June 1, 2011

Michelle M. Leonhart  
Administrator  
U.S. Drug Enforcement Administration  
600 Army Navy Drive  
Lincoln Place East – Room 6295  
Arlington, VA 22202

Dear Ms. Leonhart:

This letter is a follow-up to a meeting that took place on December 7, 2010, between members of the Healthcare Distribution Management Associations (HDMA) and representatives of the Drug Enforcement Administration (DEA) Office of Diversion Control to discuss industry monitoring and reporting of suspicious orders of controlled substances. On behalf of HDMA, I would like to reiterate our thanks to you and your staff for hosting the meeting and agreeing to continue the dialogue regarding our mutual goal of detecting and preventing diversion.

Since we met in December, HDMA has undertaken a comprehensive assessment of our member companies’ questions and concerns with the current suspicious order monitoring requirements. We appreciate the opportunity to provide this information and would greatly value the Agency’s feedback on the enclosed questions. Also enclosed is a summary of the discussion that took place during the December meeting.

We look forward to the Agency’s response and to continuing our dialogue. If we can provide further information, please contact me at 703-885-0219 or jgray@hdmanet.org; or Patrick Kelly, Senior Vice President, Government Affairs at 703-885-0233 or pkelly@hdmanet.org; or Anita Ducca, Vice President, Regulatory Affairs at 703-885-0240 or aducca@hdmanet.org. Thank you.

Sincerely,

John M. Gray  
President and CEO

Enclosures

cc: Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration  
Cathy A. Gallagher, Acting Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration
Questions for the Drug Enforcement Administration (DEA) Regarding Requirements for Suspicious Orders Monitoring and Reporting
Submitted by the Healthcare Distribution Management Association (HDMA)
June 1, 2011

The following are general questions about wholesale distributors’ responsibilities for controlled substances suspicious orders monitoring and reporting.

1. During a wholesale distributor’s efforts to fulfill the U.S. Drug Enforcement Administration’s (DEA) expectations to “know your customer,” current business practices for many Healthcare Distribution Management Association (HDMA) members include the following measures:

   - Wholesale distributors request that potential customers, prior to opening an account with the wholesale distributor, answer questions about their business based on the “Information Gathering” examples contained in the HDMA INDUSTRY COMPLIANCE GUIDELINES (ICG): REPORTING SUSPICIOUS ORDERS AND PREVENTING DIVERSION OF CONTROLLED SUBSTANCES, Section I.b. (See http://www.healthcaredistribution.org/gov_affairs/pdf_controlled/20081113_icg.pdf).
   - Wholesale distributors’ sales and inside sales staff are trained to be alert during routine communications with customers for signs that a customer’s intentions in purchasing the product may raise questions, and to report to appropriate designees within their companies, any such questions regarding a prospective customer’s intentions and/or activity so that the wholesale distributor may, if warranted, conduct further review of the customer.
   - If the wholesale distributor has reason to believe, based on a system for tracking product orders such as that described in Section II of the HDMA ICG, that a customer, or a customer’s order(s) have changed in such a manner as to suggest different ordering patterns for controlled substances, they will follow up with an additional, more extensive, review of that customer and/or the order in question.
   - Wholesale distributors will report to DEA when appropriate pursuant to 21 C.F.R. § 1301.74(b).

Questions

A. Does DEA agree that the frequency of customer review described above meets the Agency’s “know your customer” expectations?
B. If not, HDMA requests that DEA elaborate on the Agency’s expectations.

2. During its “know your customer” efforts, a wholesale distributor may also find a customer (or potential customer) is, to the best of the wholesale distributor’s ability to ascertain, following applicable laws, placing orders that are not “suspicious” for their class of trade and has not otherwise given indications of questionable business practices. At the same time, the wholesale distributor may have lingering questions about the customer’s intentions.

As a hypothetical example, suppose a customer is an owner and/or operator of more than one pain treatment clinic. The clinics maintain all required state and federal licenses/registrations,
Questions for the Drug Enforcement Administration
By HDMA
June 1, 2011

patients are given physical exams, they accept all appropriate forms of payment, and, to the best of the wholesale distributor’s ability to ascertain, follow applicable laws and regulations. However, this customer owns and operates only pain clinics, is not affiliated with other treatment programs (e.g., physical therapy) and plans to open more pain treatment clinics, potentially increasing their purchase or prescribing volume.

Questions

A. Based on DEA’s extensive experience, on ARCOS or on other data, can DEA provide guidance as to when and under what circumstances the wholesale distributor may continue to sell to the customer meeting this description, or, conversely, when they should cease distribution and report a customer operating as described above to DEA?

B. Does DEA have further guidance on other sources of information wholesale distributors might use to evaluate such customers?

C. If DEA’s answer is that it is the wholesale distributor’s “business decision” whether to sell, and the wholesale distributor proceeds to sell to this customer, will DEA communicate to its field offices that they should not take action against the wholesale distributor in the absence of additional indications of questionable practices and no indication of negative information about the customer from DEA?

D. If the wholesale distributor ceases to sell to this customer and reports them to DEA, (whether or not the wholesale distributor has more definitive information leading them to question the customer than described above) is 90 days an ample time frame for the wholesale distributor to conclude that DEA’s evaluation of the customer’s actions are consistent with the public interest? If not, what is an appropriate amount of time?\(^1\)

E. What guidance or criteria can DEA provide to wholesale distributors for use in assessing whether a pain care medical practice is considered “legitimate”? Information that would be helpful to wholesale distributors includes a definition of “legitimate” pain care clinic or medical practice and a comprehensive comparison of the characteristics of a legitimate pain care clinic versus “rogue” pain clinics (pill mills) that wholesale distributors may directly apply to their “know your customer” efforts.

F. Where can the regulated industry obtain a description of DEA’s updated methodologies and/or processes for keeping such guidance or criteria current?

3. When a wholesale distributor receives a request to provide controlled substances (either from a newer customer or an existing one) who indicates they wish to increase controlled

---

\(^1\) HDMA would like to note why the answer to this question is important. If the former customer truly is questionable, but retains a valid DEA registration, they are free to pursue “wholesaler shopping” until they find one or more that have monitoring systems with different criteria for determining what is “suspicious”. If the customer is not questionable, then the wholesale distributor that closed the account is effectively penalized for maintaining a rigorous compliance program by being placed at a competitive disadvantage. Ultimately, the public is disadvantaged most because either a criminal activity is allowed to continue or because the known benefits that competition brings to the marketplace are lost. Clearly, none of these outcomes are desirable.
substance orders, most wholesale distributors provide the customer with a questionnaire about their business. (Note: as described in #1 and #2 above.)

A wholesale distributor staff member then carefully reviews the customer’s response to determine if there is anything questionable in the answers that requires further assessment. (See the ICG Sections I.b. for recommendations on information about the customer the wholesale distributor could request, and I.c. for suggestions on reviewing the customer information, as well as the DEA guidance provided on October 20, 2009 titled: “Suggested Questions a Wholesale distributor should ask prior to shipping controlled substances”)

The ICG also recommends that the wholesale distributor ask the customer (owner, “Pharmacist in Charge,” or an equivalent designee) to sign a statement that the answers are accurate.

Questions

A. Based on DEA’s extensive experience with registrants who furnish controlled substances to their patients, can DEA identify the types of responses to the questions we ask these customers that the Agency believes are most likely to lead the wholesale distributor to conclude that further due diligence is warranted?

B. If a customer is otherwise acceptable, subsequently does not place an order determined to be suspicious, and the wholesale distributor conducts periodic updates of its “know your customer” information, can the wholesale distributor accept the responses and the signed statement as documentation that the customer is purchasing the product for legitimate purposes? If they cannot, please elaborate on what is acceptable for this purpose.

4. When a wholesale distributor reviews a potential customer who wishes to purchase controlled substances, they likely seek:
   • appropriate information, such as that described in the HDMA ICG;
   • answers to questions such as those posed in DEA’s October 20, 2009 guidance “Suggested questions a wholesale distributor should ask prior to shipping controlled substances;”
   • the information about internet pharmacies discussed in the preamble to the interim final rule: “Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008” [73 Fed. Reg. 15596 (April 6, 2009)]; and
   • guidance provided during DEA’s meetings with, and presentations to, wholesale distributors.

Questions

A. Is there any other information wholesale distributors should observe during our “know your customer” efforts that are not included in the above bullet points?

B. Does DEA have methodologies and/or processes for keeping such guidance or criteria current that they can share with wholesale distributors?
5. Due to the Health Insurance Portability and Accountability Act (HIPAA) privacy rules restricting access to patient information and records, pharmacists and practitioners cannot divulge patient records. Therefore, neither the ICG nor wholesale distributors’ individual procedures call for review of a customer’s patients.

**Questions**

A. Does DEA agree that given the law cited above, wholesale distributors are not expected to seek information about a customer’s patients?
B. If DEA believes customers’ patients should be included in the wholesale distributors’ reviews, please provide legally compliant suggestions regarding avenues of inquiry that could be used in lieu of patient records.
C. Additionally, please provide specific guidance and/or examples of when and how such avenues of inquiry can be pursued.

The following questions pertain to prescribers or to relationships between prescribers, pharmacies and the wholesale distributor

6. Due to the changes in reimbursement rates and healthcare reform measures, non-pharmacy Healthcare Provider (HCP) models are evolving. More individual practitioners, Accountable Care Organizations (ACOs) and other HCPs have told wholesale distributors that they wish to start, or increase, purchasing of controlled substances to furnish/dispense/administer directly from their offices.

Given these new and/or significantly changed models, wholesale distributors, which are not experts in providing healthcare to patients, have little or no ability to determine how to group these HCPs into classes of trade, as described in the ICG in Section II, and have limited data on which to base “thresholds” to signal purchasing patterns that may need further review under a suspicious order monitoring system. Further, these patterns are continuously changing so that determining what is “suspicious,” even based on relatively recent data, may not accurately identify questionable orders.

**Questions**

A. Section II.c. of the HDMA ICG recommends developing “thresholds” for customers grouped into “classes of trade” to signal that an order may represent an unusual pattern suggesting the need for further review. Using ARCOS or other data, we would appreciate DEA’s guidance on what types of registrants (practitioners and non-pharmacy HCPs) should be grouped together into a “class of trade” for purposes of determining “thresholds,” based on a HCP model that calls for office dispensing/administering.
B. If more than one class of trade should be formed for these HCPs, can DEA specify how to group these registrants together into several classes of trade for purposes of evaluating ordering patterns?
C. Since wholesale distributors have limited baseline data, can DEA provide further guidance on how to evaluate patterns of ordering for these HCPs that should lead to considering an order to be questionable (described as an “Order of Interest” under Section II.c. of the ICG)?

7. The following questions pertain to practitioners who order controlled substances directly from wholesale distributors with the intention of furnishing, administering or dispensing them directly from their offices.

Questions

A. Does DEA have a list of practitioner specialties that would appropriately purchase (for administration/dispensing within their practices) controlled substances that can be provided to wholesale distributors?
B. Has DEA provided guidance on the types and acceptable amounts of controlled substances and/or combinations of controlled substance products, by practitioner specialty (e.g. Family Practice) or on type of treatment needed (e.g., palliative care vs. cancer treatment vs. general surgery), or other criteria such as patient demographics (e.g. percentage of elderly vs. other age ranges within their practice) that would be appropriate for furnishing to patients directly from the practitioners’ practice?
C. If such guidance exists, HDMA requests that DEA make these guidances available to wholesale distributors. If not, can DEA recommend where wholesale distributors could obtain such guidances?
D. As part of its request for ARCOS data, HDMA would like to ensure that the request includes aggregated data on individual physicians/practitioners. Specific data, to include aggregated data for specific individual physician/individual practice registrants, would be the most helpful.

8. The following questions are very similar to those in # 7 above but pertain to practitioners who prescribe, rather than purchase, controlled substances.

Questions

A. Does DEA have a list of practitioner specialties that may be expected to prescribe higher quantities of controlled substances?
B. What controlled substances and/or combinations of products are appropriate for prescribing by the various specialties?
C. If such guidance exists, HDMA requests that DEA make them available to wholesale distributors. If not, can DEA recommend where wholesale distributors could obtain such guidances?
The following questions pertain to DEA’s guidance dated October 20, 2009, entitled “Suggested Questions a Wholesale distributor should ask prior to shipping controlled substances” (“guidance” or “DEA guidance”)

9. The guidance’s pharmacy-related questions include several that pertain to a pharmacy’s other suppliers. These questions include:

- Who is the pharmacy’s primary supplier?
- Does the pharmacy order from other suppliers as well? If so, why and what controlled substances?
- 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 these same products from other suppliers?
- What ratio will you be supplying compared to other suppliers?

While we understand these questions’ underlying purpose, wholesale distributors are subject to the U.S. anti-trust laws. Thus, asking these questions may place them in the position of stepping over the line into areas these laws restrict.

Questions

A. Has the DEA discussed these questions, in the context of the Agency’s “know your customer” guidance for wholesale distributors, with their colleagues in the Anti-Trust Division of the Department of Justice (DOJ)? If not, HDMA requests that DEA receive from DOJ an opinion as to whether these questions should be part of this guidance and part of the wholesale distributor’s “know your customer” efforts.

B. Can DEA provide a mechanism for the wholesale distributor to verify the customer’s answers with the Agency about other suppliers?

C. (The following question is applicable providing that the DOJ is in agreement that these questions are acceptable.) During the course of conducting their due diligence regarding a new customer, a wholesale distributor may find no questionable business practices at a pharmacy but the pharmacy is unwilling to answer any or all questions related to their other suppliers. Is it acceptable for the wholesale distributor to ship controlled substances to this pharmacy as long as this customer’s controlled substances orders are not identified as “suspicious” and no other red flags are raised during the course of the business arrangement?

D. If not, can DEA provide guidance or criteria for when a refusal to answer these questions about other suppliers would indicate that the wholesale distributor should either conduct further inquiry into the customer’s business practices and/or should not ship to the pharmacy in question?

E. Would DEA be willing to revise the third question as follows: If the pharmacy states that you are not their only supplier, ask the pharmacy what controlled substances they will be ordering from you, in what quantities, in what time frame, and will they be ordering these same products from other suppliers?
10. Another pharmacy question reads as follows: “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?” (Emphasis added) HDMA notes that the phrase “…to stake their professional livelihood on it?” seems to indicate that the pharmacist, who has healthcare training but not necessarily medical training or legal authority over prescribers, and does not perform physical exams of their patients, should know with certainty that every physician or other prescriber for which they fulfill prescriptions is prescribing appropriately.

Questions

A. Would DEA consider rephrasing this question as follows: “Is the pharmacist comfortable with the prescribing practices of any or all practitioners for which they fill, and do they acknowledge, in writing, that they are carrying out their corresponding responsibilities to ensure that the prescriptions they receive are issued for a legitimate medical purpose as required under 21 C.F.R. § 1306.04”

B. If not,
   a. Would DEA further define their intention in recommending that wholesale distributors ask this question?
   b. What is DEA’s expectation that a pharmacist should have certainty?
   c. Can the Agency define what is meant by this question and/or provide criteria or guidance for how the wholesale distributor should evaluate the response if the pharmacist states that they cannot stake their professional livelihood on the prescribing practices of every practitioner for which they fill prescriptions?

11. Under “Possible questions for a practitioner”, is one that reads: “Has the practitioner ever been disciplined by any state or federal authority?” This question implies an extended search for disciplinary action going back through the practitioner’s entire professional lifetime, and potentially including disciplinary actions unrelated to patient or pharmaceutical safety, security or prescribing practices (e.g., employment discrimination, workplace harassment, tax issues). When answering these questions, please assume that no other red flags are raised during the wholesale distributors’ due diligence efforts in reviewing a practitioner or during suspicious orders monitoring.

Questions

A. Does DEA agree that a review extending back two years and only to activities related to patient or pharmaceutical safety, security and prescribing or filling practices is appropriate?

B. If not, what period of years does DEA believe would be an adequate length of time?

C. If DEA believes that the length of the review should not be specified in terms of a time frame, but rather based on the wholesale distributor’s ability to adequately establish the credibility of the practitioner, could the Agency provide guidance and/or criteria for:
   a. what further information should be sought;
b. how the wholesale distributor would go about evaluating that information to
determine the practitioner’s credibility; and
c. then, how to link that information to the time frame over which the search for
disciplinary actions should be pursued?
D. If DEA believes a review of disciplinary actions that do not involve pharmaceutical
safety, security or prescribing/filling practices, is necessary even if no other red flags are
raised, HDMA requests that DEA provide:
   a. guidance on the types of disciplinary activities that should be sought and how
      they should be factored into the decisions as to whether to accept orders from this
      customer; and/or
   b. examples of instances where the Agency found that a disciplinary activity
      occurred outside of those involving pharmaceutical safety, security or
      prescribing/filling practices, and where no other reason to question the
      practitioner was found, but where the disciplinary action may have indicated that
      further review of a practitioner, or a decision not to ship controlled substances to
      them was warranted.

12. Another question reads: “How many patients is the practitioner presently treating (day,
week and month)?

**Questions**

A. Does DEA have guidance on an appropriate number (such as an average or range) of
   patients for an individual practitioner to treat, preferably by specialty?
B. Is the Agency aware of any guidances from professional societies, or similar
   knowledgeable sources, regarding this issue that DEA believes is appropriate for
   wholesale distributors to use as reference for their suspicious orders monitoring
   programs?
C. HDMA requests that DEA advise wholesale distributors on how they may access such
   guidances.

13. Although HDMA has been willing to furnish to its members the guidance referenced in
these questions and other guidances DEA might provide, we may not be able to attend every
industry meeting where such information is provided. Further, HDMA is only able to circulate
them to our own members, yet there are other legitimate wholesale distributors who are not
HDMA members that should be aware of them.

**Questions**

A. Did DEA make the guidance questions available through DEA’s Regional Offices?
B. Did DEA inform all wholesale distributor registrants through official correspondence?
Questions for the Drug Enforcement Administration
By HDMA
June 1, 2011

C. If DEA did not, would DEA be willing to do so if they plan on releasing further such guidances?
D. Additionally, if DEA did not, is there any binding responsibility upon a registrant to ascertain answers to these questions?

Additional Questions Related to Monitoring for Suspicious Orders

14. In 2011, a number of states have been considering new laws that would require wholesale distributors to provide sales data similar to what they provide to DEA in ARCOS reports. Wholesale distributors maintain large volumes of data, including data on all products, not just controlled substances, so that submitting separate reports to different agencies can pose significant IT and cost challenges. Additionally, some states unknowingly request data that differs from ARCOS either in the data fields and/or frequency of reporting, compounding these challenges.

Question

A. HDMA believes it may be very important for all agencies to work with the same data sets during a prosecution. Given the importance of good communication and coordination among local, state and federal agencies regulating controlled substances, would DEA consider establishing a mechanism for states to have access to the ARCOS data assuring local, state and federal agencies will be working with the same data?

15. Wholesale distributors often hear from their customers that their competitors either do not have controlled substances monitoring programs (CSMP) or the competitors’ programs are not as strict. Lack of consistency creates an “unlevel playing field” for wholesale distributors. It also undermines DEA’s security intentions because customers are free to conduct “wholesale distributor shopping” until they find one who’s CSMP is less sophisticated or has an unknown loophole that doesn’t identify their orders as “orders of interest.”

Question

A. How does DEA ensure that requirements are enforced across the board and uniformly for all levels of the pharmaceutical supply chain? For example, are there internal guidelines for DEA staff to help ensure uniformity?

16. HDMA noted the DEA action taken in late February 2011 under “Operation Pill Nation” resulted in arrests at a number of clinics. Further, as explained in the Miami Herald of February 23, 2011, a number of physicians have either voluntarily surrendered their DEA registrations or were arrested.
Questions

A. Can DEA release the names and/or registration numbers of the physicians who were involved in these actions? There are over 1,000,000 physicians registered with DEA, and currently, verification can only be performed through a “one-by-one” keying in of each physician customer into DEA’s data base. Direct notification to wholesale distributors would be very helpful.

B. Similarly, names of the clinics out of which these physicians operated were not published in the press reports. Could DEA release either names and/or registration numbers of these facilities?

17. On July 7, 2010, HDMA submitted a letter to then-Acting Administrator Leonhart reiterating HDMA’s verbal requests for DEA to provide aggregated, blinded ARCOS data so that distributors could evaluate when fulfillment of customer orders may first require further due diligence. At the DEA/HDMA meeting on Dec. 7, 2010, DEA staff indicated a concern that if they were to release ARCOS data, even if it were aggregated, some wholesale distributors might be able to determine what their competitors are selling, potentially resulting in confidentiality breaches. During a presentation at the most recent Distribution Management Conference (DMC – March 7, 2011), Cathy Gallagher, in reference to the request for ARCOS data, essentially indicated that existing regulations do not allow DEA to identify a registrant’s other suppliers.

Questions

A. Do these statements represent DEA’s official response to HDMA’s letter?
B. Therefore, has DEA reached a final decision that the Agency will not release aggregated ARCOS data?
C. If DEA cannot provide the requested ARCOS data, about quantities and types of purchases from other wholesale distributors, can DEA tell wholesale distributors how many other wholesale distributors the registrant is buying from?

18. The following questions refer to the status of suggestions HDMA made at the December 7, 2010 meeting between DEA and HDMA.

Questions

A. HDMA had suggested that DEA review and update the 2006 and 2007 “letters to industry” sent to wholesale distributor registrants.2 Can DEA tell us the status of this request?

---

Questions for the Drug Enforcement Administration
By HDMA
June 1, 2011

B. DEA indicated that its procedures for suspending or restricting a wholesale distributor’s DEA registration often include sending the registrant a “Letter of Admonition” outlining concerns with the registrant’s compliance. Do DEA’s procedures require the Agency to issue a written warning where there is not a finding that continued registration would constitute an imminent danger to the public health and safety before suspending a wholesale distributor’s registration?

19. In our meeting with DEA on July 17, 2008, HDMA noted the incongruity of DEA’s increases in quota sizes and the expectation that wholesale distributors will cut back on distribution. At the time, DEA seemed to understand that there needs to be a better connection between the size of the quotas and the expectations for wholesale distributors to curtail shipments if there are questionable orders.

Question

A. How has DEAA’s wholesale distributor initiative affected DEA’s decisions on quotas? For example, we note that manufacturers received their full requested quotas for oxycodone for 2011.

20. HDMA asks if DEA would be willing to encourage collaboration and provide information to the mutual benefit to both parties by aiding wholesale distributors in determining appropriate additional due diligence measures and/or revisions in selling/shipping practices.

Questions

A. In this light, would DEA be willing to support this effort through any or all of the following:
   a. Providing the names and/or registration numbers of all parties involved in the actions similar to that of “Operation Pill Nation”?
   b. Reestablish the notification system to all wholesale distributors when a single wholesale distributor has refused to deal with a particular practitioner registrant?
   c. Although DEA’s website identifies pain clinics or other registrants where DEA has taken specific enforcement action, the reports are somewhat delayed. Can DEA expedite making this information available?

B. If a registrant asks for a meeting with a DEA field office to discuss issues and seek clarification, is the field office obligated to have the meeting?

21. It is our understanding that at the start of an inspection, DEA will provide the registrant with a copy of DEA Form-82, but typically does not provide a written report to the registrant at the end of the inspection. As part of a wholesale distributor’s due diligence, they may ask a potential customer if/when the customer was last inspected by DEA, and for a copy of any
documentation related to the inspection. However, some pharmacies respond to such requests by stating that although they were inspected, DEA never leaves behind any documentation of the inspection.

**Questions**

A. Can DEA clarify what form of inspection documentation a customer receives at the beginning and at the conclusion of a DEA inspection, specifically:

   a. Does DEA provide each registrant, including pharmacies and other healthcare providers, with a copy of DEA Form-82 at the beginning of each inspection?
   b. At each inspection’s conclusion, does DEA provide the registrant with any form of written communication about the results of the inspection?
   c. If not, is there an alternate means by which wholesale distributors may find out the results of a customer’s inspection so that they may factor DEA’s findings into their “know your customer” efforts?

*******

HDMA appreciates the opportunity to submit these questions to the Drug Enforcement Administration. If there are any questions, please contact Anita Ducca, Vice President, Regulatory Affairs at 703-885-0240 or aducca@hdmanet.org.
Questions for the Drug Enforcement Administration (DEA)  
by the Healthcare Distribution Management Association (HDMA)  
Submitted July 2, 2013  
For Discussion on July 31, 2013

1. During a wholesale distributor’s efforts to fulfill the U.S. Drug Enforcement Administration’s (DEA) expectations to “know your customer,” current business practices for many Healthcare Distribution Management Association (HDMA) members may include one or more of the following measures:

   - Wholesale distributors request that potential customers, prior to opening an account with the wholesale distributor, answer certain questions about their business to better understand the expected legitimate purchase demands of that potential customer;
   - Wholesale distributors’ field sales representatives and inside sales staff are trained to be alert during routine communications with customers for signs that a customer’s intentions in purchasing the product may raise questions, and to report to appropriate designees within their companies, any such questions regarding a prospective customer’s intentions and/or activity so that the wholesale distributor may, if warranted, conduct further review of the customer;
   - If the wholesale distributor has reason to believe, based on a system for tracking product orders, that a customer, or a customer’s order(s) have changed in such a manner as to suggest different ordering patterns for controlled substances which may be indicative of diversion, they will follow up with an additional, more extensive, review of that customer and/or the order in question; and
   - Wholesale distributors will report to DEA when appropriate pursuant to 21 C.F.R. § 1301.74(b).

    a. Does DEA agree that the customer review process as described above meets the Agency’s “know your customer” expectations?
    b. If not, HDMA requests that DEA provide further clarification as to what should be included in the “know your customer” review process.

2. If sales of certain or all controlled substances to a customer are terminated, is there an appropriate amount of time (e.g., 90 days?) that is permissible to pass in which that wholesale distributor can reinstate that customer provided that customer takes reasonable steps to address conduct that gave rise to the original decision by that wholesale distributor to terminate sales of controlled substances to that customer?”

3. When a wholesale distributor receives a request to provide controlled substances (either from a newer customer or an existing one) who indicates they wish to increase controlled substance orders, wholesale distributors may provide the customer with an inquiry or questionnaire about their business asking the reason for this increase.
A wholesale distributor staff member then carefully reviews the customer’s response to determine if there is anything questionable in the answers that requires further assessment.

a. Based on DEA’s extensive experience with registrants who furnish controlled substances to their patients, can DEA identify the types of questions to be asked and what responses to those questions we receive from these customers that the Agency believes are adequate or most likely to lead the wholesale distributor to conclude that further review of this customer is warranted?

b. If a customer is otherwise acceptable, subsequently does not place an order determined to be suspicious, and the wholesale distributor conducts periodic updates of its “know your customer” information, can the wholesale distributor accept the responses and communication coming from that customer as validation that the customer is purchasing the product for legitimate purposes? If not, what would DEA suggest wholesale distributors do to help ensure this is the case?

4. DEA field offices sometimes provide guidance that differs across field offices and/or differs from 21 CFR requirements. HDMA would appreciate the opportunity to discuss the following:

- Inspections pertaining to the Controlled Substances Ordering System (CSOS) are one example. Recently, when DEA field investigators performed an inspection, they requested CSOS records so that they could compare electronic orders to records of products received at the warehouse. Many DEA investigators expect that if a record for the order is on the CSOS system, the record for the receipt of the product should also be on the CSOS system. However, most HDMA members place the record of receipt within separate systems, not solely on the CSOS system. HDMA distributor members ensure there is a means to link the two records/systems, for example, some include the order number code on both records, so that order to receipt comparisons are possible. We believe this approach should be acceptable to DEA investigators for several important reasons:

  o The CSOS system was designed to place _orders_ within a secure system that includes important regulatory/security controls. (e.g., to verify that the person placing the order is properly authorized through DEA.) However, CSOS was never designed to maintain records of receipt;
  o We are unaware of a regulatory requirement for recording receipt of the product in a specific location. In addition, the CFR does not contain a requirement for placing an electronic record of receipt on the CSOS system;
  o The preamble of the final rule is clear that wholesale distributors have the flexibility to maintain separate records. Specifically: “… _DEA’s only concern is that if it requests copies of orders_ (e.g., for a particular customer or substance), the registrant must be able to produce the requested records (i.e., _both the electronic orders and the linked distribution records_) upon request in a format that an agent can read and understand. _DEA has revised the rule to clarify that ‘readable format’ means that a person, not a computer, can easily read the documents._” 70 FR 16904 col. 3 (April 1, 2005); and
  o Placing the record of receipt on the CSOS system creates additional burdens for both distributors and DEA. Distributors would have to duplicate business
records that they keep for other reasons (taxes, inventory management, etc.) and requires unnecessary DEA resources to maintain extra data in the CSOS system.

Our members are willing to produce the requested records, but we believe the flexibility to produce them in a variety of formats as long as they can be linked and a person may read them, is imperative and what is expected under the rule pursuant to the commentary in the preamble.

a. Would DEA be willing to clarify for all their field staff that records of receipt are not required to be placed in the CSOS system and that separate systems can be used provided that those records are electronically linked?

- When a distributor member (warehouse registrant) requests a meeting with a DEA field office, some field offices will respond affirmatively that they will meet with the requesting distributor/registrant while others may deny or be nonresponsive to such requests.

  a. Are field offices obligated to meet with a registrant, for example, if a registrant requests an inspection of a new vault or has another matter requiring DEA’s input/assistance?

- Given the changes in leadership within DEA and occasional variability in positions taken by DEA field offices (which particularly affects distributors with multiple warehouse distribution points) HDMA asks:

  a. What is the best way by which our distributor members can obtain a position/guidance that is uniform across DEA field offices?
  b. Is it still acceptable for HDMA to submit such a request for clarification on behalf of its members?
  c. What can HDMA do to assist DEA in providing this clarification?

5. When a wholesale distributor reviews a potential customer who wishes to purchase controlled substances, they likely seek:

- Information obtained about the customer through the “know your customer” process;
- Answers to questions such as those pertaining to ordering excessive quantities of controlled substances, and, ordering a limited variety of controlled substances in quantities disproportionate to quantities of non-controlled substances;
- The information about internet pharmacies discussed in the preamble to the interim final rule: “Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008” 73 Fed. Reg. 15596 (April 6, 2009); and
- Guidance provided during DEA’s meetings with, and presentations to, wholesale distributors.

  a. Is there any other information wholesale distributors should observe during our “know your customer” efforts that are not included in the above bullet points?
6. Wholesale distributors often hear from their customers that their competitors either do not have controlled substances monitoring programs (CSMP) or the competitors’ programs are not as strict. Lack of consistency creates an “unlevel playing field” for wholesale distributors. It also undermines DEA’s security intentions because customers are free to conduct “wholesale distributor shopping” until they find one who’s CSMP is less sophisticated.
   a. How does DEA ensure that requirements are enforced across the board and uniformly for all levels of the pharmaceutical supply chain?
   b. For example, are there internal guidelines for DEA staff to help ensure uniformity?

7. What is DEA’s position on wholesale distributors working with customers to educate them on potential signs of diversion? Should wholesale distributors share information with pharmacies to help them understand what actions by the pharmacy might constitute potential diversion in the eyes of a third party such as a wholesaler? If so, does DEA have any recommendations as to what information wholesalers should share with pharmacies they service to help educate them so as to help prevent diversion? Can/should this information include telling customers their “thresholds”? We would appreciate any other guidance/recommendations DEA may offer regarding the best way that a wholesale distributor should educate customers on threshold levels to ensure that a customer’s legitimate needs are met.

8. Would DEA be able to provide us with suggested “model” thresholds for different customer classes that can be used as a basis for a wholesale distributor to set its own thresholds? For example, are there recommended thresholds that ideally should be acceptable or expected for products such as oxycodone and hydrocodone when supplying small, medium or large retail independent pharmacies? How do those numbers compare to pharmacies that service hospice centers? Long term care facilities? Adjacent to hospital emergency rooms? etc.

9. HDMA asks if DEA would be willing to encourage collaboration and provide information to the mutual benefit to both parties by aiding wholesale distributors in determining appropriate additional due diligence measures and/or revisions in selling/shipping practices. In this light, would DEA be willing to support this effort through any or both of the following:
   a. Providing the names and/or registration numbers of all parties involved in the actions similar to that of “Operation Pill Nation”?
   b. Although DEA’s website identifies pain clinics or other registrants where DEA has taken specific enforcement action, the reports are somewhat delayed. Can DEA expedite making this information available?

10. HDMA requests that DEA provide current trend information. For example, we’re interested in such trends as:
   a. The comparative amounts and/or percentages of controlled substances being ordered, (or shipped or dispensed) compared to non-controlled substances. A breakdown by such factors as geographical location (particularly Florida) or by the purchaser’s class of trade e.g., retail pharmacy vs. hospitals vs. pain clinic, or
specific drug product such as oxycodone, hydrocodone, etc. would also be helpful.

b. Are there other objective criteria/guidelines that the DEA can offer that we could/should take into account when using this information to evaluate potential or existing customers? For example, if a customer's controlled substance purchases are X% of its overall purchases, are there other specific criteria or factors that a wholesale distributor should consider when evaluating that customer. If so, what are they?

c. The total volumes of products being sold/shipped per distributor customer by the same factors, e.g., geographical location, class of trade, specific drug product?

d. The specific prescription drugs (or combinations of drugs or changes in combinations) that are being abused that distributors should be aware of?

e. Are there factors that are affecting the trends that wholesale distributors should be aware of as they evaluate customers and their orders?

11. Is DEA continuing to meet with individual companies to review and provide guidance on whether individual Suspicious Order Monitoring programs, including their customer “due diligence” efforts are adequate/acceptable? Does this include follow-up non-enforcement visits to the distributors if the distributor requests one?

12. Does DEA have a specified time frame for responding to registration applications? If there appears to be a lengthy wait for a response to indicate whether the registration is approved (or not) what can the registrant do assist DEA in expediting a review of that registration application?

13. In the past, DEA’s suggested guidance included several questions that pertain to a pharmacy’s other suppliers. These questions include:

- Who is the pharmacy’s primary supplier?
- Does the pharmacy order from other suppliers as well? If so, why and what controlled substances?
- 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 these same products from other suppliers?
- What ratio will you be supplying compared to other suppliers?

While we understand these questions’ underlying purpose, wholesale distributors are subject to the U.S. anti-trust laws. Thus, asking these questions may place them in the position of stepping over the line into areas these laws restrict.

a. Has the DEA discussed these questions, in the context of the Agency’s “know your customer” guidance for wholesale distributors, with their colleagues in the Anti-Trust Division of the Department of Justice (DOJ)? If not, HDMA requests that DEA obtain from DOJ an opinion as to whether these questions should be included as part of the wholesale distributor’s “know your customer” efforts.

b. Can DEA provide a mechanism for the wholesale distributor to verify the customer’s answers with the Agency about other suppliers?

c. (The following question is applicable provided that the DOJ is in agreement that these questions are acceptable.) During the course of conducting their due
diligence regarding a new customer, a wholesale distributor may find no questionable business practices at a pharmacy but the pharmacy is unwilling to answer any or all questions related to their other suppliers. Is it acceptable for the wholesale distributor to ship controlled substances to this pharmacy as long as this customer’s controlled substances orders are not identified as “suspicious” and no other red flags are raised during the course of the business arrangement?

d. If not, HDMA would appreciate DEA’s guidance or criteria for when a refusal to answer these questions about other suppliers would indicate that the wholesale distributor should either conduct further inquiry into the customer’s business practices and/or should not ship to the pharmacy in question.

e. Would DEA be willing to revise the third question as follows: If the pharmacy states that you are not their only supplier, ask the pharmacy what controlled substances they will be ordering from you, in what quantities, in what time frame, and will they be ordering these same products from other suppliers?

14. Although HDMA has been willing to furnish to its members the guidance referenced in these questions and other guidances DEA might provide, we may not be able to attend every industry meeting where such information is provided. Further, HDMA is only able to circulate them to our own members, yet there are other legitimate wholesale distributors who are not HDMA members that should be aware of them.

   a. Did DEA make the guidance questions available through DEA’s local Offices?
   b. Did DEA inform all wholesale distributor registrants through official correspondence?
   c. If DEA did not, would DEA be willing to do so if they plan on releasing further guidance?

15. In prior meetings with DEA, HDMA noted what appears to be an inconsistency between DEA’s increases in quota sizes and DEA’s expectation that wholesale distributors will cut back on distribution. At the time, DEA seemed to understand that there needs to be a better connection between the size of the quotas and the expectations for wholesale distributors to curtail shipments if there are questionable orders. How has DEA’s wholesale distributor initiative affected DEA’s decisions on quotas? For example, we note that recently, DEA issued a Federal Register notice proposing to increase manufacturers’ quotas for 2013. 78 Fed. Reg. 37237 (June 20, 2013).

16. Given the changes in staffing over the last year, would DEA kindly explain the roles of the various staff we typically hear about or interact with, including Barbara Boockholdt, Ruth Carter, Cathy Gallagher, Robert Hill, John Partridge and Al Santos? We would be interested in a revised organization chart if one is available.

17. HDMA would appreciate any update on the disposal/take back rule that was proposed late last year that DEA can provide. 77 Fed. Reg. 75783 (Dec. 21, 2012).

   a. Is a final rule still expected approximately the end of 2013?
   b. Were there any common themes among the comments received?
   c. Can HDMA help by answering any questions DEA may have about our written comments?