April 16, 2019

Drug Enforcement Administration
Attn: DEA Federal Register Representative/DPW
8701 Morrissette Drive
Springfield, Virginia 22152


Dear Sir or Madam:

The Healthcare Distribution Alliance (HDA) appreciates this opportunity to provide comments to the Drug Enforcement Administration (DEA) regarding the Proposed Rule “New Single-Sheet Format for U.S. Official Order Form for Schedule I and II Controlled Substances (DEA Form 222)” (“proposed rule” or “proposal”) Docket No. DEA 453; [84 Fed. Reg. 5395 (February 21, 2019)]

HDA represents primary pharmaceutical distributors – the vital link between the nation’s pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics, and others nationwide. This essential function is provided with little public recognition or visibility, and at great savings to the healthcare system. HDA members serve as the central link in a sophisticated national supply chain. HDA members take this mission very seriously, and we support manufacturers, healthcare providers, and the government in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient, and highly regulated.

BACKGROUND

HDA members act as purchasers of Schedule II products from suppliers, typically directly from product manufacturers. HDA’s wholesale distributor members also act as suppliers of Schedule II controlled substance products, typically directly to hospitals, pharmacies and other purchasers. Since the finalization of the regulation allowing and supporting electronic orders of controlled substances, when acting as purchasers, HDA members generally rely on the electronic Controlled Substances Ordering System (CSOS) for conducting their product ordering, although on occasion, they may place orders with their suppliers on the paper DEA Form 222.\(^1\) Despite an increase over time in CSOS usage,\(^1\) See: Electronic Orders for Controlled Substances; [70 Fed. Reg. 16915 (April 1, 2005)]
there remains a significant number of orders submitted to wholesale distributors, by dispensers and other purchasers. Thus, the proposed change to a single sheet DEA Form 222 will largely affect wholesale distributors and their customers.

HDA understands the reasoning behind DEA’s desire to propose the change from the three-part paper DEA Form 222 to a single-sheet version. Thus, the comments that follow are intended to recommend certain clarifications and further streamlining of the proposal that we believe should be regarded as “fine tuning” rather than substantial changes.

COMMENTS

1.  Page 5397, Col. 1; Justification for New Order Form

The preamble to the proposal includes the following statements:

This proposed procedure would replace requiring all suppliers, regardless of ARCOS reporting requirements, to submit Copy 2 to the DEA…

The purchaser and supplier would preserve the original order form and a copy of the original order form, respectively, for two years…

HDA believes that since many suppliers also provide DEA with Automation of Reports and Consolidated Orders System (ARCOS) data containing essentially the same ordering information as found on DEA Form 222, but in a more readily used and easier to manipulate electronic version, it is not necessary for such suppliers to also provide DEA with a paper copy of the completed DEA Form 222. Moreover, the supplier’s records of DEA Form 222 are subject to examination during DEA inspections, as appropriate, thereby providing another means of review. Thus, HDA agrees with the first statement.

Regarding the second statement, HDA agrees with the specified two-year time frame for maintaining the Form. We encourage retaining the proposed two-year record retention time frame in the final rule.

2.  Page 5397 Col. 3; Other Minor Regulatory Changes

In this part of the preamble, DEA outlines several minor regulatory changes, including to §§1305.05(a) and (d), 1305.11(b) 1305.12(a), and 1305.14(b). HDA notes that we agree with the proposed changes.

Regarding § 1305.13(d), HDA generally agrees with the provision specifying that suppliers not required to report acquisition/disposition transactions to ARCOS should provide a copy of the original DEA Form 222 to DEA by mail. However, we have included a separate comment on the requirement for suppliers to retain the original in our comment point # 5 below.
3. Page 5400 Col. 3; § 1305.13(a)

The regulatory text of § 1305.13(a) states:

A purchaser must submit the original DEA Form 222 to the supplier and retain a copy in the purchaser’s files.

HDA believes DEA intended for the purchaser to make the copy of the completed DEA Form 222 before the Form is transferred to a supplier, including when the supplier is a wholesale distributor, for order fulfillment. We recognize the desirability of such a requirement because, while unlikely, it is possible for a paper DEA Form 222 to be lost, stolen, or misplaced while en route to a wholesale distributor. Thus, retaining a copy before shipment may aid security, investigations of potentially lost or stolen forms, or, in the extreme, legal action in the event that a criminal attempted to divert and misuse a completed order form before it reached the wholesale distributor. Therefore, HDA agrees with this provision.

4. Page 5400 Col. 3; § 1305.13(b)

Proposed § 1305.13(b) states

A supplier may fill the order, if possible and if the supplier desires to do so, and must record on the original and a copy their DEA registration number and the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser. [Emphasis added]

HDA points out a likely language error in this section. Specifically, we believe the Agency did not intend to include the phrase “and a copy.” Recording the required information on both the original and a copy may effectively require wholesale distributors and other suppliers to create an additional record, i.e., an additional file with an additional copy of each form, that neither they nor DEA would need. Creating a copy would also be superfluous because the supplier already must store the original (or an electronic version of the original should DEA agree with our comment point # 5 below) and most suppliers also submit equivalent information via ARCOS reports.

For those suppliers who do not provide ARCOS reports, there is a requirement contained later in the proposal under §1305.13(d) specifying that such suppliers must make and submit a copy to DEA:

Any supplier who is not required to report acquisition/disposition transactions to [ARCOS]… under § 1304.33(c) of this chapter (such as a practitioner) must make and submit a copy of the original DEA Form 222 to DEA…

Thus, a record of each Schedule I or Schedule II order is available to DEA in some fashion.

Removing the phrase “and a copy” from § 1305.13(b) would also make this section consistent with the revision explanation provided in the preamble as described on page 5397, Col.1 as well as the proposed record retention requirements contained in proposed § 1305.17.
Therefore, HDA recommends amending proposed §1305.13(b) to remove the phrase “and a copy.” The revision would include deleting this phrase as shown below with a double strikethrough so that this section would read as follows:

A supplier may fill the order, if possible and if the supplier desires to do so, and must record on the original and a copy DEA Form 222 their DEA registration number and the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser.

5. **Page 5400 col. 3; § 1305.13(d)**

Section 1305.13(d) describes the supplier’s original order form record retention responsibilities as follows:

The supplier must retain the original DEA Form 222 for his or her files in accordance with § 1305.17(c).

As noted above, in many instances, the wholesale distributor will be the “supplier” and therefore would be required to follow this provision. To HDA, it initially appeared that DEA’s intent was that the supplier would maintain the original DEA Form 222 in paper form. This is, in part, because on page 5396 Col. 3, when discussing changes for purchasers, the preamble specifically states that *purchasers* would retain a copy which “can be scanned and stored electronically…” [emphasis added] but there is no equivalent language allowing electronic storage when describing the *suppliers’* responsibilities for retaining the original order form.

However, while there is no discussion of a supplier’s ability to maintain the original in electronic form, there is also not a specific prohibition against this practice. Thus, there is some ambiguity on this point, and HDA recommends its clarification. In particular, HDA urges DEA to clarify that wholesale distributors (and other suppliers, if appropriate) may maintain the original DEA Form 222 in an electronic form, in lieu of the paper original.

Our reasons for urging this amendment include:

- Electronic files are far more likely to survive emergencies and natural disasters such as hurricanes, fires, and tornadoes. Reliable “back up” arrangements would be part of any electronic storage system that are not possible under a paper filing system for the originals. With the proliferation of such natural disasters in recent years, HDA believes that requirements for paper storage should be reconsidered.

- While the Drug Supply Chain Security Act (DSCSA) is not administered by DEA, its requirements are *substantial*, and represented a sea change in the enhancement of product and data security. For example, to help assure product traceability, no supplier may provide a prescription drug covered by the DSCSA, including Schedule II Controlled Substances, to a purchaser without first providing the

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2 The Drug Quality and Security Act (DQSA), was enacted by Congress on November 27, 2013. [Title II of DQSA, the Drug Supply Chain Security Act](https://www.dea.gov/dockets/d453/041619cr/), outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.
DSCSA-required Transaction Information (TI), Transaction History (TH) and Transaction Statement (TS) to the same purchaser. Further, all purchasers must receive these data before they may accept a shipment of a DSCSA-covered drug product and both the supplier and the purchaser must retain records of the TI, TH, and TS data for six years. Moreover, even more DSCSA-required security measures have been put in place since its enactment, and more are being phased in over time until 2023. Thus, there are very significant new requirements for the purchase, sale and provision of prescription drug products, all designed to help with security, that did not exist before the DSCSA was enacted in 2013, well after the Controlled Substances Act (CSA) or even the November 2007 proposal. If DEA has reservations about allowing an electronic version to replace of the original paper DEA Form 222, we believe the additional DSCSA security requirements should substantially mitigate such concerns.

- Wholesale distributors also believe that an electronic storage system may be simpler and more cost-effective than a paper storage system to maintain because, for example, paper files require more office space, storage containers and other equipment.

- HDA believes that wholesale distributors can meet or exceed the same level of security under electronic storage mechanisms than what is possible with paper filing systems. Minimal access can be assured, and electronic security measures ("firewalls," encryption, etc.) can be routinely updated very rapidly and efficiently.

- If these documents were to be stored electronically, wholesale distributors would be able to meet or exceed current retrievability expectations.

By issuing this proposal, DEA has recognized the importance of moving away from reliance on the outdated three-part paper production technology for the DEA Form 222’s production. Thus, HDA urges the Agency to likewise recognize that there is a strong need to mirror that modernization shift by moving away from reliance on paper storage systems for registrants’ DEA Form 222 record retention requirements.

To indicate that electronic storage is allowed in lieu of storing the original paper DEA Form 222, HDA recommends the following language additions, shown in blue bold type font, to § 1305.13(d).

The supplier must retain the original paper DEA Form 222, or, in lieu of the original paper, in electronic form, for his or her files in accordance with § 1305.17(c).

**ADDITIONAL POINTS**

HDA would like to take this opportunity to provide a few additional suggestions that are not addressed in the proposal as they would not change the Code of Federal Regulations (CFR). We believe they would support streamlining the ordering process and/or aid registrants in their compliance efforts as well as aid DEA’s oversight of these processes.
6. **Recommended additional changes to DEA Form 222**

HDA supports DEA’s efforts to enhance DEA Form 222’s security as discussed on page 5397 Col. 1 of the preamble. Given the design changes already underway, we urge consideration of an additional enhancement involving the space on the form where the purchaser indicates which products they intend to order. Specifically, we encourage DEA to add to the lines where currently only 10 distinct products with 10 individual National Drug Codes (NDCs) may be placed on a single DEA Form 222.\(^3\)

As noted in the preamble, DEA Form 222 was designed over forty years ago. Since then, many health systems, large chain pharmacies and other healthcare providers have increased the size and scope of the patient populations they treat. Moreover, the Food and Drug Administration (FDA) has approved both more individual drugs, such as less costly generic versions, and many more alternative strengths, dosage forms (liquid, solid, injection, etc.) and other variations of the same drug to meet increasingly differing patient needs and treatment regimens. Each variation may contain the same active ingredient, and are, thus, the same drug. However, they are given different, unique, NDC codes so that important characteristics such as the package size and product manufacturer may be readily distinguished from one product to another.

Despite these substantial changes over time, the number of lines (10) on DEA Form 222 has not increased accordingly.

Given that the Agency is already revising DEA Form 222, we urge DEA to consider placing additional lines for additional products to be ordered on a single form, provided that doing so would not reduce legibility or create the need for a paper document larger than 8½” x 11”. This change would allow many more products to be ordered using only one form, thereby reducing the total number of forms for ordering the same number of products. By reducing the overall number of forms that must be copied, stored, retrieved and otherwise managed, the additional lines would therefore reduce and simplify the burden associated with the DEA Form 222 paperwork generation and recordkeeping.

While we strongly encourage adding more lines so that more than 10 individual drugs could be purchased via a single form, we would readily forego the additional lines if expanding the number of lines/products placed on each form meant that the new version of DEA Form 222 would become any larger than the traditional, and most commonly used, paper size of 8½” x 11”. Using this standard paper size (or smaller) would mean that wholesale distributors would not experience the additional expense and other storage challenges that would likely result if DEA Form 222 became enlarged any further. Allowing as much standardization of paper maintenance systems as possible, by remaining consistent with the most common sizes that paper materials that are typically used in such businesses as a wholesale distribution center, should be a primary goal when redesigning the DEA Form 222.

\(^3\) HDA also notes, if DEA is not already aware of it, that the Food and Drug Administration (FDA) is planning to change the NDC’s format. This change, which is likely to include expanding the number of digits in the NDC, is needed due to “running out of” numbers. For further information, see the FDA webpage dedicated to the NDC change, and the related Federal Register Notice. DEA may wish to factor this NDC change into the revisions both for the paper DEA Form 222 and for the electronic CSOS system.
7. **CSOS Improvements**

As HDA has noted previously, updating and streamlining the CSOS system would be beneficial for registrants, product security, and for DEA as well. Most recently, HDA explained these improvements to the Department of Justice (DOJ) when responding to DOJ’s request for public input on the administration’s Regulatory Reform Agenda.\(^4\) HDA encouraged DEA to modify CSOS to assist registrants when using that electronic system as an alternative to the longstanding paper DEA Form 222, noting:

CSOS presents a more efficient option and should be the primary method of ordering schedule II controlled substances moving forward. CSOS has been in place for 12\(^5\) years, yet ongoing technical issues mean that many transactions in schedule II controlled substances still must begin with a triplicate paper form…

greater use of CSOS should result in cost savings to the healthcare supply chain in the multi-million dollar range. Increased use of CSOS can improve patient care by facilitating faster receipt of orders and by streamlining management of the ordering system. The safeguards built into the electronic system are intended to enhance information security over the paper based system. Moreover, as DEA stated in 2005, with CSOS, “Electronic orders will be received almost instantly and can be shipped the same day. This speed may allow purchasers to . . . limit the quantity of controlled substances that they stock. Limiting the quantity of Schedule I and II controlled substances in stock reduces the possibility of diversion and the cost of security.” [footnotes omitted]

Examples of CSOS’ limitations presented in our comments to DOJ included:

- The arduous CSOS certificate retrieval process that requires the user to have clicked a mouse 32 times and to have entered information or answered acknowledgements with each click,

- When working to pull certificates from the CSOS, the portal will often time out and lock out the user, and

- The inadvertent restrictions on the use of CSOS for returns, recalls and disposal/destruction of a product – the reverse distribution aspect of the supply chain.

HDA continues to believe that our reasons for asking DEA to update and simplify the CSOS system, thereby encouraging greater usage, are sound. Some of the many anticipated benefits include:

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\(^4\) See pages 11 – 14 of the HDA letter to Robert Hinchman, Senior Counsel, Office of Legal Policy (OLP), U.S. Department of Justice dated August 14, 2017, in response to: Request for Public Comment: Enforcing the Regulatory Reform Agenda; Department of Justice Task Force on Regulatory Reform Under E.O. 13777 (Docket No. OLP 164); [82 FR 29248 (June 28, 2017)]. Copy attached.

\(^5\) HDA notes that the excerpted comments were submitted in 2017. Thus, CSOS has now been in use for approximately 14 years.
• Improvements to the CSOS system will further reduce the reliance on the paper version of DEA Form 222, thereby reducing the paperwork and record retention burdens associated with either the three part or the single sheet version,

• Registrants will have easier and more rapid order fulfillment, resulting in cost savings by reducing total inventories that must be maintained through a reduction in “lag time” between ordering via a paper form and receipt of the product,

• As DEA has recognized, additional electronic ordering will potentially aid security because lower inventory levels may result in fewer opportunities for theft and diversion, and

• DEA may experience resource savings due to fewer forms that must be printed and provided to registrants.

HDA also points out that since CSOS was established, well over a decade ago, there have been substantial advances in technology. For example, “browsers” are becoming obsolete and users are migrating to the “cloud” for data storage and other uses. We urge DEA to assess CSOS’s current structure and technology and to initiate efforts to update the system to remain in lock step with technology developments since it was first established. HDA believes that without doing so, CSOS itself will eventually, if not rapidly, become obsolete and no longer usable, inadvertently forcing suppliers, purchasers and DEA to revert back to the paper DEA Form 222.

In sum, HDA urges DEA to address the changes that will be needed to retain and increase electronic ordering, and pledges to support DEA in such an effort by participating in its evaluation and development as deemed appropriate.

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We hope that these comments are constructive in the development of a final DEA regulation. Thank you for this opportunity to express HDA’s views. If you have any questions, please feel free to contact me at aducca@hda.org or at 703-885-0240.

Sincerely,

Anita T. Ducca
Senior Vice President, Regulatory Affairs

Attachment