March 29, 2021

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

Re: Suspicious Orders of Controlled Substances; RIN 1117-AB47/Docket No. DEA-437

Dear Sir or Madam:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments in response to the Drug Enforcement Administration (DEA) proposed rule on *Suspicious Orders of Controlled Substances*.

NCPA represents America's community pharmacists, including over 21,000 independent community pharmacies. Almost half of all community pharmacies provide long-term care services (LTC) and play a critical role in ensuring patients have immediate access to medications in both community and LTC settings.[1] Together, our members represent a $74 billion healthcare marketplace, employ approximately 250,000 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. NCPA fully acknowledges and supports DEA's legal authority to implement regulations designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for a sufficient supply of controlled substances and listed chemicals for legitimate medical purposes. To that end, NCPA submits these comments on behalf of both community and LTC independent pharmacies.

<u>Two-Option System for Identifying and Reporting Suspicious Orders</u>
DEA proposes to revise its regulations relating to suspicious orders of controlled substances, in order to implement the *Preventing Drug Diversion Act of 2018* (PDDA) and to clarify the procedures a registrant must follow for orders received under suspicious circumstances (ORUSCs). Upon receipt of an ORUSC, registrants authorized to distribute controlled substances would have a choice of proceeding under one of two options:

1. Registrants can file a suspicious order report immediately through the DEA centralized database, decline to ship the ORUSC, and maintain a record of the ORUSC and any related due diligence; or

[1] National Community Pharmacists Association (2020). *2020 NCPA Digest.* Retrieved from https://ncpa.org/sites/default/files/2020-10/2020-Digest.pdf

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2. Registrants may conduct due diligence in order to "dispel each suspicious circumstance surrounding the ORUSC within seven calendar days." If registrants are able to do so, they must maintain a record of the due diligence conducted to meet this burden, and then may ship the order. If the registrant is unable to "dispel each suspicious circumstance" within seven days, they are required to file a suspicious order report through the DEA centralized database and must not ship the order.

In the proposed rule, DEA asserts that "there is no added cost associated" with the new two-option framework because it is a "codification of existing practices." However, the burden and cost with identifying and reporting suspicious orders may in fact increase, given the proposal's broad language requiring registrants to "dispel each suspicious circumstance surrounding the ORUSC" within seven days and specifically document due diligence. In addition, the proposed rule purports to require registrants to design a system "not only to identify size, pattern, and frequency [of] orders, but also to identify suspicious orders based on facts and circumstances that may be relevant indicators of diversion in determining whether a person…is engaged in, or is likely to engage in, the diversion of controlled substances." The proposed rule does not, however, provide further clarity regarding what constitutes "facts and circumstances that may be relevant indicators of diversion," thus providing no guidance to registrants to determine what information should be reviewed and what, if any, external data may be required to purchase, collect, or analyze to meet its obligations.

While NCPA agrees that under optimal conditions seven calendar days for each of these requirements would be sufficient time to conduct these activities, the proposed rule does not take into consideration situations outside the control of registrants which would impact this timing and put the registrant in violation of the proposed regulation, such as, but not limited to: holidays, extreme weather events, natural disaster, or disruptions due to civil unrest. **NCPA recommends, instead of seven calendar days, ten business days, which should assure an adequate amount of time for investigation and reporting is available to registrants whenever the ORUSC is received while meeting DEA's goal of timely reporting of suspicious orders and helping to ensure registrant compliance by creating an achievable requirement**. In addition, there is no option for a registrant to request an extension to the reporting deadline in the proposed rule; NCPA requests clarification as to whether it will be possible for registrants to request such an extension.

<u>New Recordkeeping and Reporting Requirements</u>
In addition, the proposed rule sets forth four material changes to reporting and recordkeeping requirements:

1. The proposed rule would require registrants to report any suspicious order within seven calendar days after it is received. The current regulations require that suspicious orders

be reported "when discovered," without specifying a timeframe in which a determination regarding suspicious must be made.[2]

2. The proposed rule would require registrants to maintain a record of every suspicious order and ORUSC for at least two years, and all records must be prepared within the original seven-day diligence window. These requirements are purportedly designed to enable DEA to review a registrant's decision to release ORUSCs.
    a. This requirement will likely allow DEA to more easily dispute a registrant's decision to release ORUSCs
    b. This requirement also prevents registrants from relying on due diligence conducted promptly but only documented at a later date.
3. The proposed rule would require registrants to include certain information in all suspicious order and ORUSC records. Specifically, these records include: 1) the "information and circumstances [that] rendered the order actually or potentially suspicious"; 2) the 'steps, if any, [that] the registrant took to conduct the due diligence"; 3) the "information [that] 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) "[w]hether or not the registrant distributed controlled substances pursuant to this order."

The proposed rule does not further specify the scope of this new recordkeeping provision other than that it "would require more than just a 'check-the-box' type of documentation." **NCPA requests DEA to further clarify the requirements of this new recordkeeping provision in the final rule**. Taken together, the new recordkeeping and reporting requirements in the proposed rule mark a significant change from existing regulations, and, if incorporated into the final rule, will require a comprehensive review of registrants' existing suspicious order monitoring program and recordkeeping practices. **When determining compliance dates in the final rule, NCPA requests DEA take into account that registrants will require adequate time to update their suspicious order monitoring systems consistent with the requirements of the final rule, which will likely involve updates to registrants' order review procedures and documentation standards, technology updates and enhancements, and modifications to policies and procedures—all while continuing to respond to the ongoing public health emergency (PHE) presented by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and associated coronavirus disease (COVID-19).**

<u>New Definitions for Suspicious Order Monitoring</u>

The proposed rule sets forth certain definitions in support of the new framework, in particular modifying the definition of "suspicious order"—a central term in the existing regulation—and adds definitions for three new terms: 1) "order," 2) "order received under suspicious circumstances" (ORUSC), and 3) "due diligence."

[2] 21 C.F.R. § 1301.74(b).

The proposed rule incorporates the definition of "suspicious order" as set forth in the PDDA. For almost 50 years the term "suspicious order" was defined to include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.[3] The new definition expands the current understanding of that term by specifying that a suspicious order "includes, but is not limited to" those three types of orders, and further notes that the in the new definition "an order for controlled substances can be deemed suspicious for reasons other than size, pattern, or frequency (including reasons related to the characteristics of the customer submitting the order)."NCPA is concerned that the proposed rule would codify vague and subjective standards for what constitutes a suspicious order and an ORUSC, which would lead to wholesale distributors developing dissimilar policies for identifying and resolving these orders. A clearer standard is needed to promote consistency across wholesalers to guide distributors as to the different circumstances triggering a suspicious order investigation. **NCPA requests DEA amend the definition to clarify the specific indicators that an order is a suspicious order or an ORUSC. In addition, as the proposed definition states that "an order can be deemed suspicious for reasons other than size, pattern, or frequency (including reasons related to the characteristics of the customer submitting the order)," we ask DEA to explicitly clarify what these other reasons are, and to clarify whether size, pattern, or frequency are the expected standard circumstances that would trigger a due diligence investigation.**

NCPA is concerned that the definition of "order" in the proposed rule—"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," reflects a far broader understanding of the term than is common in the industry.[4] **NCPA requests clarification regarding the definition of "order," particularly "regardless of how it is labeled by the person or the registrant."** The proposed definition provides insufficient clarity; for example, if a registrant submits an order to a wholesaler, of which there are multiple products with one or more products being controlled substances, but which do not comprise the totality of the order, wholesalers can file a suspicious order report immediately through the DEA centralized database and decline to ship the ORUSC as per the first option in the proposed two-option framework. However, the proposed definition of "order" does not make it clear whether a wholesaler would decline to ship the order in its totality, including products that are not controlled substances, or if the wholesaler would only decline to ship the controlled substance that triggered the ORUSC.

Furthermore, **NCPA is concerned that the expansive definition for "due diligence" in the proposed rule is insufficient in regards to the scope of a registrant's responsibilities and may result in extensive information requests from wholesaler distributors to pharmacies that could inadvertently insert the distributor into pharmacist professional judgment, which would be unnecessary and overly burdensome; therefore NCPA requests DEA further clarify in its**

[3] 21 C.F.R. § 1301.74(b).
[4] "except that simple price availability inquiries, standing alone, do not constitute an order."

definition of "due diligence" the scope of a registrant's duties. For example, it is unclear what constitutes an "examination of each suspicious circumstance surrounding an order," or an "examination of all facts and circumstances that may be relevant indicators of diversion" or likely diversion. Of particular concern is the inclusion in the definition of "due diligence" that a determination must be made whether "a person (or a person submitting an order) is…likely to engage in, the diversion of controlled substances," which requires a registrant to conjecture about a person's future intentions. **NCPA finds this to be both inappropriate and infeasible and recommends that the language requiring registrants to make conjectures regarding the potential future actions of a person be removed from the definition of "due diligence."**

Certain Practitioners and Dispensers to be Subject to Suspicious Order Monitoring Regulations

The proposed rule would amend DEA regulations to clarify that entities including practitioners, hospitals, and dispensers that distribute pursuant to the "five percent rule"—which allows entities to distribute up to five percent of their controlled substances to other dispensers under certain circumstances—design and operate a suspicious order monitoring system. While DEA asserts that such registrants "already understand" that they must maintain suspicious order monitoring systems under the CSA's "effective controls" requirement, the existing regulation—§1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs—requiring registrants to design and operate a suspicious order monitoring program it is not made explicitly clear in the title that it applies to pharmacies and other entities that routinely and legally distribute pursuant to the "five percent rule," especially as pharmacists are generally not considered to be non-practitioners. [5,6] **NCPA requests that DEA clarify the applicability of §1301.74 to pharmacists explicitly in its title as well as specifically reference this requirement at §1307.11**. In addition, the definition of a "system" in this context — "a combination of people, process, and tools (such as an information system)" is overly broad and insufficient to provide the kind of guidance pharmacies need to meet the proposed monitoring requirement. **NCPA requests that DEA clarify the minimum requirements of a suspicious monitoring system, provide explicit guidance to pharmacies on the scope of their responsibilities in the use of such systems, and take into account the ongoing COVID-19 PHE when determining the effective date of the proposed rule.** Independent community pharmacies have a critical role not only in the overall COVID-19 response, but especially now as the COVID-19 vaccination campaign moves forward; the involvement of independent pharmacies in the vaccination program is critical to reaching individuals who live in small towns, rural areas, and other medically underserved communities where other pharmacies or health care providers are absent. Requiring our members, many of whom do not have a depth of experience designing or operating such systems as required in the proposed rule, creates an

[5] Notice, 85 Fed. Reg. at 69,290.

[6] 21 C.F.R. § 1301.74 ("Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs."

undue burden that will take away from critical patient care activities, especially COVID-19 vaccination efforts.

NCPA greatly appreciates the opportunity to share with you our comments and suggestions on DEA's proposed rule on *Suspicious Orders of Controlled Substances*. Please feel free to contact me with any further questions at ronna.hauser@ncpa.org.

Sincerely,

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Vice President, Policy & Government Affairs Operations