January 28, 2008

VIA ELECTRONIC TRANSMISSION

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration
Washington, DC 20537

Attention:	DEA Federal Register Representative / ODL
Docket No.	DEA-303P
RIN	1117-AB15
Federal Register Publication Date:	November 27, 2007

Dear Mr. Rannazzisi:

The Healthcare Distribution Management Association (HDMA) appreciates this opportunity to provide public comments on the notice of proposed rulemaking (NPRM) regarding Proposed Rule DEA-303P, "New Single Sheet Format for U.S. Official Order Form for Schedule I and II Controlled Substances (DEA Form 222)", as published in the *Federal Register* on November 27, 2007.[1] The following comments are submitted to the Drug Enforcement Administration (referred to hereafter as the "DEA") in response to the NPRM to revise the current regulations governing the design and use of DEA order forms (referred to hereafter as "DEA Form 222").

Introduction

The design format for DEA Form 222 under the proposed regulations will require a single-sheet form to replace the current three-sheet color-coded form. The processing of the single-sheet forms will be conducted in a manner similar to the current process, except for the new requirement that DEA registrants will have to make additional copies of the proposed single-sheet DEA Form 222 to document every Schedule I and II transaction.

The revised regulations for DEA Form 222 are intended to improve security over controlled substance transactions, and allow for improved, convenient and easier handling. They are also intended to deter the diversion of Schedule I and Schedule II drugs for illegal purposes, since it has been demonstrated that users of these drugs are subject to a high risk of abuse and physical dependence. Proposed revisions to DEA Form 222 are meant to strengthen the framework established for the legal distribution of controlled substances existing under the current regulations, and to ensure that the supply of these drugs is sufficient for legitimate medical purposes.

[1] *72 Fed. Reg. 66118 (November 27, 2007).*

DEA registrants will still be responsible for maintaining their own individual original or copy of DEA Form 222 needed to comply with the order form processing, recordation and storage requirements.[2] The single-sheet order form would be available for purchasing registrants from the DEA upon request.

HDMA has concerns about how the processing of transactions for controlled substances under the proposed rule can continue to be as efficient and secure as the current format, considering the substantial revision to the design of DEA Form 222. HDMA believes that a transition to the single-sheet format will decrease rather than increase the level of security that has been achieved for Schedule I and II transactions by using the existing DEA Form 222. The security of the current order processing system would be compromised by imposing the responsibility to produce duplicate copies of the original DEA Form 222 solely onto DEA registrants.

Additionally, we believe the revised order form will be less convenient and efficient for DEA registrants to use. Making DEA registrants responsible for producing and maintaining copies of DEA Form 222 would introduce an increased risk of recordkeeping mistakes, and would necessitate additional time to produce, maintain, and manage the order forms. It is highly likely that the additional time invested into this process will diminish the efficiencies that have been developed under the current order processing system.

Recommendations

Because of our concerns about maintaining both the security and efficiencies of the current order processing system for Schedule I and II controlled substances, we believe that the DEA should not change DEA Form 222 in the manner proposed under DEA-303P. However, should DEA believe that a change from the carbon copy format is absolutely necessary, we recommend that DEA consider one or more of the following options:

1. Use Carbonless Paper

HDMA recognizes the DEA's concerns about continuing the use of outdated carbon copy order forms to process transactions. Therefore, we suggest that the DEA examine the suitability of using carbonless paper as a viable replacement for the current three-part carbon form. Adopting a carbonless paper order form would address and remedy the DEA's concerns about continuing the use of an outmoded form. A form printed on carbonless paper that preserves the color-coded feature of the current DEA Form 222 would also serve to retain the security and processing efficiencies of the current system.

Additionally, HDMA recommends that the DEA consider the following long-term and short-term measures to evaluate revisions to DEA Form 222 before moving forward with DEA-303P.

2. Consider Storing Order Forms Electronically

HDMA recommends that DEA consider evaluating the feasibility of adopting an alternative approach to maintaining paper copies of DEA Form 222 by allowing registrants who receive paper copies of the order forms to store them by electronic means. Recording DEA Form 222 in an electronic, paperless format may be a viable alternative to carbonless paper for those DEA registrants that have the capacity to maintain the

[2] *21 C.F.R. Section 1305.13*

information contained on each order form in a secure, efficient and reliable manner. Retaining copies of Form DEA 222 electronically would enable DEA registrants to maximize the efficiencies that have developed in the Schedule I and II order processing system and would permit each DEA registrant with a degree of flexibility they need to determine the best way to maintain their compliance with controlled substances order processing requirements established under 21 C.F.R. Section 1305.11 et seq.

The DEA process for submitting electronic DEA registrations and renewal registrations is well established, and supports the view that an electronic system to record and store order forms for Schedule I and II controlled substances could become a reasonable alternative to making paper copies to ensure regulatory compliance.

3. Conduct Further Studies of Alternatives

- Explore the use of comparable, lower cost document production and duplication technologies to address the reasons for discontinuing the use of the three-part carbon form.

- Make a sample template of the proposed DEA Form 222 publicly available for further analysis, review and feedback from interested DEA registrants.

- Consider developing a short-term pilot study to assess the reliability, efficiency and security of the revised DEA Form 222 order form prior to introducing it for use on a full-scale basis.

Comments on DEA's Proposed Rule

Registrants purchasing Schedule I and II controlled substances will be required to make a photocopy of the original DEA Form 222 order form before sending it to their supplier for filling. HDMA believes that transitioning to a single-sheet format under the proposed rule will increase security risks and jeopardize order processing efficiency.

1. Photocopying Could Result in an Increased Risk of Forgery

   The risk of forgery is likely to increase substantially by requiring registrant purchasers and suppliers to photocopy the original order form. Data recording the details of each controlled substance transaction entered on the appropriate fields contained on DEA Form 222 could be intentionally changed, adulterated, or otherwise corrupted in the process of making a photocopy of the original order form.

   We believe that it would not be an insurmountable task for individuals who are skilled in counterfeiting, forgery, laser print technology, or who are familiar with IT document production and duplication applications, to bypass the security measures embedded into the DEA watermark and related security technologies used in the creation of the proposed DEA Form 222. A forged copy of the order form could contain major or minor changes to it by adding, altering or concealing data entered on the original order form. Copies could be intentionally changed by editing or cropping out information contained in the original with sophisticated computer software that overwrites, replaces and adds printed information onto the form. Changes could also be accomplished manually by using standard office products to erase, white out, or tape over information and signatures entered on the original order form. The altered form

could then be introduced into the stream of commerce for controlled substances transactions handled by DEA registrants and passed along to subsequent unsuspecting recipients as a credible and reliable document.

2. Registrants Have Implemented Recordkeeping Systems That Rely on the Three-Part Color-Coded Format

   The current three part color-coded order form helps to prevent and avoid exposure to security risks that would occur by using standard white sheet paper photocopies produced by DEA registrants. Each one of the three colored sheets contained in DEA Form 222 has been specifically designated to be used and retained by either DEA registrant purchasers, suppliers or the DEA. Purchasers and suppliers have become familiar with maintaining records in the color of the order form specifically designated for them.

   The color-coded feature of the current DEA Form 222 is relied upon by DEA registrants and it has contributed to improved security and efficiency of order form processing. Lapses in security and obstacles to efficient order form processing have been avoided because large volumes of order forms are required to be maintained in one designated color. Records containing order form sheets in colors not designated for use by a particular DEA registrant are visually recognizable and stand out from the other forms. Forms that do not conform to the designated color can be easily detected by a record keeper and corrected. The three-part color-coded form has served as a valuable tool to help ensure that the integrity of the information recorded on the order forms is properly preserved.

3. The Proposed Rule Presumes Routine Access to Copy Machines

   It is unclear to us how requiring the production of photocopies of the order form would make the current order form transaction process easier. This is particularly true when one considers that a substantial number of registrant purchasers of controlled substances are retail pharmacies that operate with neither access to the use of photocopy machines, nor have the financial resources necessary to purchase, rent or maintain photocopy machines for their business operations. Moreover, many retail pharmacies do not have the available counter or office space that would be needed to accommodate copy equipment.

   All of the registrant purchasers who fall into this category will be forced to make difficult choices about prioritizing their resources. They will have to weigh the benefits and drawbacks of purchasing or renting photocopy equipment, using a vendor to make the copies, and reducing other operating costs to meet the costs of complying with this requirement.

4. Compliance Responsibility Will Likely Shift to Distributors or Third Parties

   DEA has probably not considered the strong likelihood that pharmaceutical distributors will have to assume a substantial amount of the additional administrative service workload if they are asked to produce copies of DEA Form 222 for their customers. Based upon the HDMA membership's experience with providing a variety of services to their customers, it is likely that many dispensers purchasing Schedule I and II drugs do not have access to copying equipment. HDMA believes that, for all practical

purposes, customers of our member pharmaceutical distributors will expect them to assume a substantial share of the responsibility for meeting this requirement.

Distributors may have to reallocate the use of their resources, including warehouse storage space, document production equipment and the man-hours required to produce a large volume of copies. For example, some distributors may have to take additional measures to ensure that they are able to make duplicate copies of up to 1,000 orders for Schedule I and II controlled substances that they receive on a daily basis. The additional costs incurred for providing these services may, depending upon the individual distributor's business, have to be absorbed to the detriment of other operations, or passed along to the registrant purchasers

Distributors will likely be faced with the decision as to whether or not to accept this additional task on behalf of their customers. If they decline, they may run the risk of endangering ongoing business relationships with their registrant purchasers.

Alternatively, pharmacies may seek document duplication services which could raise additional concerns about the identity and reliability of third parties who may be contracted out by purchasers to produce copies of the order forms. Document production services rendered by non-DEA registrant third parties could increase the risk of breakdowns or gaps in the security of the order form transaction process. Loss of the pharmacy's custody, control or management of the order forms during the document production process may result if original documents are not copied at the purchaser's worksite. Moreover, the content or legibility of the information contained on both the original and duplicate copies of the order forms could be compromised if pharmacies are unable to verify the accuracy or integrity of the forms after they are reproduced by third parties.

5. Potential Decrease in Customer Service Resources

Current order processing operational efficiencies developed in the distribution industry could be lost by using the revised order form. Additional costs and duplication procedures could require a reconfiguration of the order form management and recordkeeping processes, which would likely affect demands on document inventory and storage space allocation.

Moreover, distributors will have to allocate valuable additional man-hours from the limited customer service time available to render photocopying services for these customers on a regular basis to ensure compliance. Photocopying costs and related expenses incurred by distributors will result in an added financial burden for retail pharmacies, many of which are not equipped to absorb these additional costs.

6. Likely Increase in Registrant Recordkeeping Errors and Omissions That Will Lead to Civil Penalties

In the regular course of making and filling orders for Schedule I and II controlled substances by purchasers and suppliers, DEA registrant purchasers required to make record copies of DEA Form 222 under the proposed rule may unintentionally fail to do so, and not be aware of the omission until after the order has been submitted to the supplier for filling.

Additionally, registrant purchasers who produce copies of DEA Form 222 prior to submitting the original form to their registrant suppliers may unknowingly or mistakenly make illegible copies that would not be suitable for DEA auditing purposes, and could not be relied upon to accurately document the specific details contained in any particular order. Information contained on original or duplicate copies of DEA Form 222 that is illegible could create confusion between purchasers and suppliers over the accuracy and reliability of either or both versions of the form. Confusion resulting from illegible information on the DEA Form 222 could seriously impede or stop the efficiencies of the order processing system, because additional efforts required to resolve these discrepancies would be costly and time consuming. The proposed rule language does not provide any guidance to DEA registrants about how to address such circumstances, what procedures registrants should follow to resolve these problems, or other steps to avoid these problems before they occur.

Errors and omission of this nature may constitute violations of the copy requirement by DEA registrants under the proposed rule. Such unintended errors and oversights would also compromise the controlled substance order transaction process and expose it to greater risk of liability for mistakes and security breakdowns. The potential for errors and omissions would increase, of course, according to the volume of growth of orders for Schedule I and II drugs. The proposed rule offers no guidance on how registrants should handle missing, lost or illegible copies of DEA Form 222, breakdowns in copying equipment, or how to address assigning responsibility for producing copies of the forms to third parties.

Request for Further Clarification on Proposed Rule

There are several issues raised by the proposed rule which are not addressed in the rulemaking.

1. Confusion Over Endorsement of Order Forms

   Title 21 C.F.R. Section 1305.14 of the existing rule describes the procedure for endorsing orders for Schedule I and II drugs using DEA Form 222, to address those situations when a supplier is not able to fill all or part of a purchaser's order. An endorsement from the first supplier may be sent to a second supplier by completing the spaces provided for it on the reverse side of Copies 1 and 2 of the current three-sheet color-coded order form. The endorsement must contain the name and address of the second supplier, and must be signed by the first supplier.

   Under the proposed rule, endorsements of orders must be made on the front of DEA Form 222, under Part 2 of the original and all copies of the revised form. The preamble to the proposed rule provides for a one-year transition period, wherein DEA registrants will be allowed to use both the current and the revised versions of the DEA Form 222 to order Schedule I and II drugs.

   HDMA is concerned that undue confusion among purchasers and suppliers may occur about how to complete an endorsement accurately during the transition period. Mistakes could occur when registrant suppliers will be required to apply endorsement information on different portions of the either the existing or revised DEA 222 order forms. There is a strong likelihood that endorsements will not be properly recorded, transmitted or received by intended recipients if the endorsements are not properly photocopied. If endorsements mistakenly placed on the reverse side of the revised single-sheet forms

under the proposed rule are not copied or recorded, there will be confusion about whether the endorsement exists and which supplier should be responsible for filling the order.

We suggest that the DEA re-examine the implementation of this revised endorsement procedure. As indicated in the recommendations listed above, HDMA would prefer to retain the current order form process. Alternatively, we believe that transitioning over to a carbonless order form would be preferable to the revised form as proposed under the rule.

2. No Information is Provided on the Proposed Size or Format of the New DEA Form 222.

   No reference was made in the proposed rule to clarify whether DEA registrants will be required to maintain a recommended or standardized size for copies of the original single-sheet DEA Form 222. The order forms currently in use are not printed on a standard sheet of paper. Without additional information from the DEA about the size of the new form and how DEA registrants should handle variations in the size of paper sheets that they could receive or use to produce these duplicate copies, HDMA has been unable to develop reasonable alternatives for the industry to consider and is unable to provide additional comment at this time.

Conclusion

The consequences of implementing this proposed rule as written will be serious and long-lasting, and will negatively affect the operational efficiencies that have been achieved in the existing order processing system for Schedule I and II controlled substances. More importantly, HDMA strongly believes that the proposed changes will present greater risks to both the security and handling of Schedule I and II controlled substances.

As described above in the Comments to DEA's Proposed Rule, HDMA is concerned that the proposed DEA Form 222:

- Subjects the order processing system for Schedule I and II controlled substances to greater risk of forgery and jeopardizes its reliability
- Creates an increased need for access to photocopy equipment by pharmacies that are DEA registrant purchasers, decreasing current order form operating efficiencies and threatening the system's security
- Imposes new costs for making and retaining copies that must be absorbed by DEA registrants or their agents
- Shifts the burden of compliance from pharmacies and other dispensers to pharmaceutical distributors
- Reduces time and diverts resources available to distributors to address other customer service needs.

In summary, HDMA believes that the DEA should not change DEA Form 222 as proposed under DEA-303P. Additionally, HDMA urges the DEA to consider the recommendations described above as reasonable alternatives to the proposed rule.

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On behalf of HDMA and our member companies, thank you for the opportunity to provide our comments on Proposed Rule DEA-303P. We remain ready to address any questions that you may have about the important issues, concerns and suggestions discussed above.

Sincerely,

Brian M. Cherico, Esq.
Government Affairs