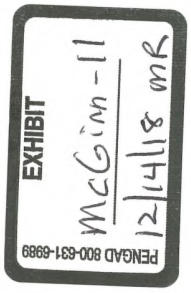
From: Chris Lowery
To: Colleen McGinn
Sent: 5/24/2012 8:20:09 PM
Subject: RE: Cardinal SOM issues
Attachments: DEA Suspicious Monitoring Compliance DRAFT.docx



OK – Good job. Add this to your white paper.

See Attached

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Woodcliff Lake, NJ 07677
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From: Colleen McGinn
Sent: Thursday, May 24, 2012 3:57 PM
To: Dennis Ferrell; Chris Lowery
Subject: Cardinal SOM issues

Check this out. Mike Meggiolaro got a copy of the Cardinal court papers…

According to the court papers, the following was cited:

Lack of site visits, which would have revealed that 40 -42 % of the oxycodone prescriptions were paid for in cash, an indicator of potential diversion under Cardinal's policies

Inadequate investigation of the exponential increase of oxycodone purchases by CVS

Awareness and approval of this dramatic increase, raising the allowed threshold amounts and sometimes disregarding the amounts

Allowing almost all shipments through, even those that had been held for further inquiry

Failure to report the two pharmacies to the DEA.

That's all I have.

Michael

EXECUTIVE SUMMARY

The goal is to create a defendable position to meet the DEA regulations and current DEA required practices. This is considered a compliance area in which we are "at risk" and therefore the highest priority should be placed to close all gaps.

I understand that there are two primary areas for consideration. They are:

1. Suspicious Ordering Program – In good shape
2. "Know your Customer" Program – Not Compliant

Regulations conflict with published requests from the DEA. Industry is trying to interpret and weigh both to find a reasonable solution. DEA and Industry continues to try and sort out the conflicting information.

DEA "will use its authority to revoke and suspend registrations in appropriate cases."

1. What are the current DEA Regs?

Title 21 United States Code (USC) Controlled Substances Act

Section 823. Registration Requirements

(a) Manufacturers of controlled substances in schedule I or II

The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(e) Distributors of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

Code of Federal Regulations

Section 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

(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.

Listed Chemicals SECURITY REQUIREMENTS

Section 1309.71 General security requirements.

(a) All applicants and registrants must provide effective controls and procedures to guard against theft and diversion of List I chemicals. Chemicals must be stored in containers sealed in such a manner as to indicate any attempts at tampering with the container. Where chemicals cannot be stored in sealed containers, access to the chemicals should be controlled through physical means or through human or electronic monitoring.

(b) In evaluating the effectiveness of security controls and procedures, the Administrator shall consider the following factors:

(8) The adequacy of the registrant's or applicant's systems for monitoring the receipt, distribution, and disposition of List I chemicals in its operations.

2. What are the current DEA Letters of Understandings?

LETTER 1 - September 27, 2006 DEA Letter to all Distributors in the U.S.

"DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion. Moreover, all registrants – manufacturers, distributors, pharmacies, and practitioners – share responsibility for maintaining appropriate safeguards against diversion. Nonetheless, given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm. Accordingly, DEA will use its authority to revoke and suspend registrations in appropriate cases.

The statutory factors DEA must consider in deciding whether to revoke a distributor's registration are set forth in 21 U.S. C. 823(e). Listed first among these factors is the duty of distributors to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. In addition, distributors must comply with applicable state and local law. Congress also gave DEA authority under this provision to revoke a registration based on the distributor's past experience in the distribution of controlled substances and based on "such other factors as may be relevant to and consistent with the public health and safety.

The DEA regulations require all distributors to report suspicious orders of controlled substances. Specifically, the regulations state in 21 C.F. R. 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."

"In a similar vein, given the requirement under section 823(e) that distributors maintain effective controls against diversion, a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances. Again, to maintain effective controls against diversion as section 823(e) requires, the distributor should exercise due care in confirming the legitimacy of all orders prior to filling."

LETTER 2 - February 7, 2007 DEA Letter to all Distributors in the U.S.

Exact same letter as September 27, 2006

LETTER 3 - December 27, 2007 DEA Letter to all Manufacturers and Distributors in the U.S.

"In addition to, and not in lieu of, the general requirement under 21 USC 823, that manufacturers and distributors maintain effective controls against diversion, DEA regulations require all manufacturers and distributors to report suspicious orders of controlled substances. Title 21 CFR 1301.74(b) specifically requires that a registrant 'design and operate a system to disclose to the registrant suspicious orders of controlled substances'. The regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system. Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications with DEA, whether implicit or

explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., 'excessive purchase report' or 'high unit purchases') does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility doesn't end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of an unusual size, orders deviating substantially from a normal patter, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive....The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders....

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion...."

DEA [Docket No. 07-7], Southwood Pharmaceuticals, Inc.; Revocation of Registration

http://www.deadiversion.usdoj.gov/fed_regs/actions/2007/fr07032.htm

The Show Cause Order alleged that between November 2005 and August 2006, Respondent's sales to pharmacies of hydrocodone products "increased from approximately 7,000 dosage units per month to approximately 3,000,000 dosage units per month," and that the increase was "directly attributable to [its] supplying controlled substances to pharmacies that it knew or should have known were engaged in the widespread diversion of controlled substances."

The Show Cause Order specifically alleged that "from December 12, 2005, to August 31, 2006, [Respondent] distributed approximately 8,671,000 dosage units of hydrocodone products to Medipharm-Rx, Inc.," and did so "under circumstances that clearly indicated that Medipharm was engaged in the diversion of controlled substances." Id. at 1-2. The Show Cause Order further alleged that these circumstances included that "ninety-nine percent of Medipharm's business [with Respondent] involved the sale of controlled substances," that Medipharm was owned by an individual who also owned a website "that solicit[ed] orders for controlled substances" and used practitioners who issued prescriptions outside of "the usual course of professional practice," and that "Medipharm's orders were of an unusual size, deviated substantially from a normal pattern, and were of an unusual frequency." Id. at 2.

Relatedly, the Show Cause Order alleged that Respondent had "also supplied controlled substances under similarly suspicious circumstances" to fourteen other pharmacies.

Next, the Show Cause Order alleged that on July 17, 2006, the Office of Diversion Control's E-Commerce Section held a conference call with Respondent's representatives to discuss "the distribution of controlled substances to Internet pharmacies." Id. at 3. During the call, DEA officials allegedly presented Respondent with "information on the characteristics of Internet pharmacies and the nature of their illegal activities." Id. DEA officials also allegedly discussed with Respondent such subjects as DEA's 2001 Guidance Document on the use of the Internet to prescribe controlled substances, the requirement for a valid prescription under federal law and existing professional standards, DEA's regulation requiring the reporting of suspicious orders, and the "practices and

ordering patterns of internet pharmacies." Id. The Show Cause Order further alleged that notwithstanding this information, in August 2006, Respondent proceeded to distribute large quantities of hydrocodone to five different internet pharmacies. Id. The Show Cause Order thus alleged that Respondent "has failed to maintain effective controls against diversion.

DEA Website – Knowing Your Customer/Suspicious Orders Reporting
http://www.deadiversion.usdoj.gov/chem_prog/susp.htm#e3
"It is fundamental for sound operations that handlers take reasonable measures to identify their customers, understand the normal and expected transactions typically conducted by those customers, and, consequently, identify those transactions conducted by their customers that are suspicious in nature."

"Representatives of government and the chemical industry worked together in 1998 in the Suspicious Orders Task Force to develop voluntary guidelines for recognizing suspicious orders. The Task Force guidelines, entitled "Suspicious Orders Identification Criteria" were endorsed by the Attorney General and widely accepted by industry: Importers & Manufacturers; Wholesale Distributors; and Retail Distributors…."

Suspicious Orders Identification Criteria

All Levels/All Chemicals (* indicates that criterion may not apply to all retail settings)

- New customer or unfamiliar representative or established customer who begins ordering listed chemicals*
- Customers who don't seem to know industry practice or who fail to provide reasons for an order at variance with accepted legitimate industry practice.
- Customer whose communications are not prepared or conducted in a professional business manner.*
- Customer who provides evasive responses to any questions or is unable to supply information as to whether chemicals are for domestic use or for export.
- Customer who has difficulty pronouncing chemical names
- New customers who don't seem to know Federal or state government regulations*
- Customers whose stated use of listed chemicals is incompatible with destination country's commercial activities or consignee's line of business*
- Customers who want predominantly or only regulated chemicals
- Customer who want multiple regulated or surveillance list products, particularly if in contrast to customary use and practice
- Customer who is vague or resists providing information about firm's address, telephone number, and reason for seeking that chemical*
- Customer who provides false or suspicious addresses, telephone numbers or references
- Customer who is vague or will not furnish references for credit purposes *
- Customer who refuses or is reluctant to establish a credit account or provide purchase order information *
- Customer who prefers to pay by cashiers check, postal money order, etc.
- Customer who desires to pay cash*
- Customer who wants to pick up the chemicals outside of normal practice in the supplier's experience
- Customer with little or no business background available*
- An established customer who deviates from previous orders or ordering methods
- Customer who want airfreight or express delivery
- Customers who want chemicals shipped to a PO Box or an address other than usual business address

- Customer using a freight forwarder as ultimate consignee
- Customer who requests unusual methods of delivery or routes of shipment
- Customer who provides unusual shipping, labeling, or packaging instructions
- Customer who requests the use of intermediate consignees whose location or business is incompatible with the purported end user's nature of business or location"

3. What are the Current Best Practices?

DEA September, 2006 Memo to all distributors

Circumstances that Might be Indicative of Diversion

1. Ordering excessive quantities of a limited variety of controlled substances (e.g., ordering only phentermine, Hydrocodone and alprazolam) while ordering few, if any, other drugs.
2. Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered.
3. Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs.
4. Ordering the same controlled substance from multiple distributors

A distributor…may wish to inquire with the ordering pharmacy about the following:

1. What percentage of the pharmacy's business does dispensing controlled substances constitute?
2. Is the pharmacy complying with the laws of every state in which it is dispensing controlled substances?
3. Is the pharmacy soliciting buyers of controlled substances via the internet or is the pharmacy associated with an Internet site that solicits orders for controlled substances?
4. Does the pharmacy or Internet site affiliated with the pharmacy; offer to facilitate the acquisition of a prescription for controlled substances from a practitioner with whom the buyer has no pre-existing relationship?
5. Does the pharmacy fill prescriptions issued by practitioners based solely on an on-line questionnaire without a medical examination or bona-fide doctor-patient relationship?
6. Are the prescribing practitioners licensed to practice medicine in the jurisdictions to which the controlled substances are being shipped, if such a license is required by state law?
7. Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy?
8. Does the pharmacy offer to sell controlled substances without a prescription?
9. Does the pharmacy charge reasonable prices for controlled substances made via the internet?

These questions are not all-inclusive; nor will the answer to any of these questions necessarily determine whether a suspicious order is indicative of diversion to other than legitimate medical channels. Distributors should consider the totality of the circumstances when evaluating an order for controlled substances, just as DEA will do when determining whether the filling of an order is consistent with the public interest within the meaning of 21 U.S.C. 823(e).

DEA October, 2009 Suggested Questions a Distributor should ask prior to shipping CS

Possible questions for a pharmacy:

- Does the pharmacy fill prescriptions via the internet? If so, is the pharmacy registered with DEA under the Ryan Haight Act?
- Is this a mail order pharmacy (fills prescriptions for insurance, etc.)?
  NOTE: A pharmacist may claim to be mail order pharmacy but may actually be operating as an Internet pharmacy. Do not accept the response to this question at face value.
- Is the pharmacy licensed in all states for which it mails or fills prescriptions?
- Does the pharmacy report to all states that have prescription monitoring programs in which their customers reside and to whom they dispense?
- Does the pharmacy report to all states that have prescription monitoring programs in which their customers reside and to whom they dispense?
- Does the pharmacy have staff or a private firm that solicits practitioners to get more business?
- What is the pharmacy's ratio of controlled vs. non-controlled orders?
- Does the pharmacy order a full variety of controlled substances and are they fairly evenly dispersed? If not, why the disparity?
- What are the hours of operation of the pharmacy?
- Does the pharmacy offer a full assortment of sundries to its customers (e.g. aspirin, snacks, cosmetics, etc.)?
- Does the pharmacy have security guards on the premises? If so, why?
- What methods of payment does the pharmacy accept (cash, insurance, Medicaid, and in what ratios)?
- Who is the pharmacy's primary supplier?
- Does the pharmacy order from other suppliers as well? If so, why and what controlled substances?
- If this is a new account, why does the pharmacy want you to be their supplier?
- If you are not the only supplier, what controlled substances will the pharmacy be ordering from you, in what quantities, in what time frame, and will they be ordering theses same products from other suppliers?
- What ratio will you be supplying compared to other suppliers?
- Does the pharmacy fill prescriptions for out of state customers? If so for how many out of state customers does the pharmacy fill (ration or approximate number)?
- If the pharmacy fills prescriptions for Pain Management or other specialty practitioners (diet, oncology, etc.), is the pharmacist comfortable with the prescribing practices of the practitioner?
- Has the pharmacist questioned or been uncomfortable with, the prescribing practices of any practitioner?
- Has the pharmacy ever refused to fill prescriptions for a practitioner? If so, why and who?
- Are there particular practitioners who constitute most of the prescriptions it fills? Who are these practitioners (Name and DEA registration number)?
- Does the pharmacy have any exclusive contracts, agreements, arrangements, etc. with any particular practitioner, business group, investors, etc.? If so, explain those arrangements and/or obtain copies of those agreements.
- Is the pharmacist comfortable enough with the prescribing practices of any or all practitioners for which they fill, to stake their professional livelihood on it?
- Does the pharmacy supply, order for, or sell to any practitioners or other pharmacies?
- How does the pharmacy sell/transfer controlled substances to other pharmacies or practitioners? Via prescription, sales invoice, or DEA Form-222? (Transfer by prescriptions is not authorized)

Possible questions for a practitioner:

- What is the practitioner's specialty, if any (family practice, oncology, geriatrics, pain management, etc)?
- Do the controlled substances being ordered correspond to his specialty or the treatment he provides?
- What method of payment does the practitioner accept (cash, insurance, Medicare) and what is the ratio of each?
- Has the practitioner ever been disciplined by any state or federal authority?
- How many patients does the practitioner see each day? What is his weekly average?
- Does the practitioner prescribe as well as dispense?
- Why does the practitioner prefer to dispense as opposed to prescribe?
- Who was the practitioner's previous supplier? Are they still ordering from this supplier? If not, why are they looking for a new supplier?
- Do the hours of operation and the facility accommodate the type of practice being conducted?
- Does the practitioner's office have security guards on site? If so, why?
- Are all applicable state, federal, local licenses current and are they issued for the registered address at which the practitioner is practicing?
- Does the practitioner see out of state patients? If so,
    - From what states,
    - How many,
    - Approximate ratio of out of state compared to local, and
    - Why, specifically, they travel so far to see him?
- Can the practitioner provide a blank copy of an agreement which they enter into with a patient, specifying the course of treatment, the patient rights and responsibilities, and reasons for termination of treatment?
- Does the practitioner conduct random unannounced drug testing?
- What measures does the practitioner employ and/or monitor to prevent addiction and diversion of controlled substances?
- Is there more than one practitioner dispensing controlled substances from the registered location?
- Do you order for just yourself or for the whole clinic?
- What controlled substances are you currently dispensing? (If only one or two controlled substances are being ordered, have the practitioner fully explain why he administers or dispenses only these specific controlled substances.)
- In what dosage levels is the practitioner dispensing (2 tablets, 4 times a day, for 30 days, or 90, 120, 240 a week, month)?
- Does the practitioner prescribe the same controlled substances as were dispensed to the patient?
- How many patients is the practitioner presently treating (day, week, and month)?

<u>Cegedim 8th Annual Controlled Substance Conference – 2010</u>

SOM Best Practices

- Threshold-based systems are not sufficient
- Cutting orders to a volume that puts the order under a threshold is not acceptable.
- Suspicious orders must be reviewed before completing sale and shipping
- Well defined and sufficient "due diligence" efforts should be in place and followed.
    - Confirm the legitimacy of new (and existing) customers
    - Balance: Motivation to quickly clear legitimate orders vs. regulatory need to hold/cancel/report orders that are truly suspicious

- Reporting an order as suspicious will not absolve the registrant of the responsibility if the registrant knew or should have known that the controlled substances were being diverted.

- Review and improve your SOM system to ensure a "total SOM solution" that includes:
  - Automated methods and statistics (highly preferred) to review each customer order product by product, comparing the order with historical ordering patterns for that customer and product.
    - Methods should look at parameters such as ordering pattern for the customer, frequency, size, ordering trends, etc.
    - Automated methods are more defensible
  - Determining the legitimacy of every order before it is shipped.
  - Includes all controlled substances and listed chemicals
- Establish appropriate practices for investigation of potentially suspicious accounts
  - SOPs on "rules" around account investigation and order release
  - Scripts for support team members to use with personnel from accounts under evaluation
  - Customer self assessment questionnaires
  - On-site account verification visits
  - Compliance certification forms
  - New account investigations
- Maintain individual customer files that include documentation, communication details, etc.
  - Request supporting documentation in writing from customers if necessary to further clear suspicion and for historical records.
- Challenge your SOM approach
  - How are orders evaluated?
  - Is the current system defensible in light of the language of the regulations and DEA's recent policy memoranda?
    - Does it identify orders of unusual size and frequency?
    - Does it identify orders that deviate from a normal buying pattern?
    - How does the system determine and evaluate the customer's normal pattern?
  - How are new accounts opened?
    - What background investigation is performed on the new customer and what assurances are in place prior to furnishing a new account with controlled substances?
  - How are orders cleared from suspicion?
    - Are they investigated by an appropriate individual or department?
    - Is the investigation documented?
    - Are there SOPs in place?
    - Is the order cancelled in its entirety?
  - Who reports the suspicious order to the DEA
    - Is an appropriate level of management involved with SOM oversight?
  - If third party distributors fulfill the orders, do they have an adequate SOM system?
- SOPs and SOM system should be reviewed at least annually
- Periodically test system to confirm large or frequent orders will be detected and flagged.

<u>H.S. Schein – Craig Schiavo</u>

- HSS's SOM program
  - Active ingredients
    - All quantities/values calculated to API level

        - Ever item setup with amount of each active ingredient contained
    - Orders of unusual size
        - Threshold value based on percentile of all monthly purchase quantities across any given customer group and active ingredient.
    - Orders deviating from customer's normal buying pattern
        - Considers the purchased quantities of the individual customer for any given active ingredient.
    - Orders of unusual frequency
        - Considers the number of times each individual customer has ordered any given active ingredient
    - All factors assigned a numerical value and the combination of these numerical values will constitute the "score" for the order detail line
    - Upfront restrictions placed in the system for out of practice orders
        - Stimulants/weight control drugs – Dental and Veterinarian
        - Steroids – Dental
        - All Controlled Substances – international customers
        - Ketaset (Vet use only) – Medical and Dental
    - Self-medicating practitioners restricted from purchasing CS and reported to DEA
    - Practitioners treating family member reviewed on case by case basis
    - "Know Your Customer" Program
        - Questionnaire sent out.
        - Once received and not comfortable releasing order, more extensive questionnaire is sent out.
        - If still not comfortable, phone interview or site visit scheduled
        - If account is restricted from ordering CS, a letter is sent to the customer and reported to DEA
        - New Account Setup
            - Customer questionnaire for every customer ordering CS
                - Information about licenses and registrations
                - Phone #, address, account specialty, practice type
                - What CS the customer anticipates ordering, including quantities
            - Review all information gathered
            - Additional call may be made by Regulatory Affairs and a site visit will be conducted for high risk accounts as necessary
    - SOPs
        - SOM Policy
            - Outlines specifications of the new SOM system and the three components that make up the entire system
            - Added "Out of Practice" section outlining practices that can/cannot purchase specific CS/Listed chemicals
        - New Item Setup
            - Outlines the process that a new CS has to go through before it can be setup for sale in the system
            - Product must be normalized before it can be sold (have active ingredient added and dosage size calculated)
        - New Account Setup
            - Lists the roles/responsibilities of all departments when a new account is being setup.

        - Includes new processes implemented such as sending each customer our due diligence questionnaire
    - Review and Release
        - Outlines the due diligence process that is required for each order that is pended by SOM system.
- Questionnaires
    - 3 categories developed
        - "Know Your Customer"
        - Self Assessment Questionnaire
        - Extensive Site Visit Questionnaire
    - Developed for each type of potential customer
        - Solo Practitioner
        - Dispensing Practitioner/Clinic
    - Sample Questions:
        - Do you use any of the medications you purchase to self-medicate?
        - Do you accept medical insurance? What % pay insurance, case, credit?
        - Is the owner a licensed physician?
        - Do you dispense or prescribe to out of state patients? If yes, ____%?
        - Controlled substances and approximate amounts do you plan to purchase?
- Site Visits
    - Conducted on "high risk" accounts and accounts that HIS is not comfortable with after due diligence
    - Process takes 6-8 weeks to complete
    - Notification sent to the customer letting them know of the visit and the reason
    - Approval process consists of detailed report that is reviewed and signed off on by upper management
    - Site visits consist of:
        - Observing patients/waiting room
        - Inventory reconciliations
        - Interviewing doctor/owner/staff
        - Observing surrounding neighborhood
        - Cars in parking lot
        - Security controls
        - Pictures
        - Recordkeeping/Protocols
- Common Red Flags
    - Cash only business
    - Large base of out of state patients
    - Lack of security

<u>Know Your Customer Program – Carlos Acquino, April, 2012</u>

- Know Your Customers Policy
    - Prepare a "Customer's Responsibility" Policy
    - Closely monitor new customer's purchases
    - Establish statistical purchase parameters
    - Establish procedures for "Orders of Interest"
    - Establish procedures for "Suspicious Orders"

- Customer Care Group
    - Liaison between sales personnel, customer and "Orders of Interest" group
    - Assures customer file has updated information and customer's purpose for orders of interest
    - Determines legitimacy of an order
    - Report all findings to orders of interest group
- Orders of Interest Group
    - Responsible to review the customer's order that is an unusual size, deviates from normal pattern and is of an unusual frequency
    - Coordinate sales orders with Customer Care Group to determine legitimacy of the order
    - Responsible to suspend any order of interest
    - Forward findings to Suspicious Orders Group
- Suspicious Orders Group
    - Responsible to review orders classified as suspicious
    - Coordinate investigations with Customer Care Group and Senior Management
    - Responsible for all on-site investigations
        - Obtain list of orders/scripts including script number and patient zip code, but never patient name, SSN, etc. Ask for dispensing records
    - Final decision to classify an order as suspicious and report to DEA
- Parameters for Orders
    - Use of electronic statistical values for all orders prior to being shipped to customer
    - Comparison made by type of registrants and their customers (Pharmacy and LTCF)
    - Computer software to compare all customer orders
    - Identify any customer whose order was questioned
- Recommendations
    - Any change in quantity of customer's order should be screened to assure it is legitimate and not for illicit purposes
    - Sales person should be immediately contacted to verify that there is a need for the order
- Customer File
    - Affidavit on Use of Controlled Substances
    - Information questionnaire
    - Corporate structure and identity of employees
    - Questionnaire about client's customer base
    - Updated prior to registration renewal
    - Communication with sales personnel
    - Result of on-site investigation
- Drugs of concern
    - Internet pharmacy operations
        - Hydrocodone
        - Codeine with APAP
        - Alprazolam
        - Diazepam
        - Carisoprodol
        - Tramadol
- On-site Inspection of Customer
    - Outer appearance of the facility
    - Compliance with DEA required records
    - Compliance with DEA security requirements

- Distribution and dispensing records
- Written report by on-site investigators
- Procedures for follow-up inspection

Cegedim 8th Annual Controlled Substance Conference - 2010

1. Balancing interests – identify suspicious orders and report to DEA.
   - How much information is available?
   - How much responsibility does a wholesaler have for physician and pharmacy conduct?
2. Preserve legitimate business relationships
3. Meet legitimate medical/patient needs

H.S. Schein – Craig Schiavo

- Met with DEA in October 2009
  - DEA reiterated information from December, 2007 letter
  - Advised HIS of what was expected as a distributor of CS
  - Provided binder containing:
    - Regulations
    - Case studies
    - ARCOS information submitted by HIS for each distribution center
      - Pointed out accounts HIS may want to take a look at that have ordered high volumes of Hydrocodone
  - Asked what HIS does for SOM
  - Put HIS on notice
- Challenges
  - Lack of guidance from DEA
  - Amount of customers (386,000 total)
  - Weekly team meetings
  - Lack of resources
    - Due diligence for new accounts
    - Review pended accounts
    - Site visits
  - Sales/Field Sales Reps
    - Training
    - Conflict of interest?
    - Communication and understanding of process
  - Cooperation from customers

Amerisource Bergen – Chris Zimmerman

- Customer Account Type and Size
  - Each customer is classified by "Customer Type" which represents how the customer is registered with DEA.
    - Hospital/Clinic, Retail Pharmacy, Distributor, etc.
    - This value is loaded using the NTIS database synch process
  - Each customer is then categorized by "Customer Size" based upon average revenue relative to its peers in the same "Customer Type".
- Item Family and Threshold
  - All controlled substances and listed chemicals are grouped into item "families" based upon the drug's active ingredient, which has a corresponding Generic Code Number (GCN).

- The SOM program will combine all sales of items within the same GCN family (e.g., Hydrocodone/Vicodin; oxycodone/Percocet, alprazolam/Xanax), for each customer
- Item threshold levels are established from accumulated monthly sales for all customers based on item family, DEA type and customer size.
- A customer's threshold level is initially set by item family based on the customer's DEA type and customer size.

- Order Processing
  - A customer's incoming orders are accumulated by item family, and the total item family order quantity is applied to the predetermined item family monthly threshold.
  - If the order quantity falls below the item family threshold, the order will process normally.
  - If the order quantity goes over the item family threshold, the order will be placed into review.
  - All subsequent orders within the same item family will be rejected while an item within the same family is under review.
  - Each distribution center is responsible for initial review of all orders in review.
    - If the DC can determine that the order is not suspicious, the DC will release the order.
    - If the DC is unsure, the order will be flagged to be investigated by Corporate.
  - All orders that are released by the DC, as well as those flagged for review are sent to the Corporate Regulatory Affairs group each morning.
  - Based upon the information available to Reg Affairs, flagged orders will either be released or placed in "Investigate" status.
  - All orders placed into Investigate status are electronically reported to DEA on a daily basis.
  - Reg Affairs conducts the investigation and will notify the DC of the final disposition of the order (release or cancel).
  - Reg Affairs will also determine if any permanent action needs to be taken with the customer.
    - Customers who have legitimate needs will have their size or threshold levels increased.
    - Customers with continued suspicious ordering patterns may have their ability to order controlled substances affected.
- Order Monitoring Program
  - Distributors can't solely rely on computer systems and programs to prevent diversion.
  - All employees have a role and responsibility in a successful Order Monitoring Program:
    - Sales
    - Procurement
    - Management (DC/HQ)
    - Order fillers
    - Customer Service
    - IT
- Investigations
  - Sources of Investigations
    - Order Monitoring Program (OMP)
    - Monthly Customer Product Mix Report (Pharmacies with more than 50% of their business as controlled substances get flagged)
    - Notification by DEA
    - Notification by Distribution Centers
  - Typical Investigation Process

        - One year purchase history
        - On-site inspection
        - Retail Pharmacy Verification Checklist
    - Decision
        - Cease distribution of CS to customer
        - Have customer sign applicable compliance agreement
- Education and Training
    - All appropriate associates are trained on Diversion Control Program
    - ABC holds training and educational courses for its customers and vendors regarding this subject matter.

DEA 14th Pharmaceutical Industry Conference – October, 2009

- What is my customer's practice area?
- How does this customer's order compare with similar customers?
- How does this customer's recent orders compare with the customer's historical orders?
- Can the customer explain peculiarities or anomalies in its orders?
- Are there readily observable warning signs about certain localities?

Cegedim 15th Annual Controlled Substance, PDMA and State Conference – April, 2012

- Distributor Initiative Program
    - In-depth briefing by DEA headquarters personnel
    - DEA Field personnel encouraged to attend
    - Company's own ARCOS data is used. Briefing book left with company
    - Registrant is apprised of DEA's regulations and obligations of the company.
    - Imparts knowledge, puts company briefed "on notice".
- Access to customer due diligence files:
    - DEA can inspect and copy records, reports and documents required to be kept under the CSA through:
        - Administrative Inspection Warrant
        - Administrative subpoena
        - Consent – DEA Notice of Inspection
- Know Yourself
    - Beware of SOPs
        - DEA continues to view violations of internal anti-diversion policies as proof that registrant does not maintain effective controls against diversion.
- Know the Future
    - Expect continued pressure from DEA on distributors and manufacturers
    - Expect diversion trends to continue to change
    - Expect volume to continue to be the primary factor that DEA considers when taking action against a distributor
    - Expect DEA to obtain your SOPs, due diligence files and emails about compliance
    - Expect some of your customers to be engaged, either wittingly or unwittingly, in diversion.
- Know Your Customers Strategies
    - Distributor Initiative "Warning Signs"
        - Type of drug(s) ordered
        - Orders of unusual size – Volume, volume, volume
        - Orders that deviate from a normal pattern
        - Frequency of orders
        - Breadth and type of products ordered

        - Location of the customer
        - Percent of controlled vs. non-controlled substances ordered
    - Questions to consider
        - How are new accounts opened?
        - What background investigation is performed on the new and existing customers
            - Professional licensing checks
            - Google searches
            - On-site visits
        - What recurring and/or follow-up on-site investigations are performed?
        - What assurances are in place prior to furnishing an account with controlled substances?

4. What are the current challenges to industry to implement these programs?

Teva Challenges

1. Sales downstream not always visible.
   - It may be possible to use chargeback/rebate information to see customers further down the supply chain, but the information is only visible for indirect shipments to wholesalers. We do not know how direct shipments are split past the regional retail distributor level. In addition, some wholesalers blind customer information on chargeback reports.
   - Customer Operations working to determine the % of direct vs. indirect shipments made by Teva.
   - We may be able to use the data to identify high risk organizations.
2. Little guidance from DEA – will not approve SOM programs; will not share information with registrants.
3. Balancing business relationships with DEA reporting requirements – what are the legal ramifications of refusing to fill an order and reporting the order as suspicious to DEA?
4. Lack of resources to conduct due diligence audits of customers and to thoroughly investigate "orders of interest".
5. Cooperation from customers – how much are they willing to share and will inquiries drive business away?

5. What 3rd party solutions are there to help Teva address these issues?

- Pharma Compliance Group

http://www.pharmacompliancegroup.com/page/33-know_your_customer/

- Cegedim Dendrite (Ron Buzzeo) provided quote on 5/8/12 for:
  - A. Onsite Customer Verifications – Wholesale Distribution/Distribution Centers
    - i. Wholesaler SOM Site Verification Questionnaire: Compliance Solutions will use and complete our proven site verifications questionnaire
    - ii. Preparation of a Compliance Agreement Form to be signed by customers during or after the verification visits to document the customer's indication of understanding DEA laws, regulations and their responsibilities under the CSA.
    - iii. Perform site verifications using highly experience, investigative resources when requested.
    - iv. Will provide a completed, post-visit summary document (checklist and short answer questions) along with digital pictures (if possible) to provide understanding of customer's operations after each visit is completed. Each report will be reviewed by one or more of our senior level, former DEA SOM experts before submitting to client.
    - v. Project coordinator: a project coordinator will be assigned to this project to assist with general coordination and scheduling for each site verification assignment, to make sure site verification questionnaires are properly completed and reviewed by our compliance Solutions consultant and provide the final site verification report to client.
    - vi. Cost: $5,000 (one-time project setup fee) + Travel Costs + Cost per Site

Customer Site Verifications – Drug Wholesaler/3PL's	**Customer Site Verifications**	**Cost per Site Verification**
Price per Site Verification is based on the cumulative number of Customer Site verifications performed.	1 to 20	$ 3,995
	21 to 40	$ 3,895
	>40	$ 3,795

*NOTE: The pricing and project details listed above are for Distribution Customer Site Verifications including high level verifications of operations and basic SOM due diligence procedures for Wholesale Distributors, Distribution Centers, or similar types of organizations only.

  - B. Onsite Customer Verifications – Pharmacies, Physicians, and Clinics
    - i. Site Verification Questionnaire: Compliance Solutions will use and complete our proven site verifications questionnaire
    - ii. Perform site verifications using highly experience, investigative resources when requested. The verifier will complete the site questionnaire.
    - iii. Preparation of a Compliance Agreement Form to be signed by customers during or after the verification visits to document the customer's indication of understanding DEA laws, regulations and their responsibilities under the CSA.
    - iv. Will provide a completed, post-visit summary document (checklist and short answer questions) along with digital pictures (if possible) to provide understanding of customer's operations after each visit is completed. Each report will be reviewed by one or more of our senior level, former DEA SOM experts before submitting to client.
    - v. Project coordinator: a project coordinator will be assigned to this project to assist with general coordination and scheduling for each site verification assignment, to

make sure site verification questionnaires are properly completed and reviewed by our compliance Solutions consultant and provide the final site verification report to client.

vi. Cost: $5,000 (one-time project setup fee is waived if Project a. is included) + Travel Costs + Cost per Site

Customer Site Verifications – Pharmacies, Physicians and Clinics	Customer Site Verifications	Cost per Site Verification
Price per Site Verification is based on the cumulative number of Customer Site verifications performed.	1 to 50	$ 1,495
	51 to 100	$ 1,445
	101 to 200	$ 1,395
	>200	$ 1,345

*NOTE: The pricing and project details listed above are for Customer Site Verifications of Pharmacies, Physicians, Clinics, or similar types of organizations only). .

It may be possible to use one of the above consulting groups to conduct on-site audits of high risk customers.

The broad steps to be completed are:

1. Conduct research
2. Distribute a White Paper
    a. List regs
    b. List industry challenges
    c. List best practices
    d. Identify Teva's current controls and gaps
    e. Provide recommendations
        i. Task Force
3. Conduct audit on existing controls
4. Create task force to complete the tasks

APPENDIX A

SUSPICIOUS ORDER MONITORING (SOM)

The Drug Enforcement Administration (DEA) requires registrants to design and operate systems to disclose suspicious orders of controlled substances (21 CFR 1301.74(b)). The DEA has increased its activity in the enforcement of this requirement:

- In November, 2006, Southwood Pharmacy's DEA registration was immediately suspended for selling large quantities of controlled substances to internet pharmacies. Their registration was revoked in June, 2007.

- In March, 2007, the DEA suspended the distributor registration of Richie Pharmacal for shipping large quantities of controlled substances to Internet pharmacies. Richie Pharmacal subsequently voluntarily surrendered their registration.

- In April of 2007, the DEA revoked the registration of AmeriSource Bergen in Orlando, Florida which resulted in the closure of its distribution center.

- In July, 2007, Bellco Drug Corporation agreed to surrender its DEA distributor registration and to pay $800,000 in civil penalties for failing to report suspicious orders o controlled substances to Internet pharmacies. Bellco also agreed to divest itself of its entire inventory of controlled substances and listed chemicals.

- In the Fall of 2007, the DEA issued "immediate suspensions" to three Cardinal distribution centers which were subsequently closed resulting in approximately 1 billion dollars in lost profits and revenues as well as $34 million in civil penalties.

- On May 6, 2008, McKesson Drug Company settled a civil prosecution with the DEA for failure to report suspicious orders by agreeing to pay the U.S. Government $13.250 million.

- In October of 2008, Cardinal settled their issues with DEA and agreed to pay a $34 million civil penalty. Despite subsequently spending more than $16 million to modify its suspicious monitoring program and hiring 14 employees exclusively dedicated to it, in February of 2012, DEA issued an immediate suspension order for Cardinal's Lakeland, FL distribution center for failure to act on a "glaring" pattern of excessive oxycodone orders to several pharmacies in Florida. The DEA alleged that Cardinal didn't question the orders or heed warnings to conduct on-site audits. As a result, Cardinal agreed to stop handling controlled substances at the site for 2 years and is facing additional civil penalties.

- In April, 2012, the DEA served seven Administrative Inspection Warrants to a Walgreens Corporation distribution center and its top six retail pharmacies in Florida to determine if the chain allowed suspiciously high sales of oxycodone. The data seized under the Inspection Warrants is still being evaluated.

From 2007 to the present the DEA has aggressively evaluated registrants' sales patterns in light of continued evidence of "down stream" diversion, primarily involving narcotics and so called "internet pharmacies". Numerous smaller and less well known registrants were the subject of investigations, revocation actions and civil prosecutions. The DEA issued three separate memorandums (one in 2006 and two in 2007) iterating the Administration's position in regards to Suspicious Order Monitoring (SOM). These memoranda cautioned registrants against sending either "excessive purchase" reports or limited-analysis SOM reports to local offices which were based upon simple mathematical formulas without forethought and investigation. The DEA stated:

> "Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient."

Based on our understanding of the regulatory requirements and DEA's current directives, Teva's SOM process focuses on satisfying four critical areas to enable a "total SOM solution":

- **A *Statistically Defensible* Order Pending System**.
- **Documented Evidence the System Performs Consistently with Regulations**.
- **Proactive Approach to Account Investigation and Disposition**.
- **An Extensive "Know Your Customer" Program**

APPENDIX B

Jason Cooper's Email:

All: This is in response to the David's email below regarding tracking processes for our controlled substance products. The following summarizes (i) Teva's obligations to track controlled substances; (ii) the current processes that Teva has in place; and (iii) recommendations to improve our systems.

1. DEA Requirements
   - DEA expects companies selling controlled substances to perform and document due diligence of their customers, maintain systems that monitor for suspicious orders, and report any suspicious orders.
   - DEA regulations state that "all applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 CFR 1301.71(a). In particular "[t]he registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances."
   - Suspicious orders "include orders of unusual size, orders deviating from a normal pattern, and orders of unusual frequency." 21 CFR 1301. 74 (b).
   - These provisions have been applied broadly by DEA to find fault with systems used by registrants to control theft and diversion. DEA's recent enforcement activities have focused on wholesales and distributers.

2. Current Process
   - Dennis Ferrell, Senior Director DEA Affairs & Supply Chain Security, and his group have primary responsibility for these activities. His group developed and uses a process ("SORDS") to indentify suspicious orders from wholesalers, pharmacy distribution centers and other direct customers.
   - Based on three year historic ordering patterns, SORDS identifies unusual purchase orders (e.g., unusual size, orders deviating from a normal pattern, and orders of unusual frequency).
   - Teva conducts investigations of suspicious orders and any such order that cannot be substantiated is cancelled and the DEA office is notified. A copy of the SORDS process is attached.
   - SORDS is similar to the approach performed by a number of other companies (e.g., Purdue, Watson, Abbott).

3. Ongoing Improvements
   - IT enhancements are currently being made to SORDS so that more detailed data can be analyzed (i.e., data at the individual SKU and individual dosage level will start to be tracked and analyzed).

4. Recommended Improvements

   Dennis Ferrell's group has been evaluating various additional initiatives to supplement the SORDS system. Based on his findings, the following 2 initiatives are being recommended.
   - Dendrite International provides a service whereby it will audit our direct customers (wholesalers and pharmacy distribution centers) to ensure that they have robust procedures in place to identify suspicious orders placed by our indirect customers (e.g., orders placed by pharmacies and other customers at the next level in the distribution chain).
   - ValueCentric has a relatively new reporting tool, the Safe and Secure Supply Chain module, which can provide reports down to the retail pharmacy and hospital level. This tool provides ValueCentric customers with the capability to monitor and analyze four areas of activity at the retail level: first-time purchases, multiple wholesaler ordering activity, above average sales, and disproportionate sales. The tool was being tested by Cephalon legacy prior to the merger. The quality of ValueCentric data/reports will be evaluated by Dennis Ferrell's group to determine its effectiveness and there may be an opportunity for Teva to receive the reports under a 90 day trial period (similar to what Cephalon was granted to test the module).

The operational aspects of tracking Teva's controlled substances fall under the primary responsibility of Chris Lowery, Chief Security Officer. (Dennis Ferrell reports to Chris Lowery). As a result of this recent initiative to analyze and assess our current systems, I was told that Chris will be sending an email to those on this distribution list with more details, timelines, etc.

Thanks. Jordan

APPENDIX C – Proposed Teva Program Outline

Item	Component	Status
Policy & Guidelines		
Suspicious Ordering Program		
Confirm Legetimacy of Customer		
Conduct Independent Analysis	**Pattern Analysis**	
	Stop Shipment Until Approval	
"Know Your Customer" Program		
Customer Questionnaire	What percentage of the pharmacy's business does dispensing controlled substances constitute?	
	Is the pharmacy complying with the laws of every state in which it is dispensing controlled substances?	
	Is the pharmacy soliciting buyers of controlled substances via the internet or is the pharmacy associated with an Internet site that solicits orders for controlled substances?	
	Does the pharmacy or Internet site affiliated with the pharmacy; offer to facilitate the acquisition of a prescription for controlled substances from a practitioner with whom the buyer has no pre-existing relationship?	
	Does the pharmacy fill prescriptions issued by practitioners based solely on an on-line questionnaire without a medical examination or bona-fide doctor-patient relationship?	
	Are the prescribing practitioners licensed to practice medicine in the jurisdictions to which	

	the controlled substances are being shipped, if such a license is required by state law?	
	Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy?	
	Does the pharmacy offer to sell controlled substances without a prescription?	
	Does the pharmacy charge reasonable prices for controlled substances made via the internet?	
	Does the pharmacy fill prescriptions via the internet? If so, is the pharmacy registered with DEA under the Ryan Haight Act?	
	Is this a mail order pharmacy (fills prescriptions for insurance, etc.)? NOTE: A pharmacist may claim to be mail order pharmacy but may actually be operating as an Internet pharmacy. Do not accept the response to this question at face value.	
	Is the pharmacy licensed in all states for which it mails or fills prescriptions?	
	Does the pharmacy report to all states that have prescription monitoring programs in which their customers reside and to whom they dispense?	
	Does the pharmacy report to all states that have prescription monitoring programs in which their customers reside and to whom they dispense?	
	Does the pharmacy have staff or a private firm that solicits practitioners to get more business?	
	What is the pharmacy's ratio of controlled vs. non-controlled orders?	
	Does the pharmacy order a full variety of controlled substances and are they fairly evenly dispersed? If not, why the disparity?	
	What are the hours of operation of the pharmacy?	
	Does the pharmacy offer a full assortment of sundries to its customers (e.g. aspirin, snacks, cosmetics, etc.)?	

	Does the pharmacy have security guards on the premises? If so, why?	
	What methods of payment does the pharmacy accept (cash, insurance, Medicaid, and in what ratios)?	
	Who is the pharmacy's primary supplier?	
	Does the pharmacy order from other suppliers as well? If so, why and what controlled substances?	
	If this is a new account, why does the pharmacy want you to be their supplier?	
	If you are not the only supplier, what controlled substances will the pharmacy be ordering from you, in what quantities, in what time frame, and will they be ordering theses same products from other suppliers?	
	What ratio will you be supplying compared to other suppliers?	
	Does the pharmacy fill prescriptions for out of state customers? If so for how many out of state customers does the pharmacy fill (ration or approximate number)?	
	If the pharmacy fills prescriptions for Pain Management or other specialty practitioners (diet, oncology, etc.), is the pharmacist comfortable with the prescribing practices of the practitioner?	
	Has the pharmacist questioned or been uncomfortable with, the prescribing practices of any practitioner?	
	Has the pharmacy ever refused to fill prescriptions for a practitioner? If so, why and who?	
	Are there particular practitioners who constitute most of the prescriptions it fills? Who are these practitioners (Name and DEA registration number)?	
	Does the pharmacy have any exclusive contracts, agreements, arrangements, etc. with any particular practitioner, business group, investors, etc.? If so, explain those arrangements and/or obtain copies of those agreements.	

	Is the pharmacist comfortable enough with the prescribing practices of any or all practitioners for which they fill, to stake their professional livelihood on it?	
	Does the pharmacy supply, order for, or sell to any practitioners or other pharmacies?	
	How does the pharmacy sell/transfer controlled substances to other pharmacies or practitioners? Via prescription, sales invoice, or DEA Form-222? (Transfer by prescriptions is not authorized)	
Rules