



Healthcare Distribution Alliance

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Injunctive Relief and CSMPs



- HDA Members' Requirements
- Communication is Key
- Don't Hesitate to Reach Out to Your Wholesale Distributor



Cardinal Health's Controlled Substance Monitoring Program (CSMP) Overview

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Disclaimers

- This presentation is intended to be a review of the various processes Cardinal Health's Controlled Substance Monitoring Program engages in with our retail pharmacy customers.
- This presentation does not identify, describe, or cover all aspects of Cardinal Health's programs regarding the distribution of controlled substances or all roles and responsibilities of Cardinal Health's CSMP.
- These processes are current as of the date of this presentation. Cardinal Health's CSMP may add, supplement and/or remove any events or tasks from the various event processes at any time due to a need to meet our various obligations under laws/regulations and our opioid settlement.



Agenda

1. CSMP Settlement Enhancements
2. Highlighting areas of the CSMP:
 1. Onboarding
 2. Thresholds
 3. Reporting
3. Resources



CSMP Settlement Enhancements



CSMP Settlement Enhancements

CONTROLLED SUBSTANCES ACT OF 1970

21 USC 802 (57) Definitions

The term "suspicious order" may include, but is not limited to-

- (A) an order of a controlled substance of unusual size;
- (B) an order of a controlled substance deviating substantially from a normal pattern; and
- (C) orders of controlled substances of unusual frequency.

21 USC 832 (a) Suspicious Orders

Each registrant shall-

- (1) design and operate a system to identify suspicious orders for the registrant;
- (2) ensure that the system designed and operated under paragraph (1) by the registrant complies with applicable Federal and State privacy laws; and
- (3) upon discovering a suspicious order or series of orders, notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the Drug Enforcement Administration for the area in which the registrant is located or conducts business.



CSMP Settlement Enhancements

SYSTEMS TO IDENTIFY SUSPICIOUS ORDERS

To comply with these statutory and regulatory requirements, many DEA-registered manufacturers and distributors establish controlled substance monitoring systems that set thresholds that may limit the amount of a customer's controlled substance purchases and may prompt a report of a suspicious order to DEA.

However, whether to set such thresholds (if any) and at what levels are decisions that each manufacturer or distributor may make in the design and implementation of its controlled substance monitoring system. DEA does not have a role in establishing or revising thresholds for controlled substances that manufacturers or distributors may set for their customers as part of the required monitoring systems.

- Excerpt from DEA Guidance issued January 20, 2023.



CSMP Settlement Enhancements

SETTLEMENT IMPOSES REQUIREMENTS ON DISTRIBUTORS

The National Opioid Settlement established injunctive relief terms that distributors must comply with regarding the sale, monitoring and reporting of controlled substances. Provisions of the settlement are comprehensive and include specific guidance on the following:

- Identifying Red Flags
- Onboarding
- Due Diligence
- Site Visits
- Establishing Thresholds
- Suspicious Order Reporting and Non-shipment
- Establishing a Clearinghouse to obtain comprehensive data from all distributors, pharmacies, and other relevant data sources to provide maximum permissible transparency into the distribution and dispensing of Controlled Substances



CSMP Enhancements

1 Pharmacy Customer Data (PCD)

- Aggregated Dispense Data
- Prescriber reviews
- Onboarding, Threshold Reviews, Ongoing Due Diligence
- Red Flag(s) Diligence
- Annual Registrant Questionnaire Refresh

2 PIC Interviews

- New PharmD Team
- Onboarding, Threshold Reviews, Ongoing Due Diligence
- Enhanced Staff Diligence

3 Site Visits

- Unannounced and Announced Visits
- Training investigators looking for signs of diversion

4 Threshold Setting

- Industry Consultants

5 Communication

- CSMP Website
- Thresholds (amounts, approaching, or suggest review)



Highlighting areas of the CSMP: Onboarding



Onboarding Overview

COMPLETION OF REGISTRANT QUESTIONNAIRE AT CARDINALHEALTH.COM/CSMP

- Completed online for:
 - All potential new customers
 - Existing secondary and tertiary customers that are moving to utilizing Cardinal Health as their primary supplier
 - Any existing customers undergoing DEA number changes (due to an ownership change or change in address)

Letter to customers

Communication regarding: Proposed opioid litigation comprehensive settlement and injunctive relief terms that may impact pharmacy customers.

[View the letter »](#)

Contact Cardinal Health CSMP

If you are a current Cardinal Health customer, contact the Cardinal Health CSMP.

[View contacts »](#)

Business Conduct Line

To confidentially report a concern related to the possible diversion of Controlled Substances, please call our Business Conduct Line which is available 24 hours-a-day, seven days-a-week.

[Learn more »](#)

Registrant questionnaire

Please click this link to complete the Registrant Questionnaire if you are new to Cardinal Health or a Cardinal Health CSMP representative has instructed you to complete it.

[Complete the questionnaire »](#)



Onboarding Overview

INFORMATION GATHERING

- Interview Pharmacist in Charge (PIC)
- Collect and review Pharmacy Customer Data (PCD): 90 days of ALL customer's dispensing. Allows us to:
 - Determine **top prescribers of certain highly diverted controlled substances** (“HDCS”) for the purposes of license review, law enforcement review, and the PIC interview;
 - Populate the **Objective Criteria** and **Red Flag Analysis** files for review in those respective tasks by a Cardinal Health pharmacist;
 - Develop an “All Aggregates” file that provides the CSMP team a high-level summary and aggregated view of the pharmacy's dispensing that, among other things, assists in setting thresholds should we decide to onboard.
- Review information on disciplinary sanctions and law enforcement action related to controlled substances for the pharmacy, its pharmacists, and top prescribers
- Identify all distributors being used by the pharmacy



Highlighting areas of the CSMP: Thresholds



Thresholds

- Each Injunctive Relief Distributor shall use Thresholds to identify potentially Suspicious Orders of Controlled Substances from Customers.
- Each Injunctive Relief Distributor's CSMP department shall be responsible for the oversight of the process for establishing and modifying Thresholds. The sales departments of the Injunctive Relief Distributors shall not have the authority to establish or adjust Thresholds for any Customer or participate in any decisions regarding establishment or adjustment of Thresholds.
- Injunctive Relief Distributors shall not provide Customers specific information about their Thresholds or how their Thresholds are calculated.
- The section on thresholds does include specific guidance about "Threshold Changes" and states that, "Any decision to raise a Customer's Threshold in response to a request by a Customer to adjust its Threshold must be documented in writing and state the reason(s) for the change. The decision must be consistent with the Injunctive Relief Distributor's CSMP and documented appropriately."



Thresholds

- “Thresholds” are ceilings above which Cardinal Health will not ship controlled substances within a specific accrual period.
 - Order exceeds a threshold = “threshold event”
- Set on a per customer, per drug family basis by DEA base code, independent of each other
 - Cardinal Health also sets and enforces sub-base code thresholds for products that can pose higher risk of diversion (*e.g.*, oxycodone single entity)
- Utilize **model-based thresholds**.
- Supports identifying orders of “unusual size, frequency, or pattern”



Thresholds

ORDERS ABOVE ESTABLISHED THRESHOLD

- Orders above threshold are automatically held and cancelled.
- Reported orders do **not** indicate that Cardinal Health suspects diversion*
- Threshold events do result in customer due diligence (the purpose of the review of the customer is to determine if additional customer due diligence is needed).

**If diversion by a customer is suspected, Cardinal Health suspends that customer's ability to receive controlled substances/listed chemicals.*



Thresholds

THRESHOLD VISIBILITY

- Cardinal Health is not permitted to inform customers when their orders are approaching a threshold, recommend the amount of a requested threshold increase, or suggest a customer request a threshold increase.
- Further, our settlement agreement requires that neither our customers nor our sales organization be told threshold limits or provided specific information on how a customer's specific thresholds are calculated.
- Cardinal Health does not share with customers our threshold reset dates (*i.e.*, when your monthly threshold “starts over”).



Thresholds

THRESHOLD ADJUSTMENTS

- Customers must provide comprehensive justification for threshold change request, including Pharmacy Customer Data.
- Cardinal Health will conduct appropriate due diligence to determine whether a threshold change is warranted.
- Thresholds continue to be dynamic.
- Resources:
 - cardinalhealth.com/csmp under the “Contact Us” section

Contact us

Controlled substance inquiry

Cardinal Health customer contact the Cardinal Health CSMP

Start the process »

Threshold change request

If you would like to request an increase in your threshold

[Start my threshold change request »](#)

[View the threshold change request user guide »](#)



Thresholds

CUSTOMER COMPLETES THRESHOLD CHANGE REQUEST FORM

- A customer completes a Threshold Change Request when it believes a threshold change is warranted.
- The customer's Threshold Change Request submission must include:
 - a detailed explanation as to why the pharmacy believes a threshold change is warranted.

CardinalHealth

Controlled Substance Inquiry

You selected drug family : (1625) LORCASERIN

Please explain in detail why you believe a threshold adjustment is warranted. Generic statements that, for example, your pharmacy is seeing an increase in prescriptions for a particular drug family, are insufficient and will be rejected unless accompanied by facts supporting the increase in prescriptions (e.g., identification of the number of new patients, identification of a new prescriber, and/or identification of the number of new prescriptions and your understanding of why you're seeing them).

By submitting this request, customer warrants and represents that, to the actual knowledge of the individual submitting this inquiry, the information contained in this form is true and accurate as of the date hereof. Customer also acknowledges that its completion of this form is no guarantee of a threshold increase.



Highlighting areas of the CSMP: Reporting



Four Types of Reports to Regulators

- **Suspicious Order Report (SOR)** – 1 page memo that details why a pharmacy customer's order is flagged as suspicious
- **Quarterly Summary Report** – breaks down the top 10 customers by volume for each Highly Diverted Controlled Substance (HDCCS) base code that have placed a suspicious order
- **Decline to Onboard Reports** – notification that a customer is refused to onboard for the sale of CS due to concerns regarding their ability to provide effective controls against potential diversion
- **Terminated Customer Reports** – notification that a customer is terminated from eligibility to receive CS due to concerns regarding their ability to provide effective controls against potential diversion
- Cardinal Health's Reports are currently made available to Board staff and the Attorney General's office.



Resources



Resources

- Access information on the Cardinal Health CSMP at cardinalhealth.com/csmp
- Contact your distributor for information on their CSMP.
- The distributor settlement agreement, including Exhibit P “Injunctive Relief”, is available online.

Thank you

