in the midst of the COVID-19 pandemic, delayed implementation of the rule will allow pharmacists to continue to focus their attention and efforts on COVID-19 testing, vaccination, and continued care of their patients.

Conclusion

APhA appreciates the opportunity to provide comments on this important issue. We support DEA’s efforts to eliminate diversion of controlled substances and stand ready to provide insights and views of pharmacists across the country. 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,

A handwritten signature in black ink, appearing to read "Ilisa BG Bernstein".

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