Suspicious Order Monitoring Program
Policy and Procedures for the Pharmaceutical Integrity Team

This **policy** and specific **procedures** govern how controlled substance orders are processed and what steps are taken by the Pharmaceutical Integrity team to investigate orders of interest in the Controlled Substance Order Monitoring system (CSOM).

Overview

Walgreens Distribution Centers (DCs) *must* take reasonable measures to identify its customers, understand the *normal and expected* transactions conducted by those customers, and identify transactions involving controlled substances that are *suspicious* in nature. For the purpose of this document, a DC "customer" is an individual Walgreen pharmacy. Orders must be assessed to ensure that quantities of controlled substances ordered by a specific location are reasonable. In making these assessments, the DC may consider the pharmacy's clinical business needs, location, and population served. Walgreens **must report** to the DEA any order that is determined to be suspicious.

How to Identify Normal, Expected Transactions

The following elements allow the Pharmaceutical Integrity team to understand and identify normal and expected transactions, which assists in identifying potentially suspicious transactions.

- **Accumulation of Receipts over time period:** The CSOM accumulates the amount of each controlled substance over a specified limitation period (i.e. over the last six weeks).
- **Ceiling Limit:** Data mining is done across Walgreens retail pharmacies to determine the maximum amount that a pharmacy should be allowed to receive in a rolling six week time period, based on statistical linear regression. The analysis compares like pharmacies across the country based on prescription volume and determines, by drug, an amount that would represent an unusual quantity.

Factors for Assessing all Orders to Determine Whether the Transaction is Reasonable

The following elements allow the Pharmaceutical Integrity team to assess <u>all</u> orders for controlled substances to determine whether the transaction is reasonable. This analysis is done for all controlled substance orders regardless of quantity.

- **Available to Order**: The pharmacy is allowed to order the quantity that is left "open," which is the ceiling limit, set through the analytical technique identified above, minus any accumulation of receipts over the six weeks along with any currently open orders that are in the supply pipeline. For example, if the pharmacy has a ceiling limit for Drug X of 10,000 dosage units, an accumulation of 5,000 dosage units, and 1,000 dosage units on order, the amount available to order is 4,000 (10,000-(5,000+1,000).
- **Central Monitoring and Control Dashboard**: The Pharmaceutical Integrity team is able to centrally monitor when a particular pharmacy is approaching a percentage of their ceiling limit (e.g. 75%) for any selected controlled substance as an early warning system to alert the corporate team of a potential concern. The team can then contact the pharmacy to determine if there is a concern or if the demand is justifiable.
- **Tolerance Limits**: Tolerance limits are in place to identify any unusual activity on an order-by-order basis to ensure that no individual order exceeds a given statistical limit. This calculation is based on that pharmacy's past order history.

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Reporting to DEA and State Agencies

Reporting is required to DEA and the applicable state agency when a transaction takes place that involves an extraordinary quantity of a controlled substance. The processes and policies put in place by Walgreens prevent any shipments from occurring that involve an extraordinary quantity; however, should any such order take place, it must be investigated to determine whether it is suspicious. If during the process the 'order of interest' is determined to be valid, documentation is required before the ceiling limit can be increased and additional orders can be shipped. If during the course of the investigation the order is deemed suspicious, the order is not shipped and it is reported to DEA and the state agency, if applicable.

In the event that a pharmacy requests that an order be shipped which exceeds the ceiling or tolerance limit, the Pharmaceutical Integrity team considers clinical business needs, location, and population served, in addition to other factors, prior to approving the order.

Using the Central Monitoring and Control Dashboard for Controlled Substance Order Monitoring

Process Overview
- Dedicated analysts investigate any order deemed an "order of interest." After investigation, any order of interest deemed suspicious will be reported to DEA.
- Pharmaceutical Integrity analysts are assigned specific markets so that the market is viewed in its entirety, as well as at the district, store and individual order level.
- Managers provide process and analytical support as needed.
- Each market is analyzed using the CSOM. The CSOM systematically highlights orders approaching tolerance and/or ceilings so that analysts can investigate the appropriateness of these orders.
- Analysts are able to drill down into the store ordering system to further evaluate the appropriateness of these orders.
- Analysts communicate with Pharmacy Supervisors to further understand the appropriateness of these orders, e.g. stores that support hospice centers, oncology centers, etc.
- Loss Prevention and Senior Management are involved as needed for escalations.

Process Steps
Use the following steps to access the system to identify orders of interest.
- To access the CSOM, type "CSOKPI" in your web browser; save it to your favorites for future use.
- Sign in with your authenticator.
- Use the screen shots below to guide you through the process of reviewing orders.

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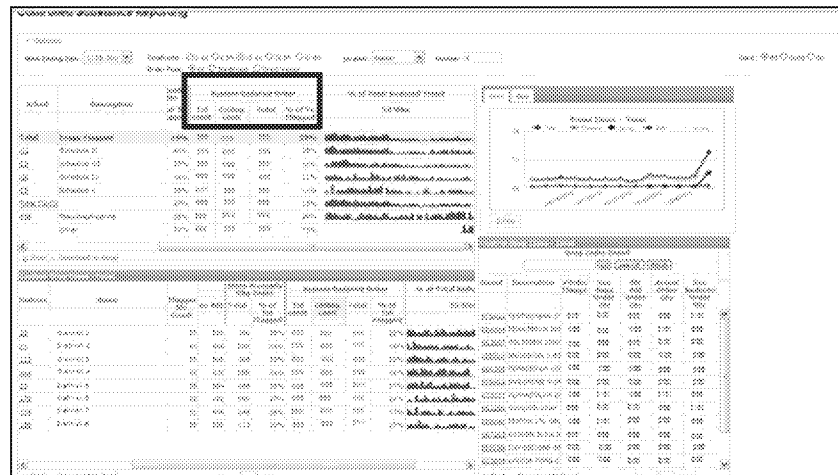1. From the Order Review home screen, use the Location drop down to choose **Market.**
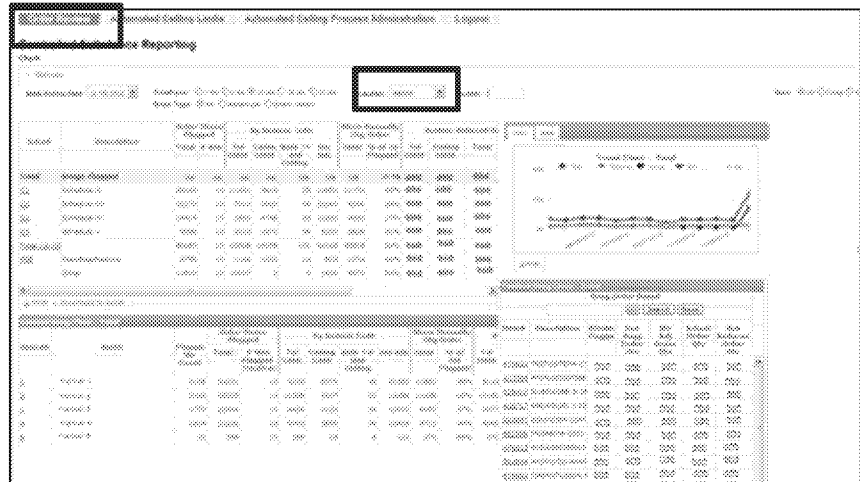
2. Enter the Market number and press enter.
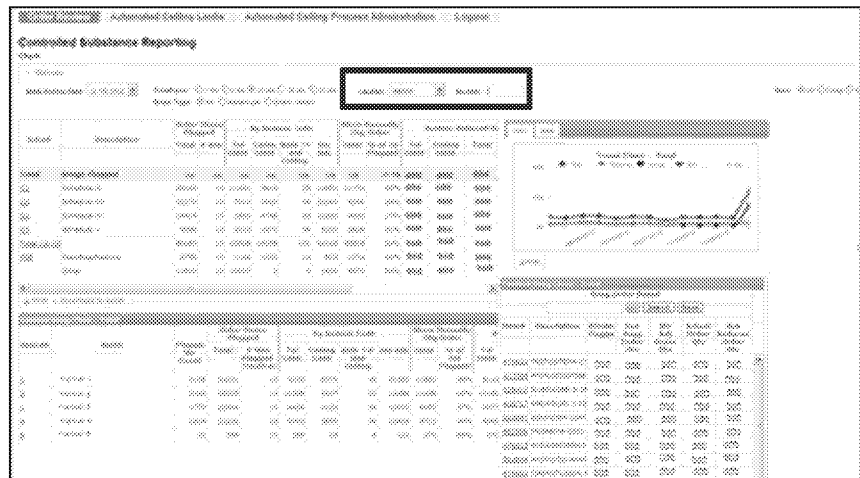
3. Scroll over in the top pane to view the number of System Reduced orders in this market.
   - The bottom left pane shows the list of districts in this market.
   - The bottom right pane shows the list of drugs ordered in this market.
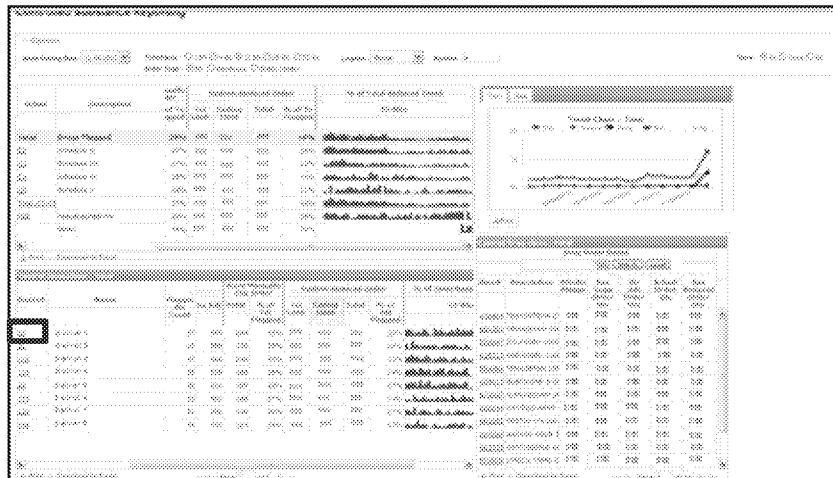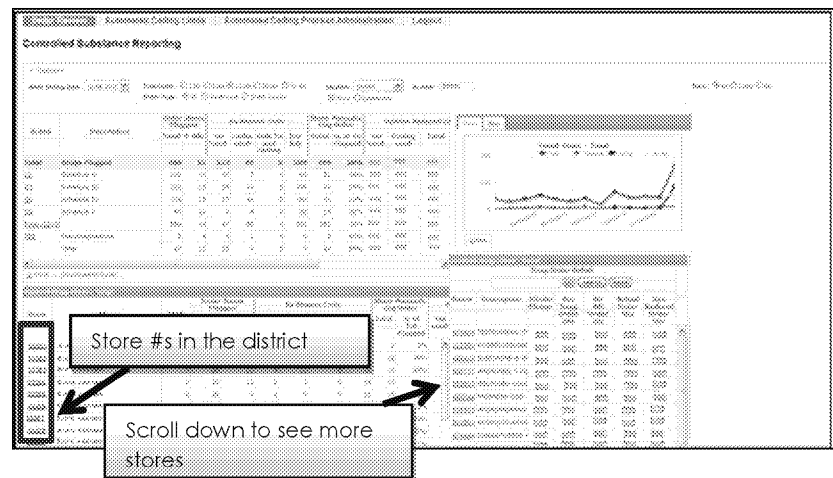
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4. Click the Ceiling Limit box in the System Reduced Order in the bottom left pane to see the rank order of districts within a market (most reduced, in descending order.)
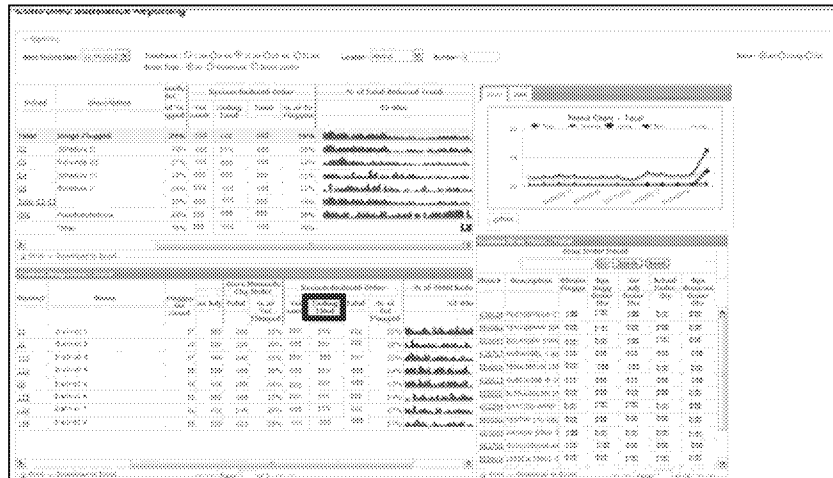
5. To view more details for a particular district, click the district number.

6. The system displays all stores in this district. All panes show data for this district only.

Store #s in the district

Scroll down to see more stores

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7. Click the Ceiling Limit box in the System Reduced Order in the bottom left pane to see the rank order of stores within a District. To see entries with a value other than 0 in the Ceiling Limit column for a specific store, click the store number.

Click store # to see store information
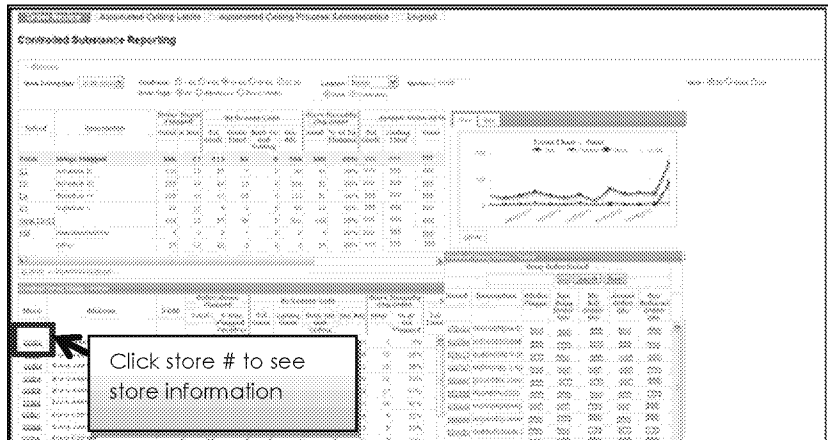
8. Now all panes display specific data for the store you selected. Analyze the data by focusing on System Reduced Order(s) reduced for ceiling limit.
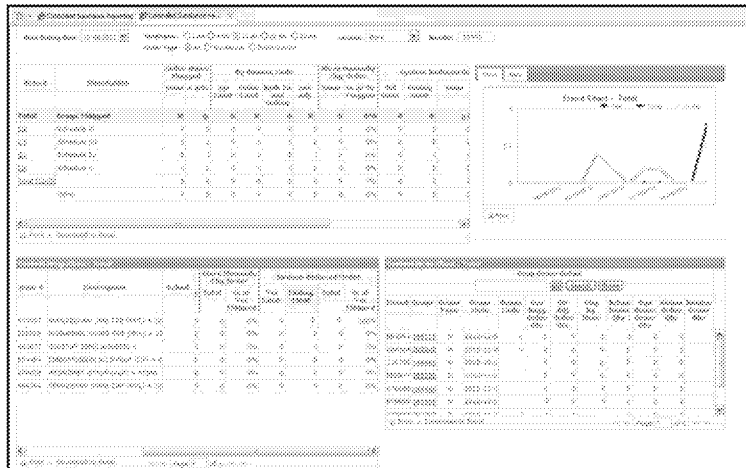
9. To evaluate each order, launch the application that connects to the Walgreens stores Strategic Inventory Management System (SIMS) on the store AS/400 server and enter the store number in the Host field.
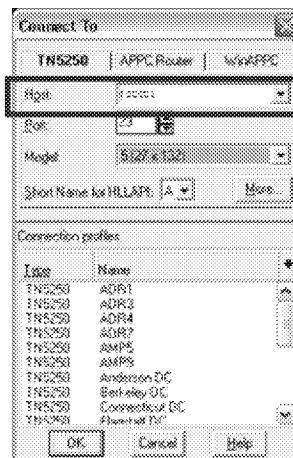
10. You are now connected to SIMS. Log in with your corporate sign-on.
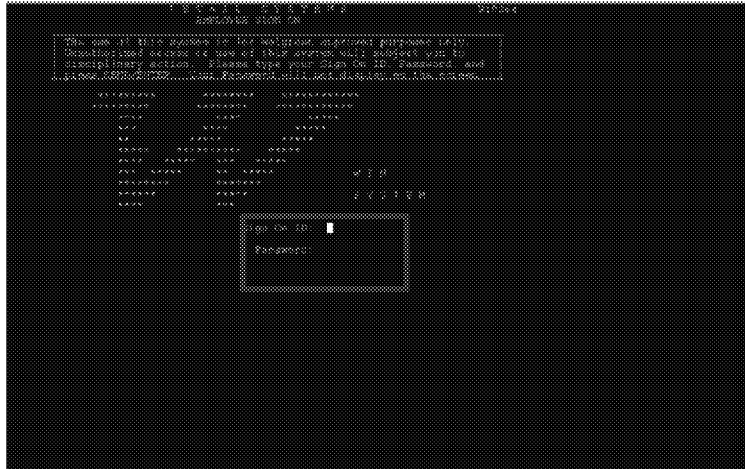
11. Type **Call ORCO400** on the selection or command line to access the store's SIMS Support screens.
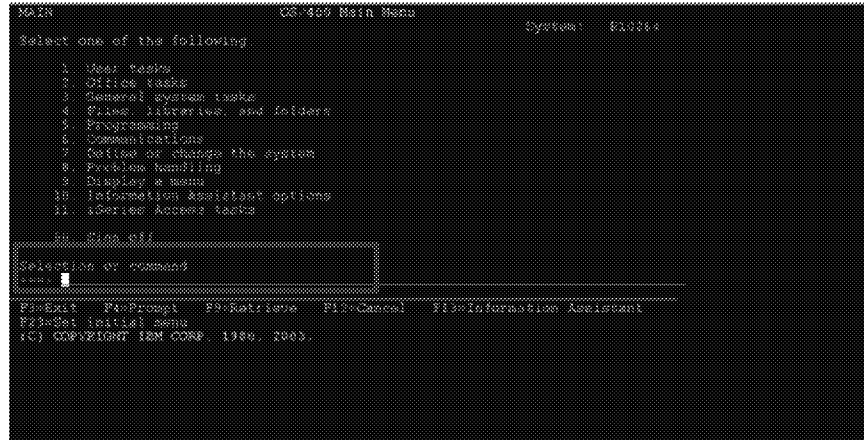
12. To view the order history of the item, query SIMS by entering any of the following for the item:

- **WIC**: Walgreens Item Code
- **UPC**: Universal Product Code
- **PLN**: Planogram Link Number, an inventory control number

and press enter.

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13. This displays the current open order. You can analyze the results of the previous query.
    - Press **F16** to view historical orders for this item.
    - Other function keys and selections drill down into more details about how and why the order was derived. Note that all details are not specific to Rx or controlled substances.

14. If, after using your professional judgment and pharmacy operations experience, you believe this order needs further investigation, email the Pharmacy Supervisor from the Pharmacy Integrity mailbox, using this email template.
    - Remember to work all appropriate drugs into one email.
    - Please add your initials only to your email.
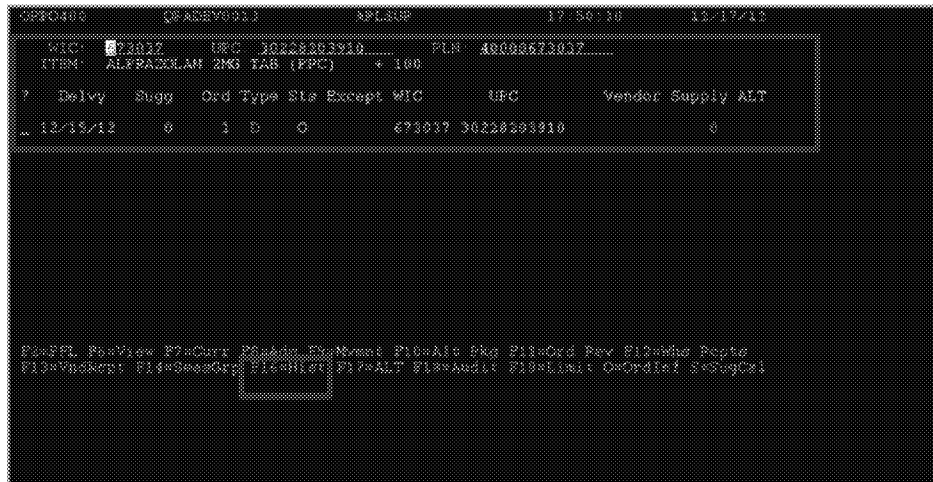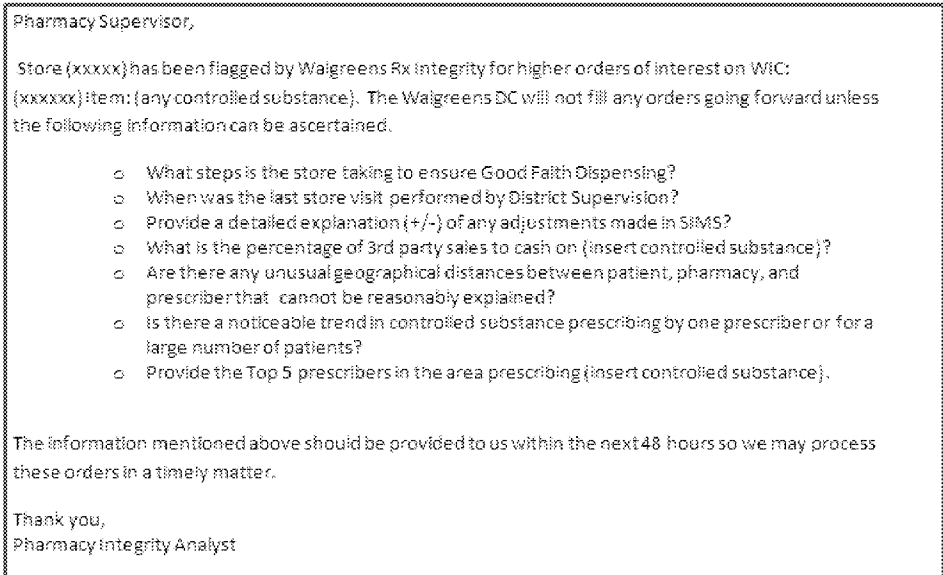   - List store number in tracker.

Pharmacy Supervisor,

Store (xxxxx) has been flagged by Walgreens Rx Integrity for higher orders of interest on WIC: (xxxxxx) item: (any controlled substance). The Walgreens DC will not fill any orders going forward unless the following information can be ascertained.

- What steps is the store taking to ensure Good Faith Dispensing?
- When was the last store visit performed by District Supervision?
- Provide a detailed explanation (+/-) of any adjustments made in SIMS?
- What is the percentage of 3rd party sales to cash on (insert controlled substance)?
- Are there any unusual geographical distances between patient, pharmacy, and prescriber that cannot be reasonably explained?
- Is there a noticeable trend in controlled substance prescribing by one prescriber or for a large number of patients?
- Provide the Top 5 prescribers in the area prescribing (insert controlled substance).

The information mentioned above should be provided to us within the next 48 hours so we may process these orders in a timely matter.

Thank you,
Pharmacy Integrity Analyst

15. After you have completed the process for one drug, move to the next on the list for the market you are reviewing.

16. After completing all drugs, move to the next market.

17. Evaluate the response from the Pharmacy Supervisor using these points:
    - If the survey is incomplete, reply to the Pharmacy Supervisor for additional information.
    - If the survey is complete:
        - Is there a legitimate reason for exceeding the ceiling limit?
            - Examples of legitimate reasons for an increase in the ceiling limit include:
                - ✓ Oncology site
                - ✓ Hospice site
                - ✓ Recent buy-out or closure of a competitor
                - ✓ Patient has insurance change leading to transfer to Walgreens
                - ✓ New medical center (ER) in area
                - ✓ Change in state or third party formulary, drug shortage, etc.
            - If, in your professional judgment, the pharmacy warrants a change in the ceiling limit, forward suggested changes to your manager.
        - Are the reasons provided inadequate?
            - Examples of potentially inadequate reasons for surpassing the ceiling limit include:
                - ✓ Favored drug of a particular prescriber
                - ✓ New pain clinic in the area
                - ✓ Good Faith Dispensing practices at the store are inadequate
                - ✓ Multiple patients with the same prescriber
                - ✓ Patients with multiple prescribers for the same prescription
    - If, in your professional judgment, the order is confirmed to be suspicious, prepare the fax template as shown below to review with your manager before faxing it to the DEA and state agency, if appropriate.

Walgreens has identified the following orders of interest that appear to be of unusual size, unusual frequency or deviate substantially from a normal pattern.

Date	Store#	Address	City	State	ZIP	DEA #	Drug Name	NDC #	Package Size	Quantity ordered (# bottles)
########	0	Store Address			####	store DEA#	Hydrocodone/APAP 10/500MG	00531-0540-05	500	30

Please feel free to contact Tasha Polster at (847) 315-3379 if you need additional information

18. Escalations
    - Use your professional judgment and pharmacy operations experience when reviewing orders.
    - You should escalate:
        - Unusual trends in the historical data
        - Patterns in drug families in certain markets and communities
    - Escalate these instances and any questions that are not covered in these policies and procedures to your manager.
    - Loss Prevention and Senior Management will be involved as needed for escalations.
        - Note that escalations may lead to policy re-education, other store level training, Loss Prevention investigations, and disciplinary action, when appropriate.

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