NABP
National Association of Boards of Pharmacy

Report of the Task Force to

REVIEW INCREASING ACCESS TO MEDICATIONS FOR OPIOID USE DISORDER

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Members Present

Chris Harlow (KY), *chair*; Jeffrey Anderson (AZ); Beverly Black (SC); Kristen Fink (MD); Victoria Kroeger (OR); Kendra Metz (MN); Lenora Newsome (AR); Danson Nganga (VI, virtual); Ashley Schaber (AK, virtual); John Weitekamp (WI).

Others Present

Stacey Ranucci, *Executive Committee liaison*; Melissa Kellstrom and Katie Laughery (Drug Enforcement Administration), Tyler Varisco (University of Texas at Austin), *guests*; Lemrey "Al" Carter, Melissa Becker, Andrew Funk, Neal Watson, Gertrude "Gg" Levine, Maureen Schanck, *NABP staff*.

Introduction

The task force met at NABP Headquarters in Mount Prospect, IL, on September 15 and 16, 2025. The task force was established pursuant to Resolution 121-8-25, Increasing Access to Medications for Opioid Use Disorder, which the NABP membership passed at the 121st NABP Annual Meeting in May 2025.

Review of the Task Force Charge

Charge of the task force:

1. Discuss how NABP should:
    a. partner with appropriate industry and federal stakeholders to advocate for Drug Enforcement Administration (DEA) to provide guidance on purchasing thresholds;
    b. advocate for wholesale distributors to develop a standardized process for pharmacies to request increases in medication for opioid use disorder (MOUD) established thresholds; and
    c. develop educational materials for its members to educate pharmacies on the process to request an increase in MOUD purchases.
2. Identify additional opportunities for collaboration with industry and federal agencies to recommend actions that NABP and its member boards of pharmacy can take to remove barriers limiting patient access to buprenorphine and other medications for use in the treatment of opioid use disorder (OUD).
3. Amend, if necessary, the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* (*Model Act*) accordingly.

Background and Discussion

The discussion began with a review of the task force charge and the recognition that the task force was established pursuant to Resolution 121-8-25, Increasing Access to Medications for Opioid Use Disorder, which the NABP membership passed at the 121st NABP Annual Meeting in May 2025.

The task force discussed barriers limiting patient access to buprenorphine and other MOUD. A central clinical concern driving this effort is that lapses in treatment for OUD can be fatal. Recognizing that this situation requires reconciling regulatory requirements with clinical need, the task force identified several interrelated regulatory, financial, and educational hurdles impeding patient access to MOUD. Key among the barriers discussed were purchasing thresholds set by wholesale drug distributors (WDDs) that limit the volume of controlled substances (CS) they will distribute to pharmacy customers.

Purchasing Thresholds

The 2022 National Opioid Settlement Final Distributor Settlement Agreement (Exhibit P) requires WDDs to monitor their distribution of CS, including buprenorphine. The agreement holds them accountable for identifying and reporting "suspicious orders," ie, "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." To meet this requirement, WDDs set thresholds for the total volume of CS that they "shall allow a customer to purchase in any particular period."

Task force members noted that due to the agreement, WDDs are perceived as having become a "pseudo-regulatory agency," making decisions and completing audits without due process, and that business decisions made by WDDs are affecting patient care, causing potential harm. WDDs' purchasing thresholds are customer-specific and generally unknown to the customers, making it difficult for pharmacies to know when they have triggered or are close to triggering a suspicious order report. Participants acknowledged that WDDs rely on a "know your customer" approach, which may involve machine learning, to determine appropriate order levels. WDDs sometimes reject pharmacy orders for CS without explanation based on these determinations.

Task force participants agreed that purchasing thresholds are often too low, preventing pharmacies from fully meeting patient needs for MOUD, and the process for requesting an increase is unclear. They noted that while the agreement allows flexibility in terms of thresholds, many WDDs do not seem to be flexible in their purchasing limits, ultimately putting patients at risk of relapse.

The task force agreed there is significant confusion among pharmacists, with many mistakenly believing that DEA or the boards of pharmacy are responsible for setting thresholds or cutting off supply, when in reality, the issue lies outside of their direct control. Participants considered whether DEA could provide guidance to pharmacies on navigating WDD thresholds and requesting increases. DEA representatives serving as guests on the task force explained that DEA is not in a position to provide guidance on specific thresholds or methodology because the agency does not set them. They said that DEA could, however, issue a statement clarifying its role. They explained that DEA focuses its enforcement efforts on "bad actors" engaged in blatant criminal activity and prefers compliance over enforcement, noting that the agency rarely conducts audits of WDD sales to pharmacies for isolated incidents.

Task force participants advocated for WDDs to develop a standardized process for requesting threshold increases. They suggested reaching out to the Healthcare Distribution Alliance (HDA) to discuss developing an online template for WDDs that would allow pharmacy customers to quickly and expediently request a threshold increase, along with educational materials to inform pharmacies about its use.

On a related topic, the task force observed a need for a platform that enables pharmacies to report incidents of threshold-related denials as a way to highlight the difficulty pharmacies have stocking MOUD. Participants likened the platform concept to a portal developed by the American Society of Addiction Medicine for reporting pharmacies that reject MOUD patients.

Participants also considered whether pharmacies and patients could use the well-established Food and Drug Administration Drug Shortages Database public portal to report lapses in MOUD availability. They noted that this approach may require encouraging pharmacies to report "shortages" when thresholds limit availability.

WDD Audits and Red Flags

The task force dedicated considerable discussion to certain pharmacy activities, or "red flags,"[1] that WDD audits identify that may lead to the rejection of an order. Participants pointed out that some such red flags hinder patient care by pressuring pharmacies to implement policies and processes that can become barriers to MOUD. These policies may include decisions not to stock MOUD or to refuse MOUD patients for various reasons to avoid triggering a suspicious order and potential enforcement action.

For instance, because the ratio of cash payments to insurance can raise a red flag for WDDs, pharmacies may not allow patients to pay for MOUD with cash, requiring them to use insurance instead. Participants noted there are legitimate reasons why patients may opt to pay for MOUD prescriptions with cash and that pharmacists should not reject prescriptions for this reason. Participants also noted that because WDDs monitor the ratio of CS compared to other legend drugs ordered, pharmacies may require patients to transfer all of their prescriptions to the pharmacy where they want to fill a MOUD prescription, which raises ethical questions. Pharmacies may also tailor their inventory orders to include additional non-CS products to avoid this red flag.

The task force discussed distance considerations in deciding whether to dispense MOUD – some pharmacies turn away patients based on the distance they travel to the pharmacy – presenting yet another barrier. Task force members evaluated this red flag in light of pharmacy deserts, where community pharmacies are few and far between; pharmacy closures, which cause patients to travel

[1] Red flags, under Exhibit P of the National Opioid Settlement Final Distributor Settlement Agreement, include but are not limited to:

- ordering ratio of highly diverted CS to non-CS;
- percentage of cash payments for patient purchases of CS;
- orders for "unusual formulations," including single-ingredient buprenorphine; and
- dispensing CS to "out-of-area" patients.

to more distant locations; and telemedicine prescribing of buprenorphine, wherein prescribers may be in a different state, all of which are valid reasons for patients to travel some distance to the pharmacy.

Task force participants also mentioned that ordering "unusual formulations," including single-ingredient buprenorphine, can raise a red flag for WDDs, which may prompt pharmacies to require patients to switch to combination formulations rather than monoproduct.

Opportunities for Collaboration

Noting that the primary concern is how WDDs' use of red flags creates barriers to access to MOUD, the task force considered whether NABP could form a coalition with other pharmacy professional organizations, such as American Pharmacists Association (APhA) and American Society of Health-System Pharmacists (ASHP), to engage with the State Review Committee, which manages the Final Distributor Settlement Agreement, regarding issues of concern. Participants also suggested that NABP, and potentially the coalition, should contact the National Association of Attorneys General (NAAG) to discuss reopening and reevaluating the agreement terms to clarify or change language that limits patient access to MOUD.

Building on the potential opportunities for collaboration, the task force considered whether NABP could work with the coalition to develop a policy statement highlighting the patient harm these red flags exacerbate. Participants said the statement should emphasize the importance of personal recovery, individualized patient outcomes, and professional judgment in making decisions about dispensing MOUD. They said the statement should support policy that facilitates wholesale purchasing and the dispensing of MOUD, reinforces patient access, and opposes WDDs withholding shipments without appropriate investigation and communication. It was suggested that NABP review APhA and ASHP policy statements that address these issues and create a statement that highlights the solutions on which the organizations align.

Educational Opportunities

Addressing the confusion and hesitation many pharmacists feel regarding the stocking and dispensing of buprenorphine, the task force agreed on the need to educate pharmacists on clinical considerations for the use of MOUD. Participants stated that pharmacists should understand evidence-based care for OUD, including off-label dosing strategies such as high-dose buprenorphine, which is sometimes necessary in post-overdose situations. In such cases, the prescribed dose may start higher than the maximum dose found in labeling. It was noted that high-dose buprenorphine prescriptions will impact thresholds. Participants mentioned other clinical knowledge gaps, such as uncertainty regarding the appropriate duration of therapy. Given that OUD is a relapsing and remitting chronic condition, there is no known maximum duration of treatment; the duration of treatment should be determined based on patient need.

The task force explored whether NABP, in conjunction with the coalition, could promote educational programming for pharmacists to advance MOUD in pharmacy settings. Noting that much of this information is available in existing continuing pharmacy education programs, participants suggested that NABP identify and share information about these programs. The task force also explored the option of working with the coalition to develop educational materials regarding the agreement, focusing on its impact on WDD threshold development and suspicious order reporting.

Administrative and Regulatory Barriers

In addition to WDDs' purchasing thresholds and red flags, other barriers limiting patient access to MOUD that the task force discussed included payer issues, such as prior authorization requirements and reimbursement losses for pharmacies. Members noted that financial burdens present barriers for some patients to access MOUD, as does the stigma that still surrounds OUD. Further, participants said pharmacists often feel constrained from ordering CS from more than one WDD, although DEA clarified there is no rule against using multiple WDDs to obtain buprenorphine.

The discussion also covered regulatory barriers that prevent pharmacists from prescribing and administering MOUD, despite the Mainstreaming Addiction Treatment Act, which allows all health care providers with a DEA registration number to prescribe MOUD. Although some states, such as Colorado, Idaho, Iowa, and Nevada, have moved toward allowing pharmacists to prescribe buprenorphine, obstacles remain in many others.

Participants expressed support for legislation intended to ease the impact of distributor thresholds, such as the Broadening Utilization of Proven and Effective Treatment for Recovery Act (BUPE for Recovery Act), which aims to improve access to buprenorphine for treating OUD by temporarily exempting it from stringent reporting requirements. However, they opposed legislative action that would require minimum stocking, noting that such decisions should be based on clinical knowledge and professional judgment.

Model Act Modifications

The discussion also included potential modifications to the *Model Act* to empower pharmacists to treat patients with MOUD. For instance, participants considered developing or modifying *Model Act* language to specifically allow pharmacists to prescribe buprenorphine for OUD, stressing that state laws must clearly establish that a pharmacist is allowed to prescribe CS for DEA to grant pharmacists in those states a registration number. They noted that adding to the limited pool of MOUD prescribers would improve patient access in health care deserts.

The task force also discussed modifying the *Model Rules for the Licensure of Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors* to align data elements with those found in the agreement. Additionally, they suggested modifying Section 8 of the model rules for WDDs by removing elements related to "methods of payment" and "ratio of out-of-state patients served compared to in-state patients." On another note, participants suggested that NABP evaluate the definition of "drug of concern" in the *Model Rules* to determine whether it introduces ambiguity or contributes to stigma related to OUD.

In sum, the task force stressed the need for greater transparency and collaboration between regulators, distributors, and pharmacy professionals to prioritize patient care over liability concerns.

Recommendations

After careful review and deliberation, the task force made the following recommendations:

1. NABP should develop a policy statement highlighting the issue of insufficient patient access to MOUD, then form a coalition with policymakers, pharmacy organizations, and other health care professional organizations to implement and disseminate the policy statement. The statement should accomplish the following objectives:
    a. reinforce the importance of patient access to MOUD;
    b. stress the importance of personal recovery and individualized patient outcomes in decisions made by prescribers, pharmacies, and WDDs;
    c. reinforce the use of professional judgment in the care of persons with OUD;
    d. support the development of policy that facilitates wholesale purchase and dispensing of MOUD but does not mandate stocking and dispensing of MOUD;
    e. state that orders for buprenorphine for OUD should not automatically be withheld from shipment without due process involving appropriate investigation, assessment, and communication with customers;
    f. state that WDDs should expeditiously evaluate and address threshold increase requests through a unique threshold review process tailored to MOUD; and
    g. evaluate buprenorphine for OUD for potential exemption from suspicious order reporting, as proposed in the BUPE for Recovery Act.

2. NABP and the coalition should reach out to NAAG to discuss reevaluating the National Opioid Settlement Final Distributor Settlement Agreement to change and clarify terms that limit patient access to MOUD.

3. NABP should work with the coalition to develop or identify and share information about educational materials for pharmacists to advance evidence-based care for persons with OUD.

4. NABP should encourage DEA to develop educational outreach to pharmacies regarding DEA's role in evaluating suspicious order reports and its non-involvement in the determination of purchasing thresholds.

5. NABP, its member boards of pharmacy, and the coalition should make formal recommendations to the State Review Committee, which manages the National Opioid Settlement Final Distributor Settlement Agreement, to discuss the following issues of concern:
    a. lack of focus on clinical outcomes for patients;
    b. prioritization of liability avoidance over patient care based on red flags being used by WDDs during audits that create barriers to MOUD access:
        i. ordering ratio of highly diverted CS to non-CS;
        ii. percentage of cash payments for patient purchases of CS;
        iii. orders for "unusual formulations," including single-ingredient buprenorphine; and
        iv. dispensing CS to "out-of-area" patients; and
    c. lack of board of pharmacy authority to enforce the agreement.

6. NABP should work with the coalition and HDA to discuss the development of an online template for WDDs to use to allow their pharmacy customers to expedite requests for a threshold increase. When this template becomes available, NABP should develop educational

materials to inform pharmacies about suspicious order reporting, thresholds, and threshold modification.

7. NABP should develop *Model Act* language that allows prescribing and administering of MOUD by pharmacists to expand patient access in remote areas and pharmacy deserts. Such language should align with the language used by states where DEA has granted pharmacists DEA registration.

8. NABP should modify the current *Model Rules for the Licensure of Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors* to align the data elements in Section 8, paragraph 2a, with those found in the National Opioid Settlement Final Distributor Settlement Agreement.

9. NABP should modify the current *Model Rules for the Licensure of Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors* as follows:
    a. in Section 8, paragraph 3b, remove "specialty practice area";
    b. in Section 8, paragraph 3d, remove "methods of payment" and "ratio of out-of-state patients served compared to in-state patients"; and
    c. in Section 8, remove paragraph 4 because it is impossible to conduct this evaluation for an "initial sale."

10. The NABP Committee on Law Enforcement/Legislation should evaluate the definition of "drug of concern" in the *Model Act* to determine if it introduces ambiguity or contributes to stigma related to OUD.

Recommended modifications to the *Model Act* are denoted by ~~strikethroughs~~ and underlines in the following excerpts.

National Association of Boards of Pharmacy
Model State Pharmacy Act

Article I
Title, Purpose, and Definitions

...

Section 105. Definitions.

...

"Drug of concern" means any prescription or over-the-counter drug identified by the board of pharmacy that demonstrates a potential for abuse and is not currently scheduled as a controlled substance by state or federal law~~, particularly those identified by boards of pharmacy, law enforcement, and addiction treatment professionals~~.

...

Model Rules for the Licensure of Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors

Section 1. Definitions.

...

"Diversion activity" means activity where evidence exists that drugs, including controlled substances or drugs of concern, are being diverted from legitimate channels.

...

Section 8. Operations/Reporting Requirements.

(1) Manufacturers, repackagers, ~~third-party logistics providers,~~ and wholesale drug distributors must comply with all reporting requirements and exchange transaction history, transaction information, and transaction statements with authorized trading partners as outlined in federal law.

(2) Manufacturers, repackagers, ~~third-party logistics providers~~, and wholesale distributors shall design and operate a system to identify and report suspicious orders of controlled substances and drugs of concern to a program approved by the board.

(a) Suspicious orders shall be submitted electronically to an approved program within five (5) days of the order being identified as suspicious by the manufacturer, repackager, ~~third-party logistics provider,~~ or wholesale distributor, and must include, but not be limited to:

(i) customer name;

~~(ii) NABP e-Profile ID;~~

(iii) customer address;

(iv) customer DEA registration number;

(v) state pharmacy license number(s);

(vi) ~~transaction~~ date of order;

~~(vii) drug name;~~

(viii) NDC number;

(ix) quantity ordered; and

(x) ~~indication of whether the drug was shipped, and if not, the factual basis for the refusal to supply.~~ explanation for why the order is suspicious: details that are order-specific regarding why an order was flagged as a suspicious order, including specific criteria used by the manufacturers, repackagers, and wholesale distributors threshold system (except, phrases such as "order is of unusual size" without any additional detail are not acceptable).

(xi) Name and contact information for a knowledgeable designated point of contact for the suspicious order report.

(b) Zero reports shall be submitted if no suspicious orders have been identified in a calendar month, and such reports shall be submitted within fifteen (15) days of the end of the calendar month.

(c) Manufacturers, repackagers, ~~third-party logistics providers,~~ and wholesale distributors may apply to the board for an exemption from the reporting requirements if they do not distribute controlled substances or drugs of concern.

(3) Except as described in paragraph 9(4), a manufacturer, repackager, ~~third-party logistics provider,~~ or wholesale distributor shall exercise due diligence to identify customers ordering or seeking to order controlled substances or drugs of concern and establish the normal and expected transactions conducted by those customers, as well as to identify and prevent the sale of controlled substances or drugs of concern that are likely to be diverted from legitimate channels. Such due diligence measures shall include, but are not limited to, the following, which shall be conducted prior to an initial sale and on a regular basis, as necessary:

(a) questionnaires and affirmative steps by the manufacturer, repackager, ~~third-party logistics provider,~~ or wholesale distributor to confirm the accuracy and validity of the information provided;

(b) for a customer who is a prescriber, confirmation of prescriber type~~, specialty practice area,~~ and if the prescriber personally furnishes controlled substances or drugs of concern, the quantity furnished;

(c) review of drug utilization reports; and

(d) obtaining and conducting a review of the following:

~~(i) methods of payment accepted and in what ratios;~~

(ii) the ratio of controlled versus non-controlled drug orders and overall sales; and

(iii) orders for controlled substances or drugs of concern from other manufacturers, repackagers, ~~third-party logistics providers~~, or wholesale distributors made available by US DEA's Automation of Reports and Consolidated Orders System (ARCOS). ~~; and~~

~~(iv) the ratio of out-of-state patients served compared to in-state patients.~~

~~(4) A manufacturer, repackager, third-party logistics provider, or wholesale distributor receiving a request for an initial sale of a controlled substance or drug of concern may conduct the sale before complying with paragraph 8(3) if all the following apply:~~

~~(a) the sale is to a new customer;~~

~~(b) the manufacturer, repackager, third-party logistics provider, or wholesale distributor documents that the order is to meet an emergent need;~~

~~(c) the manufacturer, repackager, third-party logistics provider, or wholesale distributor completes the requirements of paragraph 8(3) no later than sixty (60) days from the date of sale.~~

(5) A manufacturer, repackager, ~~third-party logistics provider,~~ or wholesale distributor receiving a request from an existing customer to purchase a controlled substance or drug of concern, the size/quantity of which exceeds the established algorithm limitations or quota restrictions for such customer, may sell the drug of concern or controlled substance provided that the customer submits documentation of an emergent need for a specific patient.

(6) Any customer that is believed to be engaged in potential diversion activities, including those to whom a manufacturer, repackager, ~~third-party logistics provider,~~ or wholesale distributor refuses to sell, shall be electronically reported to a program approved by the board. Such reports shall include:

(a) customer name;

(b) NABP e-Profile ID;

(c) customer address;

(d) DEA number;

(e) state license number(s); and

(f) a detailed explanation of why the manufacturer, repackager, t~~hird-party logistics provider,~~ or wholesale distributor identified the customer as a possible diversion risk.

(g) Such reports shall be submitted within thirty (30) days of refusal, cessation, or identification by the manufacturer, repackager, ~~third-party logistics provider,~~ or wholesale distributor.

(7) Within ninety (90) days of the effective date of this rule, a manufacturer, repackager, ~~third-party logistics provider,~~ or wholesale distributor shall provide to a program approved by the board, information on all customers in the state where the manufacturer, repackager, ~~third-party logistics provider,~~ or wholesale distributor has refused to sell or has stopped selling within the past year because the manufacturer, repackager, ~~third-party logistics provider,~~ or wholesale distributor has identified the customer(s) as engaging in potential diversion activity that may cause reported drugs to be diverted from legitimate channels.

(8) All licensed manufacturers, repackagers, ~~third-party logistics providers,~~ and wholesale distributors shall submit all reports to a board-approved program in a DEA ARCOS format.

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