Report of the Suspicious Orders Work Group

Members Present:

Steven Schierholt (OH), *chair;* Jessica Baer (IL); Traci Collier (SC); Darren Covington (IN); Kimberly Gaedeke (MI); Virginia Herold (CA); Lisa Hunt (WY).

Others Present:

Reginald Dilliard, *Executive Committee liaison;* Gary Cacciatore, *Cardinal Health*; Gary Davis, *McKesson Corporation*; George Euson, *H.D. Smith*; Steve Mays, *AmerisourceBergen Corp*; *guests;* Carmen Catizone; Josh Bolin; Melissa Madigan; Kevin McGlynn; Eileen Lewalski; Gregg Jones; Maureen Schanck; Angelica Alderton, *NABP staff*.

Introduction:

The work group met on August 29-30, 2018, at NABP Headquarters in Mount Prospect, IL. This work group was established in response to member input.

Review of the Work Group Charge:

Work group members reviewed their charge and accepted it as follows:

1. Review existing state and federal laws and regulations regarding suspicious orders of controlled substances placed by pharmacies to wholesale distributors.
2. Recommend, if necessary, amending the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* to include a definition of a suspicious order.
3. Examine the feasibility of developing a database that would house wholesale transaction data, analyze purchasing patterns, identify suspicious orders, and report activity to appropriate enforcement authorities.

<u>Recommendation #1: NABP Should Amend the Model Act.</u>

The work group recommends that NABP amend the *Model Act*. The amendments recommended by the work group are denoted by <u>underlines</u>.

National Association of Boards of Pharmacy
Model State Pharmacy Act

Article V

Licensing of Facilities

Introductory Comment to Article V

The fifth and last substantive Article of the Model Act *concerns licensure of Pharmacies, Manufacturers, Wholesale Distributors, Repackagers, Third-Party Logistics Providers, and the like. The licensure requirements of this Article will provide a Board with knowledge of all facilities involved in the storage, Distribution, and sale of Drugs or Devices within the state and those located outside the state that are shipping Drugs or Devices into the state. They will permit a Board to verify compliance with federal requirements and better ensure against Drug or Device diversion from the legitimate channels of commerce and provide the necessary data for effective recalls and the dissemination of information.*

. . .

Section 504. Grounds, Penalties, and Reinstatement.

(a) No Person, Pharmacy, or Pharmacy Benefits Manager designated in Section 501 of this Act shall operate until a license has been issued to said Person, Pharmacy, or Pharmacy Benefits Manager by the Board.

(b) Except where otherwise permitted by law, it shall be unlawful for a Manufacturer or a Wholesale Distributor to Distribute or Deliver Drugs or Devices to any Person in this State not licensed under this statute. Any Person who shall Distribute or Deliver Drugs or Devices to a Person not licensed shall be subject to a fine to be imposed by the Board not to exceed one thousand dollars ($1,000) for each offense in addition to such other disciplinary action the Board may take under this Act. Except as otherwise indicated in this Act, each such violation shall also constitute a misdemeanor punishable upon conviction as provided in the criminal code of this State.

(c) The Board may Suspend, Revoke, deny, or refuse to renew the license of any Person, Wholesale Distributor, Pharmacy, or Pharmacy Benefits Manager on any of the following grounds:[1]

(1) the finding by the Board of violations of any Federal, State, or local laws relating to the Practice of Pharmacy, Drug samples, Wholesale or retail Drug or Device Distribution, or Distribution of controlled substances;

(2) any felony convictions under Federal, State, or local laws;

(3) the furnishing of false or fraudulent material in any application made in connection with Drug or Device Manufacturing or Distribution;

[1] The Prescription Drug Marketing Act of 1987 (PDMA) requires that the state licensing laws provide for the Suspension or Revocation of licenses upon conviction for violation of Federal, State, or local Drug laws or rules pertaining to the unlawful Distribution of Drugs at wholesale. The PDMA defines fines, imprisonment, or civil penalties.

(4) suspension or Revocation by Federal, State, or local government of any license currently or previously held by the applicant for the Manufacture or Distribution of any Drugs or Devices, including controlled substances;

(5) the furnishing of false or fraudulent information or omitting information on due diligence questionnaires and/or attestation documents regarding the purchase or receipt of Drugs from Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors.

…

Model Rules for the Practice of Pharmacy

…

Section 3. Personnel.

(a) Duties and Responsibilities of the Pharmacist-in-Charge

(1) No Person shall operate a Pharmacy without a Pharmacist-in-Charge. The Pharmacist-in-Charge of a Pharmacy shall be designated in the application of the Pharmacy for license, and in each renewal thereof. A Pharmacist may not serve as Pharmacist-in-Charge unless he or she is physically present in the Pharmacy a sufficient amount of time to provide supervision and control. A Pharmacist may not serve as Pharmacist-in-Charge for more than one Pharmacy at any one time except upon obtaining written permission from the Board.

(2) The Pharmacist-in-Charge has the following responsibilities:

(i) Developing or adopting, implementing, and maintaining:[2]

(A) Policies and procedures addressing the following:

(-a-) the provision of Pharmacy services;[3]

(-b-) the procurement, storage, security, and disposition of Drugs and Devices, particularly controlled substances and drugs of concern and the accurate completion and submission of due diligence questionnaires and attestation documents regarding the purchase or receipt of Drugs from Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors;

(-c-) computerized recordkeeping systems;

(-d-) Automated Pharmacy Systems;

(-e-) preventing the illegal use or disclosure of Protected Health Information, or verifying the existence thereof and ensuring that all employees of the Pharmacy read, sign, and comply with such established policies and procedures;

[2] The owner and/or pharmacy permit holder, along with the Pharmacist-in-Charge, are responsible for these policies and procedures.

[3] The Pharmacist-in-Charge, as part of the responsibilities to manage as effectively as possible a patient's therapy to avoid a harmful interruption of therapy because of a shortage or limited Distribution of medications, can proactively improve Pharmacy operations by developing a systematic approach to address such circumstances. References such as the American Society of Health-System Pharmacists (ASHP) Guidelines in Managing Drug Product Shortages could be used as resources for developing policies and procedures if appropriate. Additionally, Food and Drug Administration maintains a list of current and resolved drug shortages, as well as discontinued drugs on the agency's Drug Shortages Web page at **www.fda.gov/cder/drug/shortages**.

(-f-) operation of the Pharmacy in the event of a fire, flood, pandemic, or other natural or man-made disaster or emergency, to the extent that the Pharmacy can be safely and effectively operated and the Drugs contained therein can be safely stored and Dispensed. Such policies and procedures shall include reporting to the Board the occurrence of any

…

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

Add definition of Drug of Concern

"Drug of Concern" means any prescription or over-the-counter medication that demonstrates a potential for abuse, particularly controlled substances and those identified by Boards of Pharmacy and legislative or regulatory enactments.

Add definition of Suspicious Order

"Suspicious Order" includes, but is not limited to, the following:

1. Orders of unusual size;
2. Orders deviating substantially from a normal pattern;
3. Orders of unusual frequency.

Add definition of Potential Diversion Activity

"Potential Diversion Activity" means activity where evidence exists that drugs of concern are likely being diverted or have the potential for diversion from legitimate channels.

…

Section 7. Operations/Reporting Requirements.

(a) Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale 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.

(b) Wholesale Distributors shall design and operate a system to identify and report to a program approved by the Board for Suspicious Orders or Drugs of Concern by customers and potential customers.

(1) Suspicious Orders shall be submitted electronically to the NABP Suspicious Orders System within five days of the order being identified as suspicious by the 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 license number;
vi. Transaction date;
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.

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

(c) Except as described in paragraph 7(d), a Wholesale Distributor shall exercise due diligence to identify customers ordering or seeking to order Drugs of Concern and establish the normal and expected transactions conducted by those customers, as well as to identify and prevent the sale of 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 an annual basis:

(1) Questionnaires and affirmative steps by the Wholesale Distributor to confirm the accuracy and validity of the information provided;

(2) For a customer who is a prescriber, confirmation of prescriber type, specialty practice area, and if the prescriber personally furnishes Drugs of Concern and the quantity furnished;

(3) Review of drug utilization reports; and

(4) 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;

(iii) Orders for Drugs of Concern from other Wholesale Distributors made available by US DEA's Automation of Reports and Consolidated Orders System; and

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

(d) A Wholesale Distributor receiving a request for an initial sale for a Drug of Concern may conduct the sale without complying with Paragraph 7(c) if all the following apply:

(1) The sale is to a new customer;

(2) The Wholesale Distributor documents that the order is to meet an emergent need; and

(3) The Wholesale Distributor completes the requirements of 7(c) no later than 60 days from the date of sale.

(e) Any customer that is believed to likely be engaged in Potential Diversion Activities, including those to whom a Wholesale Distributor refuses to sell, shall be electronically reported by a Wholesale Distributor to a program approved by the Board. Such reports shall include:

i. Customer name;

ii. NABP e-Profile ID;

iii. Customer address;

iv. DEA number;

v. State license number(s); and

vi. A detailed explanation of why the Wholesale Distributor identified the customer as a possible diversion risk.

Such reports shall be submitted within five days of refusal, cessation, or identification by the Wholesale Distributor.

(f) Within 90 days of the effective date of this rule, a Wholesale Distributor shall provide to a program approved by the Board, information on all customers in the state where the Wholesale Distributor has refused to or has stopped selling to within the past year because the Wholesale

Distributor has identified the customer as engaging in possible activities that may cause reported drugs to be diverted from legitimate channels.

(g) All licensed Wholesale Distributors shall submit all reports to the NABP Suspicious Orders System in a DEA Automation of Reports and Consolidated Orders System format.

…

Section 10. Policies and Procedures.

Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, and shipping and Wholesale Distribution of Prescription Drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors shall include in their written policies and procedures the following:[4]

(a) A procedure to be followed for handling recalls and withdrawals of Prescription Drugs and Devices. Such procedure shall be adequate to deal with recalls and withdrawals due to:
  (1) Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy; or
  (2) Any volunteer action by the Manufacturer to remove defective or potentially defective Prescription Drugs or Devices from the market.

(b) A procedure to ensure that Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, State, or national emergency.

(c) A procedure to ensure that any outdated Prescription Drugs shall be segregated from other Prescription Drugs and either returned to the Manufacturer or destroyed in accordance with Federal and State laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated Prescription Drugs.

(d) A procedure for the destruction of outdated Prescription Drugs in accordance with federal and state laws.

(e) A procedure for the disposing and destruction of containers, Labels, and packaging to ensure that the containers, Labels, and packaging cannot be used in Counterfeiting activities, including all necessary documentation, maintained for a minimum of three (3) years, and the appropriate witnessing of the destruction of any Labels, packaging, Immediate Containers, or containers in accordance with all applicable Federal and State requirements.

(f) A procedure for identifying, investigating and reporting significant Prescription Drug inventory discrepancies involving Counterfeit, suspect of being Counterfeit, Contraband, or suspect of being Contraband, in the inventory and reporting of such discrepancies as required to FDA, Board and/or appropriate Federal or State agency upon discovery of such discrepancies.

[4] In developing policies and procedures for the management and quality improvement of the Wholesale Distribution activities of a Wholesale Distributor, the Board may want to refer to the Healthcare Distribution Management Association and the National Association of Chain Drug Stores.

(g) A procedure for reporting criminal or suspected criminal activities involving the inventory of Prescription Drug(s) and Device(s) as required to the Board, FDA, and, if applicable, DEA.

(h) A procedure for verifying security provisions of Common Carriers.

(i) Procedures addressing:

(1) The design and operation of the Suspicious Order monitoring and reporting system;

(2) Mandatory annual training for staff responsible for identifying and reporting suspicious orders and potential diversion activities. Such training must include the following:

(i) The Wholesale Distributors Suspicious Order monitoring system

(ii) The process to collect all relevant information on customers in accordance with Paragraph 7(c);

(iii) The requirement and process for submission of Suspicious Orders and information on customers who may likely engage in Potential Diversion Activities.

…

Background:

Work group members representing various state pharmacy boards and industry representatives discussed the complexities associated with suspicious order reporting requirements, particularly the determination of what is a suspicious order. Currently, wholesale distributors must comply with federal requirements that mandate reporting suspicious orders for controlled substances to the Drug Enforcement Administration (DEA).[5] Several states require suspicious order reporting as well. Industry representatives explained that their review process to determine what is a suspicious order includes industry accepted algorithms that utilize thresholds.

State board of pharmacy executive officers in attendance explained that suspicious order reporting is currently of limited usefulness, primarily due to the confusion about what is a suspicious order. In some instances, wholesaler distributors are reporting every order received (what one participant deemed "malicious compliance"), while in other instances, some wholesale distributors report none. They also explained that they need more information to discern the value of the reports to best serve and protect the public - they need to know why an order would cause wholesale distributors to pause from routine order fulfillment. In addition, industry representatives were urged to timely reach out to state boards to specifically express concern about any pharmacy that appears to be a danger due to suspicious activity.

Further, board executives explained that halting orders may result in harm to patients who have a legitimate medical need for opioid medications. Some pharmacies may run out of those needed medications. Other pharmacies may refuse to accept new patients to avoid a sudden spike in order quantities, thus avoiding the risk of being cut off by their wholesale distributor. This is particularly problematic in rural areas where there may be limited access to pharmacies.

[5] 21 CFR 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.

With input from industry experts, members recommended amending the *Model Act* to:

1. Include a definition for "Suspicious Order" that is consistent with DEA regulations and the state of Ohio's definition;
2. Make the act of providing inaccurate or fraudulent information about purchase orders to wholesale distributors grounds for discipline; and
3. Designate the pharmacist-in-charge responsible for ensuring that truthful information is submitted to wholesale distributors regarding controlled substance purchases and receipt.

The aim of this recommendation was to close any loopholes that may exist within wholesale distributors' due diligence surveillance processes.

In addition, work group members recommended that all suspicious order reports should be routed through a centralized NABP Suspicious Orders System for state boards of pharmacy to view and monitor. State representatives reviewed examples of suspicious order reports and noted that some wholesale distributors provide more helpful information than others. Routing orders through an NABP system will ensure that all wholesale distributor drug sales reports conform to one standard, outlined by NABP's *Model Act*, and provide states with the necessary information to make the best decisions to protect the public health.

Recommendation #2: NABP Should Review the CMS Algorithm for Appropriate Incorporation.

The work group recommends that NABP review the Centers for Medicare and Medicaid Services (CMS) algorithm for appropriate incorporation into state suspicious order reporting regulations.

Background:

Work group discussion focused on how CMS assesses opioid usage with an algorithm to detect fraud and abuse that is also being used by some wholesale distributors to flag suspicious orders. Work group members recommended that NABP research this topic more closely to explore if the CMS algorithm can be utilized by state pharmacy boards as a standardized measurement to assist in evaluating suspicious order reports. Members noted that it would be ideal if all stakeholders used the same, or similar, algorithm when assessing purchase orders for suspicious activity to bring about uniform assessments and actions.

Recommendation #3: NABP Should Create Model Language to Require Wholesale Distributors to Submit to the NABP System all Sales Data for Controlled Substances and Drugs of Concern.

The work group recommends that NABP create model language to require wholesale distributors to submit to the NABP system all sales data for controlled substances and drugs of concern for enhanced oversight.

Background:

Work group members were mindful that pending federal bills may mandate that controlled substance purchase orders be reported to a central database. If this federal legislation fails to pass, work group members suggested that NABP serve as a central storage hub for all controlled substance sales records that should be reported in the ARCOS format. An NABP database of wholesale distributor drug sales will reinforce state efforts to track and investigate suspicious controlled substance ordering and sales activity by allowing state regulators to match prescription monitoring program data to sales data. However, such a reporting program must be financially feasible for NABP and cost neutral for NABP member boards.

Recommendation #4: NABP Should Create and Maintain Appropriate Contacts to Share With Industry Stakeholders for Suspicious Order Reporting.

The work group recommends that NABP create and maintain appropriate contacts to share with industry stakeholders for suspicious order reporting to bolster state regulatory efforts.

Background:

Industry representatives explained that they wish to comply and assist the boards in investigating suspicious orders; however, they also expressed the need for pharmacy board and DEA actions against pharmacies that they have reported as engaging in suspicious activity to be more timely. Wholesale distributors that comply with reporting requirements are left to question decisions to halt sales when the pharmacy is free to purchase the controlled substances from other distributors. Furthermore, industry representatives stressed that it would be helpful if some states were more responsive to their notifications about suspicious orders. States agreed that better communication is crucial. Therefore, it was determined that NABP should compile and maintain a list of direct board contacts for industry representatives to use to notify states about suspicious orders. The contact list would contain information provided by the boards to be used for this specific purpose.