HDA
Healthcare Distribution Alliance
HEALTH DELIVERED

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Re: Joint Consensus Practice Guideline from the National Association of Boards of Pharmacy (NABP) and the National Community Pharmacists Association (NCPA)

To Whom It May Concern,

The Healthcare Distribution Alliance (HDA) submits these comments in response to the "Joint Consensus Practice Guideline from the National Association of Boards of Pharmacy (NABP) and the National Community Pharmacists Association (NCPA)" (the "guidelines").[1] 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.

It is HDA's understanding that the purpose of these guidelines is to suggest ways in which pharmacists[2] can increase access at the pharmacy counter to medications for opioid use disorder (MOUD) treatment, specifically with respect to buprenorphine. We also understand that later this summer the authors of the guidelines intend to disseminate the final guidelines "nationwide through accredited continuing professional education and a hybrid digital, print, and social media campaign in collaboration with [the University of Houston], University of Southern California, University of Texas at Austin, NCPA, and NABP."[3]

HDA agrees with the guidelines' statement that pharmacists can play a critical role in protecting the health and safety of persons with opioid use disorder by stocking and dispensing buprenorphine. To that end, HDA appreciates the guidelines' intended purpose because it aligns with our goal to help ensure a safe supply of medicines while minimizing the potential for their abuse or misuse.[4] **However, despite the intended purpose, we have concerns that the guidelines misstate and misinterpret**

[1] The Pharmacy Access to Resources and Medication for Opioid Use Disorder Guideline, *available at* https://nabp.pharmacy/buprenorphine-guidelines/.
[2] We use the term pharmacists throughout this comment letter to align with the language in the guidelines. The pharmacist is typically used to describe the practitioner. However, it is generally understood that a contractual arrangement with a distributor is with the pharmacy that employs the pharmacist(s). Pharmacies are also called "customers."
[3] NABP, Invitation to Panelists to Review Public Comments to the Draft Guidelines (Apr. 3, 2024).
[4] HDA, Expanding Access to Medications for Opioid Use Disorder, *available at* https://www.hda.org/prescription-drug-diversion/.

current legal requirements for distributors registered with the Drug Enforcement Administration (DEA) ("DEA Registrants"). In some instances, the guidelines directly contradict applicable statute, regulation, or other legal requirements.

As we detail below, the guidelines should accurately describe that distributors must comply with overall security requirements including maintaining effective controls against diversion per 21 C.F.R. § 1301.71 and identifying and reporting suspicious orders under 21 U.S.C. § 832(a); 21 C.F.R. § 1301.74(b), as well as guidance that DEA has provided to the industry and separately, related terms and requirements of the 2021 National Opioid Settlement Agreement (the "Injunctive Relief"),[5] which nearly every state in the country has adopted. **Compliance with these legal requirements cannot be negotiated between supply chain actors and any language within the guidelines that suggest otherwise should be removed.**

Accuracy on these points is critical to the effectiveness of these guidelines, especially as the authors intend to disseminate the final guidelines to practitioners throughout the country. Without accurate information, the intended purpose of these guidelines will be undermined, causing confusion, conflict and possible risk of non-compliance for pharmacists and pharmacies.

In addition to our comments provided below, HDA looks forward to its continued support of efforts to fight against the ongoing public health risks of drug abuse, misuse, and diversion associated with controlled substances.

1. **The guidelines should accurately describe that distributors must identify and report suspicious orders.**

Distributors that are DEA Registrants must create and administer suspicious order monitoring (SOM) programs to comply with statutory and regulatory requirements.[6] The DEA recently summarized these requirements as follows:

> The [Controlled Substance Act], as amended by the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment Act (SUPPORT Act) requires each DEA registrant to: 1) design and operate a system to identify suspicious orders for the registrant; 2) ensure that the system complies with applicable Federal and State privacy laws; and 3) upon discovering a suspicious order or series of orders, notify the Administrator of the DEA and the Special Agent in Charge of the Division Office of the DEA for the area in which the registrant is located or conducts business. 21 U.S.C. § 832(a). Suspicious orders may include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 21 U.S.C. § 802(57). Furthermore, all applicants and registrants must maintain effective controls and procedures to guard against theft and diversion. 21 C.F.R. § 1301.71(a).

DEA, Suspicious Orders (SORS) Q&A, DEA-DC-065, EO-DEA258 (Jan. 20, 2023).

As part of their SOM program, some distributors use thresholds to identify and then report suspicious orders of controlled substances, including those orders of unusual size, orders deviating substantially

[5] Distributor Settlement Agreement, Exhibit P, *available at* https://nationalopioidsettlement.com/wp-content/uploads/2023/01/Final-Distributor-Settlement-Agreement-3.25.22-Final-Exhibit-C-as-of-5.27.22_-Exhibit-G-as-of-01.10.23_4498795_1.pdf. The Injunctive Relief went into effect on July 1, 2022.
[6] DEA, Suspicious Orders (SORS) Q&A, DEA-DC-065, EO-DEA258 (Jan. 20, 2023), *available at* https://www.deadiversion.usdoj.gov/faq/sors-faq.html#:~:text=To%20comply%20with%20these%20statutory,a%20suspicious%20order%20to%20DEA.

from a normal pattern, and orders of unusual frequency (all factors enumerated in the Controlled Substance Act).[7] Certain legislative and regulatory initiatives have modified and reinforced distributors' suspicious orders reporting responsibilities. Further, distributors subject to the Injunctive Relief[8] are required to use thresholds and specify methods, established around suspicious order requirements, which must be applied to their development and use.

However, the guidelines contain inaccurate information with respect to SOM programs. First, the guidelines suggest that pharmacists can simply negotiate different terms and conditions for buprenorphine ordering that would not be subject to the same requirements as other controlled substance ordering[9]. State and federal law, as well as the Injunctive Relief terms, require that suspicious orders be reported for all controlled substances, including buprenorphine.

The guidelines also imply that distributors have implemented policies that effectively limit a pharmacist's ability to dispense buprenorphine.[10] The current regulatory landscape requires that distributors employ long-identified dispensing "red flags" like distance between the patient's home and their provider, the distance between their home and the pharmacy, or the distance between provider and pharmacy.[11] The Injunctive Relief further identifies a pharmacy's disproportionate filling of controlled verses non-controlled prescriptions, cash payments, and other actions as red flags.[12] Statements within the guidelines that lead pharmacists to conclude actions like those identified in the Injunctive Relief are not a red flag may be oversimplistic and are likely to steer pharmacists in the wrong direction.

2. The guidelines should accurately describe that distributors can and do update customer thresholds.

When distributors set thresholds, distributors are complying with their obligations under 21 C.F.R. § 1301.71 to maintain effective controls against diversion and 21 C.F.R. § 1301.74 to identify suspicious orders. Most distributors have established threshold methodologies that have been developed using statistical methods and computerized models whereby one or more thresholds are used as a base of comparison for every controlled substance order a distributor receives.

Still, ordering patterns for controlled substances may change for various reasons, and there are many legitimate reasons for increasing customer thresholds like an increase in new patients. Thus, most distributors have processes in place to amend and change customer thresholds. Threshold changes must be supported by documentation and may take time to approve.

Distributors subject to the Injunctive Relief also have a multi-prong process, detailed within three pages of directives, mandating specific methods that must be applied for adjusting thresholds. For instance, under the Injunctive Relief, a "[d]istributor may increase or decrease a [c]ustomer [t]hreshold as set forth in its [Controlled Substance Monitoring Program] policies and procedures, subject to Sections

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[7] 21 U.S.C. § 802(57).
[8] Distributor Settlement Agreement, Exhibit P, *available at* https://nationalopioidsettlement.com/wp-content/uploads/2023/01/Final-Distributor-Settlement-Agreement-3.25.22-Final-Exhibit-C-as-of-5.27.22_-Exhibit-G-as-of-01.10.23_4498795_1.pdf.
[9] E.g., under section heading "Improving Wholesaler Relationships" of the guidelines.
[10] E.g., under section heading "Impact or Corporate Policy on Patient Care" of the guidelines.
[11] 21 C.F.R. § 1306.04. There is no definitive list of red flags.
[12] Distributor Settlement Agreement, Exhibit P-10, Term VIII(D), PDF p. 510, *available at* https://nationalopioidsettlement.com/wp-content/uploads/2023/01/Final-Distributor-Settlement-Agreement-3.25.22-Final-Exhibit-C-as-of-5.27.22_-Exhibit-G-as-of-01.10.23_4498795_1.pdf.

XII.C.3.b through XII.C.3.e [of the Injunctive Relief]."[13] Many, if not most, of the distributors not subject to the Injunctive Relief maintain similar processes for adjusting thresholds.[14]

While distributors can and do adjust thresholds, the guidelines contain inaccurate information on that process. First, the guidelines do not accurately describe how distributors subject to the Injunctive Relief evaluate threshold changes.[15] Prior to approving any threshold change request by a customer, a distributor subject to the Injunctive Relief must conduct extensive due diligence to determine whether an increase to the threshold is warranted.[16] For example, pharmacists can request an increase to their thresholds for a specific drug if they plan to take on a new patient population that will cause the ordering of specific controlled substances to increase. However, beyond the basis for the threshold change request, under the Injunctive Relief, a distributor must review dispensing data and/or pharmacy customer data, and as needed, conduct an on-site visit to the customer to increase a threshold.[17]

The guidelines also suggest that pharmacists should be able to know when thresholds are exceeded.[18] Under the Injunctive Relief, and a practice generally employed as a good security practice by the industry, distributors cannot tell customers what their thresholds are; therefore, pharmacists cannot know when those thresholds are exceeded.[19] Specifically, the Injunctive Relief reads in relevant part:

> Injunctive Relief Distributors shall not provide Customers specific information about their Thresholds or how their Thresholds are calculated.

Distributor Settlement Agreement, Exhibit P-16, Term XII.C., PDF p. 516.

Importantly, however, exceeding a buprenorphine threshold would not necessarily lead a distributor to bar a customer from purchasing controlled substances absent other concerns about the order. The overall concerns with a customer's ordering pattern and/or a customer's dispensing practices are what could lead to termination.

The guidelines also mistakenly imply that buprenorphine thresholds are entangled with other thresholds, which is not accurate.[20] While methodologies may differ among distributors, thresholds are set at the drug family level (e.g., for buprenorphine) and are independent from each other.

The guidelines mischaracterize the DEA's letter to DEA Registrants on March 8, 2024, with respect to access MOUD medications. The guidelines state that the letter "clarifies that wholesalers should

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[13] Distributor Settlement Agreement, Exhibit P-18, Term XII(C)(3)(a), PDF p. 518, *available at* https://nationalopioidsettlement.com/wp-content/uploads/2023/01/Final-Distributor-Settlement-Agreement-3.25.22-Final-Exhibit-C-as-of-5.27.22_-Exhibit-G-as-of-01.10.23_4498795_1.pdf.
[14] HDA, Expanding Access to Medications for Opioid Use Disorder, *available at* https://www.hda.org/prescription-drug-diversion/.
[15] E.g., under the sections "Buprenorphine's Regulatory Status" and "Consideration for legitimacy of telehealth prescriptions" of the guidelines.
[16] Distributor Settlement Agreement, Exhibit P-16, Term XII, PDF p. 516, *available at* https://nationalopioidsettlement.com/wp-content/uploads/2023/01/Final-Distributor-Settlement-Agreement-3.25.22-Final-Exhibit-C-as-of-5.27.22_-Exhibit-G-as-of-01.10.23_4498795_1.pdf.
[17] *Id.*
[18] E.g., under the section heading "Buprenorphine's Regulatory Status" of the guidelines.
[19] Distributor Settlement Agreement, Exhibit P-16, Term XII, PDF p. 516, *available at* https://nationalopioidsettlement.com/wp-content/uploads/2023/01/Final-Distributor-Settlement-Agreement-3.25.22-Final-Exhibit-C-as-of-5.27.22_-Exhibit-G-as-of-01.10.23_4498795_1.pdf.
[20] E.g., under the section heading "Wholesale restriction are not a reason to force prescription transfer" of the guidelines.

monitor buprenorphine separately from other controlled substances."[21] This is incorrect. Instead, the DEA stated in part:

> DEA supports collaboration amongst all DEA registrants to ensure there is an adequate and uninterrupted supply of MOUD products when these products are appropriately prescribed. Distributors should carefully examine quantitative thresholds they have established to ensure that individuals with OUD who need buprenorphine are able to access it without undue delay.

Drug Enforcement Administration, Dear Registrant Letter (Mar. 8, 2024).

Finally, the guidelines imply that distributors are not already considering the legitimate need for buprenorphine when setting thresholds.[22] Distributors account for legitimate needs of all controlled substances, including buprenorphine, when setting thresholds. Moreover, if a customer experiences an increase in MOUD patients that need buprenorphine to the point where the customer's orders are being cancelled by the distributor, the customer can provide its supplier with information regarding its legitimate need for a threshold adjustment. Importantly, it is HDA's general understanding that distributors have not reported seeing an increase in threshold change requests for buprenorphine.

3. The guidelines should use relevant terms of the Injunctive Relief.

The Injunctive Relief is a critical document for the guidelines to accurately reference to avoid misinterpretation and inaccurate standards. In addition to the above legal requirements, we recommend that the authors reflect the language of the Injunctive Relief, such as using the term "distributors" instead of "wholesalers." Finally, we caution the authors to not use incorrect phrases when describing the 2021 National Opioid Settlement Agreement that would incorrectly imply admissions outside of those in the Agreement.[23]

Conclusion

Thank you for the opportunity to provide these educational comments to the guidelines, as we continue to support initiatives aimed at combating the ongoing public health crisis related to the abuse, misuse, and diversion of controlled substances. Should you have any questions, please contact me at kshankle@hda.org.

Sincerely,

/s/ Kala Shankle

Kala Shankle
Vice President, Regulatory Affairs

[21] E.g., under the section heading "Buprenorphine's Regulatory Status" of the guidelines.
[22] E.g., in the fourth paragraph under the sections "barriers to buprenorphine access" and "Impact or Corporate Policy on Patient Care" of the guidelines.
[23] E.g., in the fourth paragraph under the section heading "barriers to buprenorphine access" of the guidelines.