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 Heath'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. Onboarding
3. Thresholds

CSMP Overview & 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 Overview & 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 distributer 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 Overview & Enhancements

SETTLEMENT IMPOSES REQUIREMENTS ON DISTRIBUTORS

The National Opioid Settlement established injunctive relief terms (Exhibit P) 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 Program Enhancements

1

Pharmacy Customer Data (PCD)

- Aggregated Dispense Data
- Prescriber reviews
- Onboarding, Threshold Reviews, Ongoing Due Diligence
- Red Flag(s) Diligence
- Annual RQ (KYC) refresh
- Six ways to retrieve

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

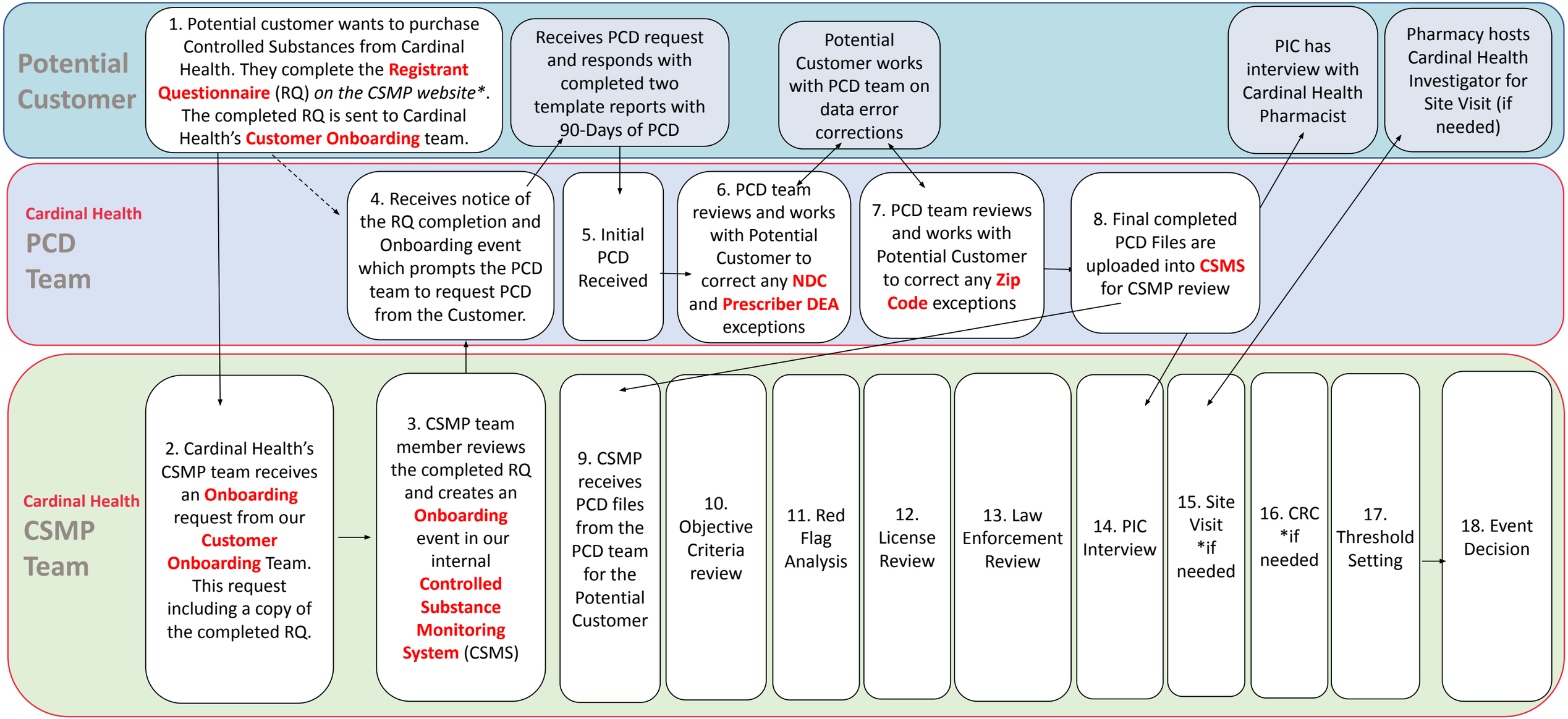
5

Communication

- CSMP Website
- Thresholds (amounts, approaching, or suggest review)
- Engagement with other IR Distributors

Onboarding

Customer Onboarding Overview

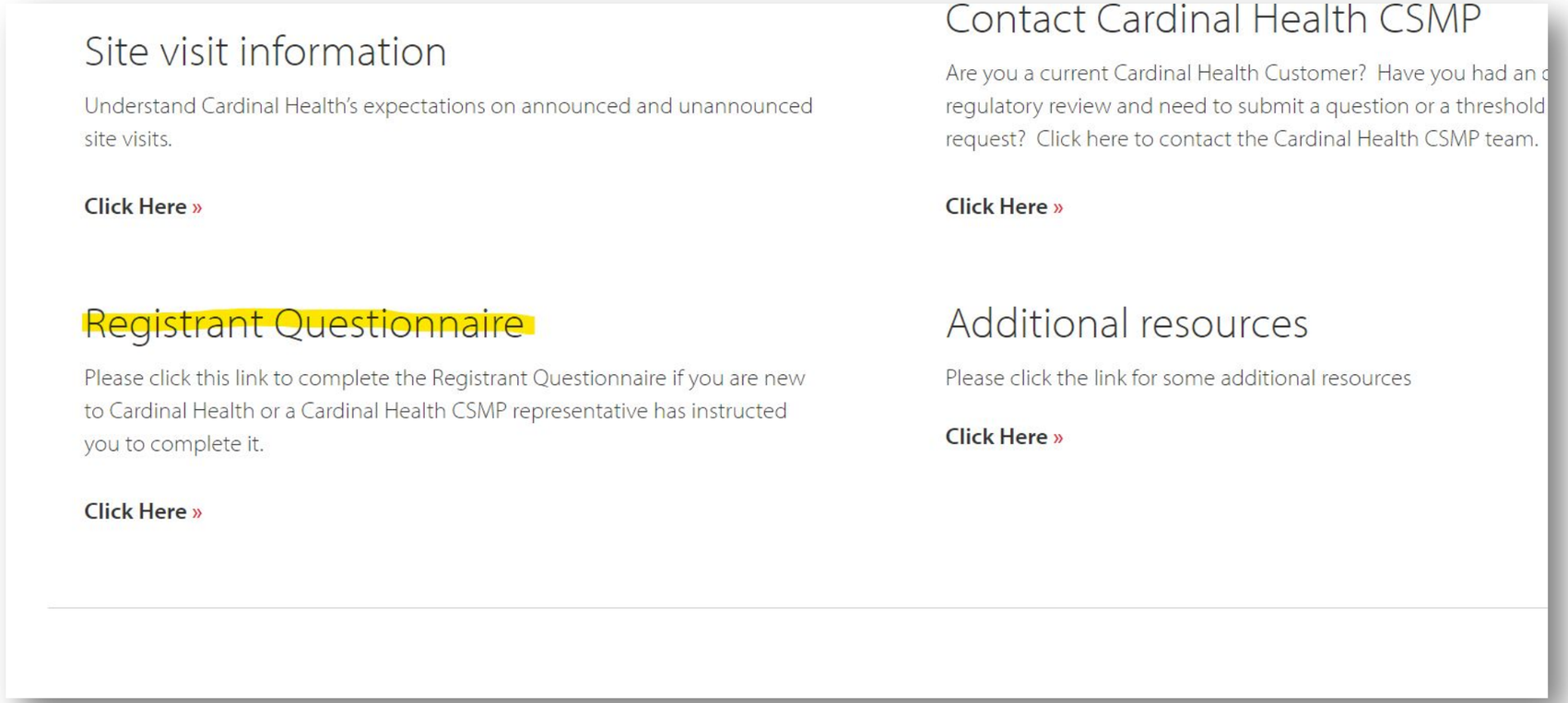


Onboarding Overview

COMPLETION OF REGISTRANT QUESTIONNAIRE

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)



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

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”

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*

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's threshold setting methodology includes the implementation of daily, monthly, and quarterly threshold limits.
- Cardinal Health does not share with customers our threshold reset dates (*i.e.*, when your monthly threshold "starts over").

Threshold Adjustments

- Threshold Change Request Overview
- 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.

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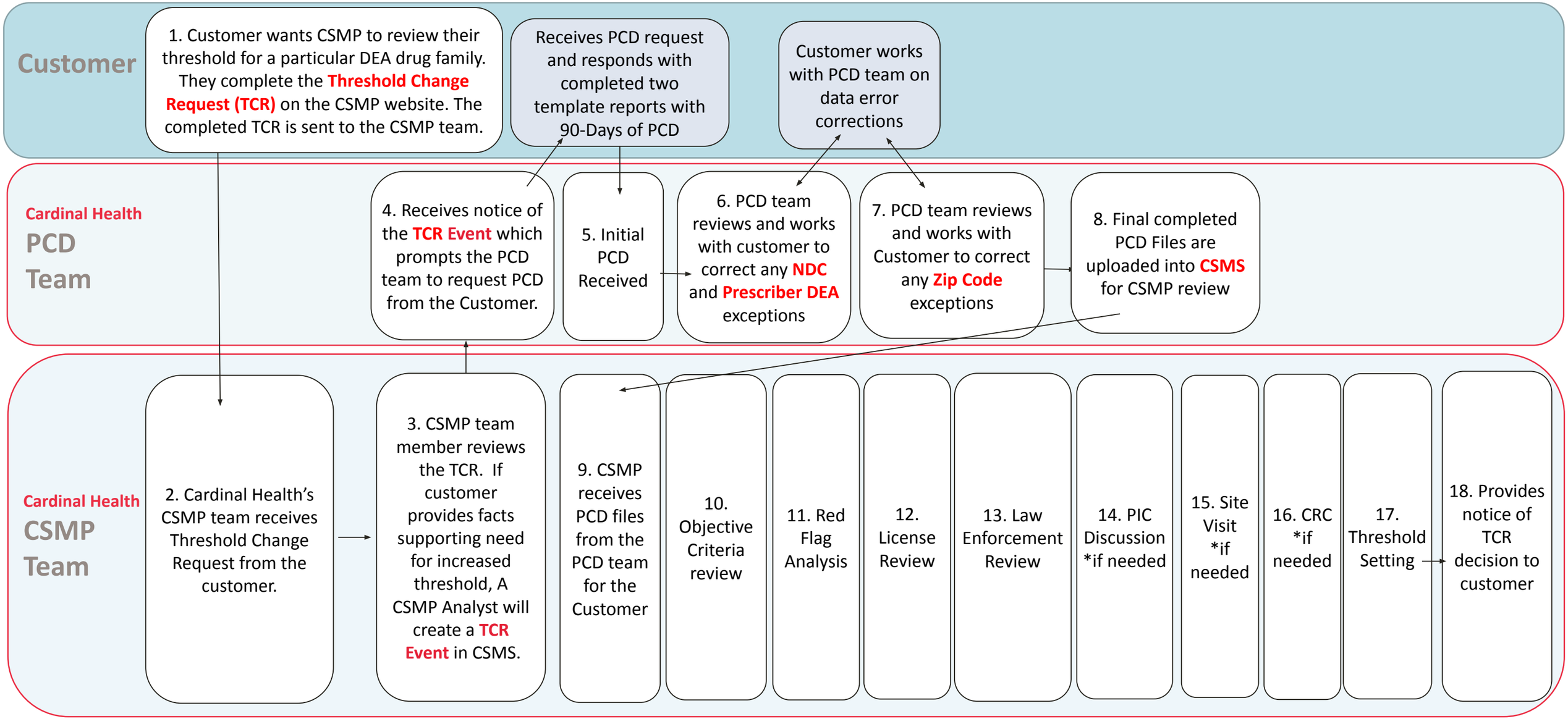
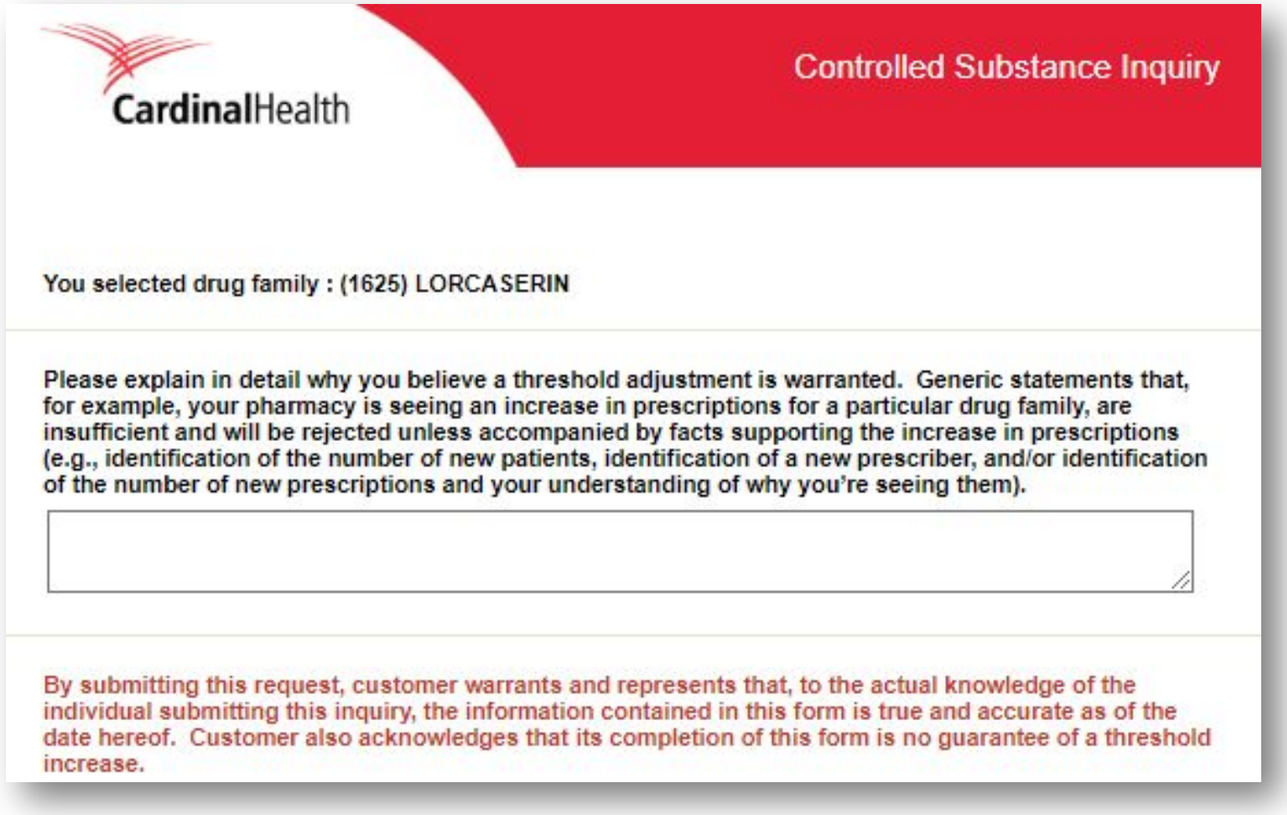
THRESHOLD CHANGE REQUEST



THRESHOLD CHANGE REQUEST

1. CUSTOMER COMPLETES THRESHOLD CHANGE REQUEST FORM

- A customer completed the PDF Threshold Change Request (and submits to their specific CSMP group mailbox) 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.



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