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Healthcare Distribution Alliance

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January 4, 2021

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

RE: Notice of Proposed Rulemaking: Suspicious Orders of Controlled Substances [85 Fed. Reg. 69282 (November 2, 2020)] Docket No. DEA-437

Dear Sir or Madam:

The Healthcare Distribution Alliance (HDA) appreciates this opportunity to provide comments to the Drug Enforcement Administration (DEA) regarding the Proposed Rule "Suspicious Orders of Controlled Substances" ("proposed rule" or "proposal") [85 Fed. Reg. 69282 (November 2, 2020)] Docket No. DEA-437.

HDA represents primary pharmaceutical distributors – the vital link between the nation's pharmaceutical manufacturers and more than 180,000 pharmacies, hospitals, long-term care facilities, clinics, and others nationwide. This essential function is provided with little public recognition or visibility, and at great savings to the healthcare system. HDA members serve as the central link in a sophisticated national supply chain. HDA members take this mission very seriously, and we support manufacturers, healthcare providers, and the government in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient, and highly regulated.

INTRODUCTION

HDA recognizes, and supports, the Agency's effort to implement the Preventing Drug Diversion Act of 2018 (PDDA), which in effect codified existing practices related to identification and reporting of suspicious orders. We also appreciate that the proposed rule is intended to be an important step in aiding the fight against the current public health crisis of abuse and misuse of controlled substances. Thus, HDA and its members recognize that the prevalence of controlled substance misuse warrants a concurrent and concerted effort to update the regulations pertaining to the suspicious order reporting requirement.

As DEA is aware, over the last 15 years, the pharmaceutical supply chain as a whole has taken significant steps to improve upon policies and procedures related to suspicious orders. As discussed in more detail

below, these comments are intended to help ensure that these regulations promote the ongoing public interest in preventing abuse and misuse while minimizing any disruption to efforts to efficiently supply medicines to patients who need them.

Providing meaningful comments on all aspects of the proposal in the 60-day time frame, given its scope and the importance of ensuring that DEA and registrants move forward with a full understanding of the expectations for suspicious order monitoring, is a highly challenging endeavor. In view of the significance of this rulemaking, our members have supported the creation of the comments contained in this letter.

However, we wish to emphasize that the rule has the potential to significantly impact both the way in which distributors help to prevent the abuse and misuse of controlled substances, as well as the customers and patients who rely on the swift, safe and accurate distribution of the products they need for medical care. HDA's members take their role in the supply chain, and their responsibilities for compliance with DEA's regulations and guidance, very seriously. Moreover, to HDA's knowledge, this would be the first substantive change to the suspicious orders regulation in almost 50 years.

Thus, it is critically important to provide additional time to respond and we, therefore, renew our request for an extension of the comment period HDA provided to the docket last month.[1] We believe the additional 90 days requested, to April 4, 2021, would help enable us to perform an even more extensive review and analysis of the proposals, and to offer what we believe will be an even more thorough set of comments that will benefit all parties, including the Agency, as consideration is given to a final rule's development. Given that these comments are being submitted as of the current due date of January 4, 2021, HDA recognizes that under rulemaking procedures, the appropriate action may be for DEA to reopen the public comment period, rather than extending the current deadline. Therefore, we would defer to DEA's judgment to determine the appropriate administrative mechanism by which an additional 90 days for providing public comments could be established.

Finally, we also propose that DEA consider holding a meeting with the appropriate stakeholders after the comment period closes. We believe the goals of such a meeting would be to promote further discussion, aid implementation of systems that will benefit both DEA and the healthcare industry, and foster cooperation to further the public interest and dual objectives of preventing the misuse of controlled substances, while providing pharmaceutical products to the patients who genuinely need them.

PRELIMINARY COMMENTS

1. HDA Generally Agrees with DEA's Proposed "Two-Option Framework" for Identifying and Reporting Suspicious Orders.

HDA appreciates DEA's effort to propose a process for reviewing and submitting reports of suspicious orders of controlled substances, a process that includes a "two-option framework." As noted in the

[1] *See*: Letter from Anita T. Ducca, HDA, to Docket # DEA-437 Suspicious Orders of Controlled Substances, dated Dec. 11, 2020, Comment Tracking Number: 1k4-9klr-iq8b.

proposal, registrants (including most wholesale distributors) have already generally implemented a version of either of the two options outlined as fundamental elements of their current suspicious order reporting systems. Given the differences in how registrants approach their reporting responsibilities, we believe this framework allows for a workable approach to evaluating and reporting suspicious orders.

Under the first option (Option 1), if a registrant receives an Order Received Under Suspicious Circumstances (ORUSC), the registrant may immediately cancel and report the order to DEA as suspicious. DEA also proposes a second option (Option 2) wherein the registrant may conduct a further evaluation of the ORUSC to dispel all circumstances that initially rendered the order potentially suspicious, and after having successfully done so, may ship the order. Otherwise, the registrant must cancel the order and report it to DEA as suspicious within the designated time period.

As explained in the preamble,

> The DEA is revising its regulations relating to suspicious orders of controlled substances… 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 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.[2]

We believe incorporating this "two-option framework" into DEA regulations represents a common-sense approach to evaluating and reporting suspicious orders. It also allows wholesale distributor registrants a certain amount of flexibility in their effort to balance the competing public health priorities of continuing to support crucial patient care when orders are needed while helping avoid the abuse and misuse of these controlled substances.

2. HDA Supports DEA's Clarification that a Registrant Must Decline to Distribute an Order Reported to DEA as a Suspicious Order

The rule proposes to clarify an area of order fulfillment practice that, until now, has not been addressed in DEA's regulations. Specifically, we are referring to the scope of a registrant's responsibility when an order is designated by the registrant as "suspicious" and reported as such. Clarifying that the registrant must "decline to distribute" an ORUSC, and, likewise, decline to distribute if the order is ultimately reported as suspicious, removes this uncertainty. HDA believes the clarification is appropriate and agrees with its inclusion.

[2] Page 69283, col. 2 (footnotes omitted).

3. HDA Agrees that Suspicious Orders should be Electronically Reported to a DEA Centralized Database

The proposal specifies that registrants should "file a suspicious order report through the DEA centralized database." HDA and its members fully agree with this directive. Submission of all reports to a single, centralized database, rather than separately to various DEA field offices will ease the reporting process for registrants and simplify DEA's management of the reports.

4. The Definition of "Order" Contained in the Proposed Rule is Vague, Excessively Broad and Should be Limited.

The rule proposes to add the following definition of "**Order**" to §1300.01(b):

> 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. [3] [emphasis added]

This very broad definition coupled with its lack of specificity raises a number of questions as to how the definition should be interpreted. We note that "any communication" could be interpreted to include informal verbal discussions, questions received by electronic mail, or other communications which would be inappropriate in the context of identifying and reporting suspicious orders. Further, such communications could generally include discussions regarding business arrangements between a wholesale distributor and a customer, or a prospective customer, about the wholesale distributor's services. For example,

- The proposed definition might be interpreted to include the process of applying to become a customer, approved by the registrant, to order controlled substances, such as when a potential customer's application to begin sourcing controlled substances from a wholesale distributor occurs long before the applicant places its first "order" as an actual customer.
- A customer's request for an increase in the total volume of controlled substances they purchase due to a legitimate and demonstrable increase in demand, *e.g.,* by discussing a change in the terms of the customer's contractual arrangement with the distributor, even though the customer had not actually "ordered" any additional product.

While neither of the above-described situations are considered "orders" by wholesale distributors, the proposed rule is ambiguous as to whether such customer interactions constitute "orders" for purposes of compliance.

Recommendation: We are hopeful that DEA will grant our comment period extension request so that we may continue our assessment of the definition of the term "order." If left as currently drafted, the proposed rule's overbroad and vague definition of "order" could lead to significant confusion and

[3] Page 69298, col. 2.

disparate outcomes in the healthcare industry, with registrants left to resolve these (and other) open questions on their own. As part of its extended evaluation, HDA will seek to further clarify the concept of "order" and potentially offer a definition for DEA's usage, one that will likely contain the following characteristics:

- The definition would not include, either directly or by implication, verbal communications (unless, for example, the wholesale distributor receives an order verbally but with a specific number and type of units identified and enters this information into their product ordering and suspicious orders monitoring systems).
- Specify that an "order" must be in writing, (*e.g.*, an order placed by a prospective purchaser on a wholesale distributor's electronic ordering system; orders provided to the wholesale distributor in hard copy, such as on a Paper Form 222; or a phone order such as one noted above, but only after it is placed on the wholesale distributor's systems).
- Clarify that the order must be quantified, for example, by a specific number of units that the purchasing registrant wishes to have delivered.
- Strive to ensure that communications of a business nature, including but not limited to, contract negotiations; inventory management-related information (*e.g.*, size, weight, or shape of a newly FDA-approved product); price; availability; etc., are not inadvertently built into the definition.

5. § 1300.01 and § 1301.74(b)(1) - Due Diligence

Section §1300.01 includes a definition of due diligence. Moreover, a key element of the definition is incorporated into the requirements for Other Security Controls in § 1301.74(b)(1). The definition reads as follows:

> *Due diligence* means a reasonable and documented investigation into **persons** and orders . . . that includes . . . 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.**[4] [emphasis added]

HDA believes that this definition creates an unreasonable requirement not contained in the statute that the registrant should seek to determine "whether a person (or a person submitting an order) is engaged in, or is likely to engage in, the diversion of controlled substances." The Controlled Substances Act's (CSA) directive is clear that registrants' obligations involve detecting and reporting suspicious "**orders**." Specifically, the CSA states:

> Reporting -- Each registrant shall—
> (1) design and operate a system to identify suspicious orders for the registrant,
> (2) ensure that the system designed and operated under paragraph (1) by the registrant complies with applicable Federal and State privacy laws; and

[4] Page 69298, col. 1 - 2.

> (3) upon discovering a suspicious **order** or **series of orders**, notify the Administrator of the Drug Enforcement Administration…[5]
> [emphasis added]

There is, importantly, no indication in the CSA that the design and operation of such a system would include examining an individual *person,* or a *person* submitting an order, and making a determination whether the *person* is engaged in, or likely engaged in, the diversion of controlled substances. Indeed, it appears that the proposal is conflating the concept of "suspicious customer" with the requirement to identify and report "suspicious orders." We support maintaining a distinct separation between these two concepts both because of the existing legal authority contained within the CSA and because, in reliance on existing laws and regulations, distributors typically undertake due diligence reviews of customers separately from their process for identifying and reporting suspicious orders.

In addition, while wholesale distributors, at various points during their interactions with customers, conduct customer-specific due diligence to determine if they should distribute (or continue to distribute) controlled substances to a particular registrant, law enforcement authorities have the exclusive authority to investigate the illegal distribution of controlled substances. The highlighted phrase could be interpreted to place the wholesale distributor in the position of attempting to determine if someone is engaged in, or likely engaged in, criminal conduct -- a position that a wholesale distributor should never, nor could ever, assume.

Recommendation: HDA recommends that DEA delete the phrase "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" from both the definition of "due diligence" and from § 1301.74(b)(1) regarding other security controls. HDA also recommends deletion of the words "persons and" from the beginning of the definition as follows: *"Due diligence* means a reasonable and documented investigation into ~~persons and~~ orders…".

6. HDA Supports the Exclusion of Reverse Distributors from the Proposed Rule but the Agency Should Correct the Process of How Order Forms are Executed when Returning Controlled Substances

The preamble clearly indicates that DEA intended to exclude reverse distributors from the suspicious orders requirements. HDA agrees with this intention, described as follows:

> …the rule does not apply to reverse distributors, who are authorized by their registration to *acquire* controlled substances for the purpose of return or destruction after receiving an order from another DEA registrant.[6]

However, HDA believes that the regulatory text in §1301.74(b)(3) may be written incorrectly. Specifically, this proposed section states:

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[5] CSA § 832 Suspicious orders; (a) Reporting.
[6] Page 69289, col. 2.

> **orders placed by registrants to DEA registered reverse distributors** requesting the return or destruction of controlled substances, are not distributions subject to the provisions of this part.[7] [emphasis added]

It appears that the wording may have been inadvertently reversed. It is the registered reverse distributors who would place the orders to return controlled substances, not the registrants, as written in the proposed language.

Recommendation: HDA believes it would be better to word this portion of the text as follows:

> … orders placed **by DEA registered reverse distributors to registrants…**

7. DEA Should Clarify that No Further Due Diligence is Required Where a Registrant Using Option 1 Immediately Reports the Order to DEA and Terminates the Order

While HDA agrees with the concept and approach to a two-option framework, we recommend certain clarifications and revisions as described below.

Section 1301.78(a)(1) specifies that a registrant, upon receipt of an ORUSC, could follow the first option by declining to distribute the order and immediately filing a suspicious order report with DEA. Should a registrant employ this option, they are also required to

> maintain a record of the suspicious order and any due diligence related to the suspicious order (which includes at least the information described in paragraph (c) of this section)[8]

and the records described in paragraph (c) include

> (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…[9] [emphasis added]

HDA believes that the statement in the D.C. Circuit's decision in *Masters Pharmaceuticals, Inc. v. DEA* that "it is not necessary for a distributor of controlled substances to investigate suspicious orders if it reports them to DEA and declines to fill them"[10] has set a precedent. Specifically, if the wholesale distributor receiving the order avails itself of Option 1, receives an ORUSC that it immediately reports to DEA, and does not distribute the product, the wholesale distributor is not

[7] Page 69298, col. 3.
[8] Page 69298, col. 2.
[9] Page 69299, col. 2.
[10] Page 69287, col. 3, *citing Masters Pharmaceuticals, Inc. v. DEA*, 861 F. 3d 206, 212-13 (D.C. Cir. 2017).

required to conduct any further investigation. Thus, consistent with established precedent, HDA interprets DEA's proposed rule to mean that the terms "if any" and "if" as highlighted, indicate that while the distributor *may* conduct further due diligence, they are *not required* to do so.

Recommendation: To avoid potential confusion, DEA should confirm that, under the first option, the proposed rule would not require further action, including conducting due diligence, on the part of the wholesale distributor registrant once an order is identified as an ORUSC, withheld from distribution, and reported to DEA.

8. DEA Should Confirm that Under Option 2, While all Suspicious Circumstances Must be Investigated Before Deciding to Ship, only One Suspicious Circumstance Need be Investigated and Documented if the Registrant Decides to Decline to Distribute and Report the Order

Section 1301.78(a)(2) also specifies that should a wholesale distributor exercise Option 2, they would then conduct due diligence to "investigate **each** suspicious circumstance surrounding the order." [emphasis added] HDA agrees with DEA's intention to require investigation of "each" suspicious circumstance surrounding the order before distributing the product.

However, a reasonable interpretation of the proposal is to *only* require that the wholesale distributor dispel *each* suspicious circumstance *before they distribute* the product. When the wholesale distributor investigates the order, they may go so far with their investigation as to identify only one (or a few) of all of the suspicious circumstances, that they are not able to dispel. In such instances, they should be able to report the order to DEA, and decline to distribute it, even if they do not investigate *each* of the additional suspicious circumstances that they have identified. This is particularly important given DEA's proposals that reports must be submitted in a very short period of time.

Recommendation: HDA requests that DEA affirmatively state that a wholesale distributor pursuing the second option may determine that the product is "suspicious" based on only one of perhaps multiple suspicious circumstances that they may have identified. Further, in this circumstance, the wholesale distributor is not required to investigate the remaining suspicious circumstances.

9. DEA Should Increase the Time Frame for Review and Reporting Suspicious Orders to a Minimum of Seven Business Days

The seven calendar-day time frame the wholesale distributor would be allowed to review and, if appropriate, report an ORUSC as suspicious is found in §§ 1301.78(2)(i) and (ii).

The preamble to the rule indicates that most suspicious orders reports are provided within seven days of the order's receipt. Therefore, the Agency postulates, registrants should be able to meet the proposed seven-day regulatory time frame for conducting due diligence and either dispel each suspicious circumstance or decline to fill the order and report it as suspicious to DEA.

However, the time frame for completing suspicious orders review experienced under the current regulations may not be applicable under the proposed regulations. DEA's proposed rule would establish new requirements not contained in the current regulations. These include, for example, a proposed new definition and new requirements for due diligence, and the concept of an ORUSC, including the recordkeeping for such orders, which are not part of the current regulations.

Moreover, there have been instances where, even under the current regulations, seven days has not been enough time to make a final determination. For example, a wholesale distributor may wish to conduct a site visit of the registrant placing the order, to better understand the order's nature and veracity. A site visit would likely require well beyond the seven-day time frame to schedule, much less to conduct, with follow-up evaluations and internal wholesale distribution company discussions, legal review, and decision-making about the order.

The circumstance described above is only one of many that could arise where more time is needed. For example, as part of their due diligence, a wholesale distributor may also need to wait for access to, or responses from, state authorities or local law enforcement to answer important questions. They may decide to conduct painstaking internet research or other efforts to complete their due diligence.

We also note that, on occasion, a registrant has reported an order as "suspicious" to DEA but sometime after the report is filed, they are able to dispel each suspicious circumstance. Currently, such instances are rare, but we believe they are more likely to occur if DEA were to impose a time limit for completing the due diligence and to report an order as suspicious. They may also become more frequent should DEA finalize such obligations as the new recordkeeping requirements and the new specifications for ORUSC orders.

Finally, because the registrant must hold the order, the potential for future misuse of the product is minimized, and it is worth remembering that the intent of the suspicious order reporting requirement is to provide DEA with information that would be useful to investigation cases of possible diversion. Thus, allowing enough time to obtain and provide complete and accurate information is critical to this process, and poses extremely little, if any, additional risk.

Recommendation: Thus, DEA should recognize that the seven calendar-day time frame is not sufficient and may require registrants to report before an investigation is complete leading to potential over-reporting of suspicious orders. We believe the following adjustments prior to finalizing the rule would be appropriate:

- HDA urges DEA to amend the deadline from seven *calendar* days to a minimum of seven *business* days. This would give registrants a little more time flexibility to conduct their due diligence, particularly useful if entities that are not employees of the wholesale distributor must be consulted for information as part of the wholesale distributor's due diligence.
- Second, we urge DEA to modify the final rule so that a wholesale distributor, or other supplier registrant, may obtain an extension of the reporting time frame. While we are open to DEA's suggestions for how this could be accomplished, we suggest that DEA incorporate into a final rule a provision for a simple notification to the registrant's local Field Office that

the registrant intends to take additional time to complete their due diligence. Should DEA prefer, the registrant could provide an estimate of the time frame the additional due diligence is expected to take. We urge DEA to make provisions for such a request as simple as possible, such as by phone conversation, and for the Field Office to be authorized, and encouraged, to respond in a timely fashion. A rapid notification and response arrangement will help avoid unnecessary reporting, or incomplete information, provided by a registrant who is uncertain about whether the request will be granted, and therefore reports in order to meet the deadline. While we anticipate such extensions will be necessary, we do not expect them to be frequent, or of long duration. Thus, extensive back-up justification should not be necessary when either DEA will have a suspicious order report shortly thereafter, or, the registrant dispels each suspicious circumstance, and determines that the order was not suspicious in the first instance. Moreover, the new recordkeeping requirements for ORUSC orders will provide DEA inspectors a means of following up on the wholesale distributor's due diligence efforts and determine if anything amiss has occurred.

10. An ORUSC Related to a Specific NDC Must be Reported/Investigated; Other Orders Received from a Customer May be Filled or Shipped

As noted earlier, it is quite common in today's healthcare delivery system for a registrant to order more than one controlled substance at a time. To complicate things further, products and their characteristics are constantly changing as new ones receive Food and Drug Administration (FDA) approval, new concentrations or packaging configurations become available, old products are taken off the market, generic versions become available, and so on. Thus, a registrant may order multiple different controlled substance Stock Keeping Units (SKUs). These controlled substances may be entirely different products, or, they may be products with similar characteristics, such as manufactured with the same active ingredient but in different concentrations or dosage forms, or are of differing packaging sizes and configurations, or may differ slightly in other ways.

The question arises as to how the wholesale distributor should interpret the definition of "order," and what becomes subject to §1301.78, if the registrant placing the order requests multiple different controlled substances at the same time, and a wholesale distributor's system flags only one of them as an ORUSC. In other words, does the "ORUSC" (if identified as such) consist of all the controlled substances that a registrant ordered at a single point in time and that are placed into a wholesale distributor's suspicious orders monitoring system for evaluation? Or, does it consist of all units, requested at a single point in time, of controlled substances included under a specific DEA-Drug Code Number? Or, does it refer to controlled substances identified by a single FDA-registered National Drug Code (NDC)? Or does it consist of something else?

In this circumstance, HDA believes that if a prospective customer registrant orders several controlled substances at a single point in time, and only one of the controlled substances (with its own, separate and distinct NDC) was identified as ORUSC, only this individual product would need to be treated as an ORUSC. It would be inconsistent with the plain reading of the law and prior interpretation of the DEA regulation, going back some 50 years, as well as being unfair to the purchasing registrant, and their patients, to sweep all controlled substances into an ORUSC designation, merely because one of the controlled substances was flagged as an ORUSC.

Additionally, this reasoning should apply regardless of how the wholesale distributor may have configured its system for analyzing orders, including if the distributor's system grouped controlled substances, for analytical purposes, based on certain similar characteristics.[11]

This means that wholesale distributor registrants would decline to distribute only the controlled substances, with that individual NDC, that had been flagged as ORUSC. They would be allowed to distribute all other controlled substances ordered at the same time including those that the system grouped together for analytical purposes. Similarly, the wholesale distributor would conduct other required measures for the ORUSC, such as reporting and recordkeeping if the first option is used, or due diligence if the second option is used, but only for the controlled substances with the NDC that the system identified as the ORUSC.

We would also note that this interpretation would not prevent a distributor registrant's system, under §1301.78, to identify more than one controlled substance at a time as ORUSC, and to treat each of them as such. However, this would occur based on the system's analysis, not because the regulation required additional controlled substances to become part of an assemblage of controlled substances collectively regarded as ORUSC.

Also, such an interpretation would not prevent a registrant from flagging additional controlled substances "ordered" at the same time as the ORUSC because of extenuating circumstances. This could occur, for example, if information comes to the attention of a wholesale distributor separate from the analysis performed by an automated suspicious order monitoring program that is part of a wholesale distributor's total system for evaluating orders for their ORUSC and/or suspicious properties.

Basing the ORUSC designation, (and, if warranted, the eventual suspicious order designation) on a controlled substance's NDC is appropriate for a number of reasons. First, it is the clear intent based on the law and prior regulation. Second, there is an important issue of patient care. Wholesale distributors' ability to support purchasing registrants' and patients' needs could be jeopardized if additional controlled substances are unnecessarily put on "hold" where there is no indication that such orders were received under suspicious circumstances. Moreover, a suspicious order "is not limited to" an unusual size, or deviating substantially from a normal pattern, or of unusual frequency. Thus, the circumstances that may trigger an ORUSC are designed to focus on potentially problematic controlled substance orders. Adding yet another "stop" to efforts to provide patients with the products they need would be overly restrictive and unnecessarily burdensome to both registrants and to DEA.

We believe the above description explains the complexity of efforts needed to remain in compliance, and the urgent need to have a final regulation that supports the wholesale distributor registrant's ability to appropriately evaluate, and act on, orders that may be suspicious. Without

[11] A number of wholesale distributors' existing suspicious orders monitoring systems will group together several different controlled substances, even those with different NDCs, into "families" of controlled substances based on certain characteristics of the controlled substances. This grouping is done to help facilitate the analysis of the orders they receive. However, it is important to emphasize this is done for analytical purposes, only. We also note that each wholesale distributor is not necessarily using the same criteria for creating those groupings. For example, some may group them according to their DEA-Drug Code Number, and others may not group them together, at all.

such clarification, there is a risk that unnecessary reporting may occur, and that prospective purchasing registrants become unable to offer the treatments and medical care that their patients need.

Recommendation: We request that DEA positively affirm, in its final rule, that the wholesale distributor would

- Decline to distribute only the specific controlled substance identified by a single NDC that the distributor's system flagged as an ORUSC.
- Subject only the single controlled substance identified as an ORUSC, to the final rule's investigation, reporting and other requirements.
- Enable shipping, and otherwise filling, orders for all other controlled substances not flagged as ORUSC. Such orders would not be subject to a final rule's recordkeeping or other requirements.
- HDA also urges DEA to consider amending the definition of "order" to reflect this approach.

11. Registrants Should not be Required to Investigate/Report Subsequent Orders, from the Same Customer, Received for the Same NDC Within the Designated Time Period for Investigation/Reporting

Another challenging implementation circumstance revolves around the practice of "just in time" inventory management used by most registrants placing controlled substance orders. That is, at the end of each day, the registrant will place an order, typically requesting only the amount of the controlled substance that they anticipate they will require to meet the next day's medical activities. Wholesale distributors then deliver the products to the purchaser the day after the order is placed. This practice has many advantages for dispensers, such as minimizing the need to identify adequate internal storage space, minimizing the registrant's cash outlays to purchase products, and it is safer because having fewer total products on hand means there are fewer products within a registrant's facility that may be targets for theft or diversion.

If a wholesale distributor's system identifies one of the controlled substances requested as an ORUSC, they may engage in the second option, including not shipping the order the next day and conduct due diligence over the allowable time frame. But if the ordering registrant does not receive the product in the next day's delivery, their internal automatic ordering system may assume they did not receive it due to a wholesale distributor oversight, and then reorders the same product from the same wholesale distributor.

Additionally, because the purchaser is now "short" of product for that day, the purchasing registrant's automated ordering system will likely order more units in the follow-up order than what was in the original ORUSC to make up for the missing products. The wholesale distributor's system may or may not flag the follow-up order as ORUSC, as well. Wholesale distributors have had instances where each day that the purchasing registrant does not receive the product, their ordering system places yet another order, and each time, the order is for larger and larger volumes to make up for the missing deliveries.

Should the rule be finalized as proposed, this reordering could happen over and over again each day, over the seven days or other allowable review time frame. While the wholesale distributor conducts their due diligence, they continue to receive more and more orders, and for increasingly larger volumes of products. The wholesale distributor is not able to stop the customer's automated reordering process, and each time, the same customer's order may be flagged as ORUSC.

Thus, we believe it is appropriate to clearly indicate what the wholesale distributor's actions should be under these circumstances.

Recommendation: We request that DEA positively affirm, that if, on succeeding days during the Option 2 review time frame, the purchasing registrant's automated system reorders the same controlled substance NDC on which the wholesale distributor is conducting due diligence, the wholesale distributor is obligated to decline to distribute the successive controlled substance order(s) only if they are flagged as ORUSC, but

- The wholesale distributor does not need to conduct separate due diligence on the renewed order(s). Instead, the wholesale distributor may assume its due diligence efforts on the initial order is applicable to the new order(s),
- If, after conducting the due diligence, the wholesale distributor determines the order is not suspicious, the wholesale distributor is allowed to ship the original and subsequent ORUSCs received for the same controlled substance NDC.

12. Ambiguities in Certain Terms and Requirements Supports HDA's Request that DEA Extend the Comment Period and Consider a Healthcare Industry Meeting in Furtherance of a Process that Best Serves the Public Interest

HDA would like to provide additional comments to DEA offering more explicit suggestions for refining the definitions as well as additional explanations of many of the terms contained in the proposal. However, as noted in our letter to DEA requesting an extension of the comment period due date, it would be a significant challenge to provide meaningful comments on all areas of the proposed rule in the currently allowed 60-day time frame. For example, HDA found that most of the definitions contained in the proposal lack specificity and remain ambiguous. Moreover, the proposal introduces several new terms that are not defined at all. Some of these new terms are contained within the definitions themselves and some refer to other terms that have not been defined and/or are subjective.

Below we provide brief descriptions of a few of the terms, phrases, and concepts contained in the proposal that would benefit from further clarification.

Suspicious order – The proposed definition of "suspicious order" does not include any changes to, or comments on, the terms "unusual size," "deviating substantially from a normal pattern," or "unusual frequency." The proposed rule offers no clarity, nor does it acknowledge the long history of registrants raising concerns that the existing terms are vague and difficult to interpret without DEA engaging with distributors regarding their application. DEA should engage with its registrants to develop meaningful standards that can be applied consistently to identify those orders to be reported.

Order received under suspicious circumstances – the ORUSC definition states that this is an "order **potentially** meeting the definition of suspicious order." [emphasis added] Given that the definition of "suspicious order" is itself ambiguous, it is unclear how registrants could determine if there is a *potential* that an order may be suspicious based upon evaluating conditions describing suspicious orders that are, themselves, ambiguous.

System requirements - The system proposed in §1301.74(b)(1) would "identify suspicious orders based on facts and circumstances that may be **relevant indicators** of **diversion**…" [emphasis added] These terms raises questions that DEA should address, such as what would constitute a "relevant indicator" of diversion? And most important, since there is not an applicable definition of "diversion," registrants would have to make their own determination of what these vague terms mean, and, potentially, would be subject to enforcement for failing to satisfy a regulatory requirement by looking for undefined indicia of an undefined term.

"Actually" suspicious – DEA's proposed regulation inserts the word "actually" before "suspicious" in § 1301.78(b)(1)(vii) and proposes to require that the suspicious order report would include "what information and circumstances rendered the order **actually** suspicious." [emphasis added] Such a distinction, if there is one, is not a reasonable interpretation of the requirements of the law or prior DEA regulations. Specifically, the PDDA calls for reporting suspicious orders, but there is no provision for distinguishing what is "actually" suspicious. Use of the phrase "actually suspicious" introduces further ambiguity into what must be reported by distributors and is inconsistent with the statute's focus on size, pattern, and frequency. DEA should clarify that for ORUSCs reported as suspicious under Option 1, the proposed rule would impose no obligation on registrants to (a) determine whether the ORUSC was "actually suspicious," or (b) otherwise confirm or dispel whatever suspicious circumstances accompanied the order. Rather, the suspicious order report would simply need to reflect the circumstance(s) rendering the order as "suspicious."

Information Sources for "Due Diligence" - Also missing was further guidance on the types and sources of background information about the order that would be relevant and appropriate for a wholesale distributor to explore as part of their due diligence. While wholesale distributors appreciate the ability to access certain limited information contained within the ARCOS[12] database as a source of information, we believe DEA expects registrants to evaluate additional information. However, the proposal does not offer insight into what such information would consist of.

HDA believes that the concerns expressed above pose substantial operational and other challenges, some of which will likely be experienced by DEA. Of greatest significance, providers and patients may experience medication access issues if, given the uncertainties noted above, a wholesale distributor settles on overly conservative interpretations of the terms and definitions, and unnecessarily undertakes the process for reviewing orders and delays a shipment and/or declines to fill orders for legitimate medical needs.

[12] SUPPORT Act, Pub. L. 115-271, *See*: https://www.deadiversion.usdoj.gov/sors/index.html.

Recommendation: As we have noted earlier:

- Given the scope of the proposed rule and the importance of ensuring that DEA and the healthcare industry move forward with a full understanding of the expectations for suspicious order monitoring, coupled with the challenges of engaging in ongoing response efforts for the COVID-19 pandemic, we believe grating additional time to provide public comments is imperative.
- We also recommend that DEA schedule a meeting (within 60 days of the close of the comment period) and invite interested parties to participate. Such a meeting would give DEA the opportunity to ask questions and seek clarification regarding registrants' comments and concerns. Such an approach would ultimately serve both DEA and the healthcare industry by supporting efforts to implement a final rule.

13. MISCELLANEOUS COMMENTS/RECOMMENDATIONS

HDA also wishes to take the opportunity to point out certain questions and request additional clarification regarding implementation that DEA did not necessarily discuss in the proposed rule.

Effective Date - HDA believes it is important to allow a long lead time for implementation to provide wholesale distributors with adequate time to develop, modify and implement systems and procedures to comply. One example of a modification involves the use of the DEA centralized database for reporting suspicious orders. Those wholesale distributors who have begun to use the DEA centralized database found that the Information Technology (IT) work to ensure that reporting was set up correctly was a significant undertaking, consuming both time and expertise to establish appropriate information sharing protocols and automation. Those wholesale distributors that are not yet "connected" will need ample time to make comparable IT modifications.

Regardless of whether a wholesale distributor is already submitting to the centralized database, there may be additional steps that need to be undertaken in order to meet the final rule's specifications, including but not limited to:

- Review and amend current systems for initially detecting ORUSCs,
- Review and amend recordkeeping systems to appropriately accommodate the new recordkeeping requirements, particularly for ORUSCs,
- Preparation of IT systems to enable direct and automatic reporting to the DEA's online centralized database. This is likely to include, but not be limited to, evaluating, revising, testing connections, and possibly undertaking further revisions based on test results,
- Review, and if necessary, amend the company's internal written Standard Operating Procedures to ensure they are consistent with the new regulations,
- Train employees on any new terms, requirements and/or evaluation techniques that the wholesale distributor may need to institute.

Moreover, we remind DEA that all wholesale distributors are under exceptional challenges related to the need to address the COVID-19 pandemic. Human and financial resources are constrained, and the strains are likely to continue well into the future.

Recommendation: HDA encourages DEA to allow ample lead time for implementation to help ensure that the swift, safe, efficient provision of drug products to customers and patients is not inadvertently negatively impacted. HDA recommends that DEA allow a one-year time frame for implementation once the final rule is published.

Ratio of Suspicious Orders and Cost Estimates - In the preamble, DEA estimates that the industry will receive 338,840 ORUSCs in a given year and that only ten percent (10%) of them (33,884) will be reported as suspicious orders under Option 1.[13] Despite DEA's statement that these figures are "based on a general understanding of registrant operations and informal and anecdotal discussions with registrants," the estimates do not appear to take into account current practices of some HDA members. We further note that some of the justification for the cost estimates presented in the preamble contains the assertion that "a total of 20% of ORUSCs are suspicious orders that require reporting to DEA. The remaining 80%..." are dispelled.[14] HDA does not know the source of the 80/20 ratio split, particularly since currently only suspicious orders are submitted to DEA.

Regardless of the ratio's source, it is conceivable that a ratio based on the current practices will change, possibly substantially, after the rule is finalized, implemented, and wholesale distributors begin to evaluate and report under the new regulatory requirements. While it is still too early to tell, since the final rule may differ significantly from the proposal, HDA believes that the number of suspicious orders reports may escalate further than this estimate, perhaps substantially.

HDA is also uncertain as to the potential future use of this ratio. For example, is it intended to serve as a benchmark for registrants against which DEA will measure the volume of suspicious orders they report?

Recommendation: We are hopeful that DEA will provide further detail on the source of this ratio analysis, and how the ratio was derived, in the future. In addition to seeking clarity from DEA regarding how the Agency estimated this ratio, we also wish to understand the Agency's possible for future use of the ratio. Thus, we ask DEA to clarify its intent to use the 80/20 ratio going forward.

Cost Estimate - Although HDA attempted to evaluate the cost estimates that DEA provided in the preamble,[15] how the estimate was derived is unclear to us. We were uncertain, for example, as to whether DEA had included the proposal's impact on the new set of entities, that is, practitioners selling products under the five percent rule, in the estimates.

As another example, related to the IT work discussed above, we understand from HDA's members that have revised their IT systems to allow connecting with, and reporting to, the online database, the changes involved considerable time and resources. Thus, we question whether the final rule would result in a net cost savings, based on the costs to wholesale distributors, alone, of establishing these connections to make online reporting possible. And, although the preamble states that implementation of the ARCOS tool by wholesale distributors saves time, wholesale distributors

[13] Page 69290, col. 3 to 69201, col. 1
[14] Page 69292, col. 1, footnote #115.
[15] Page 69292, col. 1, Summary of Costs; and col. 3, Regulatory Flexibility Act.

have found that while they value having the access to the ARCOS tool, it is an extra step, not a time saver.

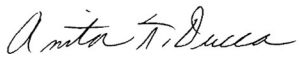
Recommendation: We encourage DEA to provide additional detail on the derivation of the cost estimates in the preamble. It is hoped that DEA would include an indication of whether the Agency had considered other factors that were not discussed in the preamble, the new requirements contained in the rule, and the additional registrants not previously covered by the current suspicious orders regulation to help enable us to offer further input on the estimates.

CONCLUSION

HDA and its members understand the importance of continuing to do our part to reduce the potential for misuse of controlled substances and appreciates the opportunity to provide these comments. While the suspicious order requirement has existed for almost 50 years, the effort to refine and develop meaningful requirements to assist the public interest is more recent. Thus, we hope the Agency will take this opportunity to ensure that both the Agency and regulated industry work together towards a solution that will make a difference in reducing opportunities for controlled substance misuse. Thus, it is hoped that we will be afforded an opportunity to continue communications with the Agency by extending the comment period and by a meeting with interested parties.

If you have any questions, please contact me at 703-885-0240 or at aducca@hda.org.

Sincerely,



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