HDA
Healthcare Distribution Alliance
HEALTH DELIVERED

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Robert Baillieu, MD, MPH
Physician and Senior Advisor
SAMHSA/CSAT
5600 Fishers Lane
Room 13-E-30
Rockville, MD 20857
Robert.Baillieu@SAMHSA.hhs.gov

Re: Medications for the Treatment of Opioid Use Disorder; 87 Fed. Reg. 77330 (December 16, 2022) RIN 0930-AA39

Dear Dr. Baillieu:

The Healthcare Distribution Alliance (HDA) thanks the Substance Abuse and Mental Health Services Administration (SAMHSA) of the Department of Health and Human Services (HHS) for this opportunity to submit comments regarding the proposed rule "Medications for the Treatment of Opioid Use Disorder" 87 Fed. Reg. 77330 (December 16, 2022) RIN 0930-AA39 ("proposed rule" or "proposal"). We greatly appreciate the agency's efforts to address accreditation, certification and treatment standards for the provision of medications for opioid use disorder (MOUD) as dispensed by Opioid Treatment Programs (OTPs).

The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics, and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA Research Foundation, HDA's nonprofit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues.

I. INTRODUCTION

HDA recognizes, appreciates and supports efforts to fight against the current public health crisis of drug abuse, misuse, and diversion associated with controlled substances. For many years, wholesale distributors and other entities responsible for handling such products have pointed out that the pace of drug abuse and diversion needed a concurrent effort to enhance regulatory and other policies as key to aiding the effort to combat such abuse.

HDA has also supported SAMHSA's educational efforts such as by participating in SAMHSA-sponsored meetings and conferences. We believe that further educating the public, those whose primary concern is the care of patients, and other stakeholders about the importance of avoiding diversion, and the role of wholesale distributors in doing so, can only enhance both SAMHSA's efforts

and that of our wholesale distributor members. As we engage in the fight to stem the tide of drug diversion and abuse, we pledge to continue our concerted efforts to ensure ongoing communication and support for education that we believe will aid all parties in their joint goals of combatting drug abuse.

HDA defers to SAMHSA's judgment, as informed by the public comments it is likely to receive including those from the medical community, such as prescribers and dispensers, as well as by patients and their representative organizations, regarding the standards outlined in the proposed rule. However, below, HDA will point out potential implementation challenges that we urge SAMHSA to address either through clarifications in the final rule or through its implementation support once the rule is finalized.

II. BACKGROUND

To set our comments in context, below we first provide a brief explanation of the role of the wholesale distributor in the provision of pharmaceutical products, as well as a brief overview of certain critically important regulations and legal agreements wholesale distributors must follow as part of managing these products. We believe this information will aid in implementing a final rule given the significant bearing on the provision of MOUD products that these additional rules and directives have.

A. Description of Wholesale Distribution

Pharmaceutical product manufacturers make, sell, and ship final finished pharmaceutical product to a wholesale distributor. Upon receipt, the wholesale distributor which has purchased the product(s), will sort and store them in very large, highly secured warehouses, sometimes following additional safety or special handling practices (e.g., in a refrigeration unit if the product must be stored at special cold temperatures; in a cage or vault if the product is a Drug Enforcement Administration (DEA) scheduled controlled substance).

When dispensers,[1] including OTPs, wish to obtain a product for patient care purposes, they will place an order for the product(s) with a wholesale distributor.[2] The ordering and shipping process usually occurs on an overnight basis, where the dispenser will place the order with their wholesale distributor sometime during the day they identify a need for the product. The wholesale distributor will locate and retrieve the product from within the warehouse, pack it appropriately, and ship it to arrive at the dispenser's receiving location usually by the next morning.

A more detailed description of the pharmaceutical supply chain and the wholesale distributors' role in it can be found in an interactive educational resource prepared by the HDA Research Foundation, see: "2022 Understanding Pharmaceutical Distribution." But we emphasize a critical point about this distribution system. That is, manufacturers only distribute about seven percent of their products directly to dispensers. The rest or approximately **93 percent of their final finished**

[1] HDA generally follows the definition of "Dispenser" found in § 851(3)(A) of Title II of the DQSA, the Drug Supply Chain Security Act (DSCSA), "The term `dispenser'… means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor".

[2] On occasion, a dispenser may find that maintaining a business relationship with more than one wholesale distributor is necessary. For example, the needed product may be distributed by a specialty distributor, different from a dispenser's usual wholesale distributor trading partner, due to certain handling specifications.

products are sold directly to wholesale distributors who are then solely responsible for the products' further distribution to dispensers.[3]

Thus, the vast majority of healthcare products furnished to patients by dispensers will have reached them by way of a wholesale distributor who owned the product prior to the dispenser's purchasing it.

B. Regulatory and Related Requirements Pertaining to Pharmaceutical Product Distribution

The wholesale distribution of drug products is highly regulated by multiple federal, state and local regulatory authorities. For example, the Drug Supply Chain Security Act (DSCSA),[4] administered by the Food and Drug Administration (FDA), contains detailed requirements designed to further secure the pharmaceutical supply chain, too numerous to exhaustively list here. A few such requirements include, but are not limited to, wholesale distributor licensure requirements, and directives to manufacturers, wholesale distributors, dispensers and others to provide and/or receive and maintain data associated with each DSCSA-covered products' transaction. Other federal agencies also regulate certain aspects of pharmaceutical product handling and distribution.[5] Most individual states also establish their own regulatory controls, typically mirroring and/or expanding upon those of the various federal agencies.

However, the regulatory controls applicable to MOUD products that we believe are most likely to interact with this proposed rule, once finalized, are those that stem from the Controlled Substances Act (CSA) and its implementing regulations administered by the Drug Enforcement Administration (DEA). Chief among those are requirements for wholesale distributors (and manufacturers) to monitor their customers' orders and report to DEA any "suspicious orders" of controlled substances they might receive. Certain state regulatory authorities also have suspicious order regulatory or legislative requirements that include reporting to the state.

C. Monitoring and Reporting Suspicious Orders of Controlled Substances

The requirement for wholesale distributors to report suspicious orders is found in 21 C.F.R. § 1301.74(b):

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Since this regulation was established, certain legislative and regulatory initiatives have modified and/or reinforced the wholesale distributors' suspicious orders reporting responsibilities,

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[3] Source: 92nd Edition: FACTBOOK The Facts, Figures and Trends in Healthcare (2021–2022). Copyright © 2021 by the HDA Research Foundation.

[4] Title II of DQSA, the Drug Supply Chain Security Act (DSCSA), was enacted by Congress on November 27, 2013. It outlines steps to achieve interoperable, electronic tracing of products at the package level to identify and trace certain prescription drugs as they are distributed in the United States.

[5] Handling of pharmaceutical products is also regulated by such federal agencies as the Department of Transportation (DOT); the Occupational Safety and Health Administration (OSHA), and the Environmental Protection Agency (EPA).

including many established by individual states. In late 2020, DEA issued a proposed rule to update this Suspicious Order regulation.[6] However, the fundamental requirements for monitoring and reporting suspicious orders have generally been retained throughout these initiatives.

Further, in July 2021 three of HDA's largest wholesale distributor members entered into settlement agreements (the 2021 Comprehensive Opioid Settlement Agreement) stemming from litigation by numerous states and localities.[7] Among these localities' allegations were that these three distributors failed to effectively monitor and report suspicious orders of prescription opioids. As part of the settlement agreement, the three distributors are subject to a number of Injunctive Relief terms that contain requirements that these wholesale distributors must follow regarding further efforts for the detection and reporting of suspicious orders. We estimate that these three distributors, collectively, distribute the vast majority – likely over 90 percent -- of the pharmaceutical products used by patients throughout the US.

While on the surface, monitoring and reporting of suspicious orders appears to be relatively straightforward, in practice, compliance with these requirements involves highly complex efforts. A "normal" controlled substance order is not defined or even alluded to in any of these directives. Moreover, there is a high degree of variability among the over 180,000 sites we estimate that wholesale distributors ship to within the U.S. They are of differing sizes, from tiny "mom and pop" independent pharmacies to large chain pharmacies, to campus health systems spread over many acres and with hundreds if not thousands of employees. They have differing patient volumes and care needs, treat different medical conditions and disease states, are in different physical locations from sparsely populated rural areas to densely populated urban centers, have different business models, and much more.

With very little in the way of regulatory definitions to go on, and with so much variability in dispenser needs, determining what is "usual" or "normal" to serve as a base of comparison for what is "***un***usual" or ***not*** a "normal pattern" becomes even more challenging.

Given that the total volume of products dispensers, collectively, order on any given day is so high, most wholesale distributors have established methodologies that have been developed using statistical techniques and computerized models whereby a "threshold" – or, more likely, multiple "thresholds" – are used as a base of comparison for every controlled substance order the wholesale distributor receives. Indeed, the Injunctive Relief terms and requirements mentioned above contain three pages of directives ***mandating*** the use of thresholds and specifying methods that must be applied to their development and use. These directives include the information that should be considered, updating frequency, use of statistical techniques, and much more.

For further information on identifying suspicious orders of controlled substances and the application of thresholds to their identification, including when evaluating MOUD products, please see the fact sheet "*Expanding Access to Medication Assisted Treatment (MAT) Therapies*."[8]

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[6] See: Proposed Rule Suspicious Orders of Controlled Substance 85 Fed. Reg. 69282 (Nov. 2, 2020). We understand that DEA intends to publish a final rule sometime later this year.

[7] The details of this litigation, one of the most extensive, if not the most extensive, "Multi District Litigation" efforts ever undertaken in the U.S., and the final agreements signed by the litigants can be found at: https://nationalopioidsettlement.com/

[8] HDA is currently updating this fact sheet in light of the recently enacted Consolidated Appropriations Act of 2023. The updated version will be placed on our website upon completion.

D. Customer and Order "Due Diligence"

While specific processes vary from wholesale distributor to wholesale distributor, even prior to agreeing to do business with a new customer, most will conduct a review or "due diligence" evaluation of that prospective customer. For example, they may look into the dispenser's patient volume, compare their likely controlled substance dispensing volume to non-controlled substance dispensing, conduct federal and state licensing, registration, and disciplinary checks, and conduct financial and/or criminal background checks, as key components of their customer due diligence.

The information gathered as part of these due diligence reviews is designed to help avoid, in the first instance, doing business with those who may be intent on purchasing controlled substances for purposes other than what the products are intended for, including outright criminal activity. Such information may also be used as factors in the development of the thresholds.

Depending on the individual distributor's suspicious order monitoring system, if an order is "run through" the firm's system, and triggers a "threshold" the distributor likely will not ship the order. Some firms will report the order right away, while others may perform further "due diligence" on the order and the customer. Due diligence on the order is intended to determine if there is a plausible explanation for why the dispenser's order seems out of line with their usual practice. Resolution is sometimes nothing more than calling the customer and finding that there was a typo in the order, e.g., the dispenser unintentionally ordered 500 units when they needed only 50.

It should be noted that the terms of the settlement agreement mentioned above, do not allow this form of order due diligence. If an order received by the wholesale distributors covered by the settlement agreement's Injunctive Relief terms triggers a threshold, the wholesale distributor must immediately treat that order as a "suspicious order" and report it to those settling states that have opted in to receive such reports.

In some instances, a dispenser will have foreknowledge that its business could expand, for example, a new healthcare facility or long-term care facility may open near a pharmacy, or a nearby pharmacy closes resulting in its former customers finding a new pharmacy to fill their prescriptions. If these or other circumstances occur and potentially lead to increases in ordering volumes, most wholesale distributors have defined processes for working with their dispenser customers to help identify when increases are warranted. Such changes or increases often involve asking the dispenser to provide additional documentation and justifications to the wholesale distributor so that the wholesale distributor has the information needed to adjust the underlying analyses, models and/or thresholds. These adjustments will help avoid unintentionally flagging a product order as potentially suspicious, when it is likely an appropriate increase in demand or change in an ordering pattern, while still aiming to flag those that are not in sync with the norm.

III. HDA COMMENTS

A. Increases in dispensing MOUD may result in increases in orders placed with wholesale distributors.

A likely outcome of this rule will be an increase in the amount of MOUD products being dispensed. With the anticipated increases in dispensing, wholesale distributors will receive corresponding increases in orders for MOUD products.

As we've pointed out above, however, wholesale distributors must monitor their controlled substances orders, and report any that do not follow a normal pattern or otherwise appear to be out of line with the norm. Hence, wholesale distributors cannot simply begin filling larger orders, they would first document the underlying reasons for the potential ordering changes, and adjust their systems, including their computer algorithms, modeling and other methodologies for suspicious order monitoring accordingly.

In such instances, the wholesale distributor will request that the dispenser provide additional information to justify any anticipated increases. The information that a wholesale distributor will need will likely vary from distributor to distributor and from customer to customer, but could include such information as the amount of the anticipated volume increase or whether the OTP will increase their ordering frequency.

Recommendation: In light of the above, we urge SAMHSA to:

- Clarify that the Certification program outlined in the proposed rule does not relieve either the OTPs or those who supply products to them, from following requirements established by other (non-SAMHSA) federal, state, local or related mandates for appropriately handling controlled substances.
- Clarify that SAMHSA's final rule does not contain a provision by which a Certified OTP's ability to obtain an increase in supplies of MOUD products from wholesale distributors occurs automatically upon Certification.
- State that wholesale distributors are unlikely to increase the amount of product in the orders they fill, or in the amount of orders they accept for MOUD products, without an assurance of the accuracy of an OTP's claim that they are Certified under this rule.
- We urge that SAMHSA recommend to OTPs who wish to participate in the Certification program to consult with their wholesale distributors and provide supporting documentation for any anticipated changes in prescribing and/or dispensing practices.

B. Identification of "Certified" OTPs

HDA's members would like to verify the dispenser's Certification status with a secure, reliable government source so that we are not left to merely "take the word of" an OTP. The vast majority of them will be legitimate practitioners intent only on good patient care. However, HDA's members have encountered instances of imposters and other criminals intent on theft and diversion by pretending to be legitimate dispensers. Thus, we believe it will be urgent to have a mechanism to verify claims of "Certification."

One possible method for this verification is hinted at in Proposed § 8.11 - Opioid Treatment Program certification, which states that the OTP must be DEA registered to dispense MOUD.[9]

> **§ 8.11 Opioid Treatment Program certification.**
> **(a)** General. (1) An OTP must be the subject of a current, valid certification from the Secretary to be considered qualified by the Secretary under section 303(g)(1) of the Controlled Substances Act (21 U.S.C. 823(g)(1)) to dispense MOUD in the treatment of OUD. An OTP must be determined

[9] *See* page 77355, Col 2, of the proposal.

> to be qualified under section 303(g)(1) of the Controlled Substances Act, **and must be determined to be qualified by the Attorney General under section 303(g)(1), to be registered by the Attorney General to dispense MOUD to individuals for treatment of OUD.** [emphasis added]

Thus, it would appear that a wholesale distributor might be able to verify whether a dispenser has received a Certification, based on reviewing the dispenser's DEA registration. However, as HDA understands it, DEA registers dispensers based on the schedule of the controlled substance(s) they may dispense and not based on specific products or categories, such as MOUD products. Currently, DEA also does not register a dispenser based on whether they have obtained a "Certification" such as what would be provided for under this rule.

Moreover, the proposed regulation does not indicate whether dispensers would need to submit to DEA any information to change their registration status or if SAMHSA would automatically notify DEA of Certification of a particular dispenser.

HDA's members report that they have also noted a Buprenorphine Treatment Practitioner Locator on the SAMHSA website. We were encouraged to find this site as it may be a possible means of identifying entities who have received Certification to help with the customer due diligence discussed above. However, upon a cursory review of this website, we found,

- In some instances, there were duplicate records,
- There were also practitioners included on the list who were not DEA registered,
- We also could not search by clinic, only practitioner by practitioner.

Thus, we are hesitant to use this site as a means to verify a dispenser's Certification status.

Finally, it is likely that from time to time, an OTP's status or other legal requirements they must follow may change. For example, some practitioners may obtain Certification, but later decide they will no longer be able to treat patients for opioid misuse. As another example, a DEA DATA-Waiver registration is no longer required to treat patients with buprenorphine for opioid use disorder.

HDA's members wish to be sure that they are filling orders placed by those appropriately authorized to receive the products they request while being able to identify those who are not appropriately authorized, thus, it will be very important to update any verification site rapidly and reliably as quickly as possible.

Recommendations:

- We urge SAMHSA to ensure that there will be a reliable, highly secure mechanism by which wholesale distributors will be able to verify the Certification status of the entities (whether individual practitioners, a clinic or a group practice) who wish to prescribe or dispense MOUD products.
- While updating the SAMHSA website might be one option for verifying an OTP's Certification, HDA recommends that SAMHSA does so by working with the DEA to modify the information available through the OTP's DEA registration.
- However, HDA is open to considering other options if SAMHSA were to decide there is another means for conducting such verification.

- Regardless of the mechanism employed to verify the OTP's status, we urge SAMHSA to institute a rapid and robust mechanism to update the information used to verify an OTP's Certification or other status. A long lead time to affect such changes could result, in some instances, in patients missing out on treatment, and in other instances, in diverting products for purposes other than intended.

C. Dispensing vs. Prescribing

As discussed in the preamble, such as under "*The Opioid Treatment Program Flexibility To Prescribe MOUD via Telehealth Without an Initial In-Person Physical Evaluation,"*[10] SAMHSA expresses support for treatment using telehealth methods. Presumably, prescribing without directly dispensing MOUD products to the patients during such telehealth visits will be inevitable. Elsewhere in the preamble, there is a brief discussion of OTPs who dispense MOUDs directly and those "…eligible to dispense (**including by prescribing**) certain types of MOUD…"[11] [emphasis added] reinforcing our interpretation that the proposal assumes that some OTPs will write prescriptions that a patient would take to a pharmacy for fulfilment rather than receiving the MOUD directly from the OTP practitioner.

However, we found very little additional discussion as to the role of the pharmacies that fill such prescriptions. Will they have any specific obligations under this rule, if there are instances where a patient takes a prescription to them, as a dispensing pharmacy, rather than obtaining the product at the time of the patient's OTP visit? In these circumstances, will the final rule distinguish between where/when the prescribing practitioner's responsibilities end and where/when obligations of a pharmacy filling the prescription (but does not have direct treatment responsibilities) begin?

For example, some requirements, such as packaging and safe transporting requirements in proposed § 8.12(i)(4)[12] appeared to us to be more suitable as a dispensing pharmacy's responsibility, not a telehealth prescriber's. Yet these requirements are specified in the proposal's sections establishing standards for the OTP treating the patient, which could be problematic for OTPs who provide a patient with a prescription that is filled by a dispenser, not by the OTP. Moreover, there is no indication, that we have found, as to whether the pharmacy fulfilling such prescriptions will likewise need to be "Certified."

We also point out that all dispensers, including pharmacies filling prescriptions for patients of OTPs, are evaluated as part of a wholesale distributor's compliance processes and procedures mentioned under Section II.B.C. and D. above.

Recommendations:

- We do not believe it was SAMHSA's intent to require pharmacies filling prescriptions of MOUD products written by Certified OTPs to become Certified themselves. However, we encourage SAMHSA to clarify whether we correctly interpret how the rule would be applied (if at all) to such pharmacies, including whether or not such pharmacies will also need to obtain Certification.

[10] *See:* Page 77336 Col. 2 of the preamble.
[11] *See*: Page 77330 col. 3 continuing onto page 77311.
[12] *See*: Page 77359 col. 3.

- HDA also requests that SAMHSA clarify that, in addition to OTPs, all pharmacies dispensing MOUD products would be covered by the requirements of the CSA, its implementing regulations, and related agreements.
- We also suggest that SAMHSA clarify whether some components of the rule's requirements, such as the shipping and transporting requirements mentioned above, are better carried out by a pharmacist if they perform the function of filling prescriptions issued by Certified OTPs.

D. The X-Waiver Change

As noted above, in late December 2022, Congress eliminated the "DATA-Waiver Program" (or X-Waiver), effectively removing an existing requirement for a special registration for physicians who wished to prescribe buprenorphine when treating opioid-misuse patients. Recently, DEA issued a letter explaining their interpretation of the Consolidated Appropriations Act of 2023 (the Act). Other changes in the legislation were similarly designed to ease prescribing of buprenorphine for addiction and misuse treatment purposes.

There appears to us to be a potential for discrepancies between the specific requirements proposed in SAMHSA's rule, and the specifications that were alleviated by this legislation, particularly as it applies to buprenorphine products.

Recommendation:

- HDA urges SAMHSA to evaluate the proposed rule in light of the Act's specifications.
- Prior to promulgating a final rule, we urge SAMHSA to modify the proposal, if appropriate, to closely fit the requirements of the Act and/or to eliminate any requirements that are contrary to the Act.

* * *

We thank SAMHSA for this opportunity to provide comments on this important initiative. If you have any questions, please contact me at 202-964-4439, 301-461-9539 or aducca@hda.org.

Sincerely,

Anita T. Ducca
Senior Vice President, Regulatory Affairs