



Healthcare Distribution Alliance

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<http://www.regulations.gov>, Docket No. DEA-662

August 17, 2021

Drug Enforcement Administration

Attn: DEA Federal Register Representative/DPW

8701 Morrisette Drive

Springfield, Virginia 22152

**RE: Clarification Regarding the Supplier's DEA Registration Number on the Single-Sheet DEA Form 222; Direct Final Rule, Docket No. DEA-662 [86 Fed. Reg. 38230 (July 20, 2021)].**

Dear Sir or Madam:

The Healthcare Distribution Alliance (HDA) appreciates this opportunity to provide comments to the Drug Enforcement Administration (DEA) regarding the Direct Final Rule "[Clarification Regarding the Supplier's DEA Registration Number on the Single-Sheet DEA Form 222](#)" ("rule" or "direct final rule") Docket No. DEA-662 [86 Fed. Reg. 38230 (July 20, 2021)].

HDA represents primary pharmaceutical distributors – the vital link between the nation's pharmaceutical manufacturers and more than 180,000 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.

We understand that the change from the triplicate form to a single sheet version<sup>1</sup> necessitated a change in the format and placement of the information to be provided on the form. However, as noted in the federal register notice's description of the direct final rule, there has been some confusion regarding who must record the supplier's DEA registration number on the single-sheet DEA Form 222.<sup>2</sup>

HDA members, therefore, appreciate DEA's recognition of the need for clarification, and the action DEA has taken to address this need, by issuance of the direct final rule. Moreover, we agree with the rule's provision to allow and clarify, that either the purchaser or the supplier may fill in the information.

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<sup>1</sup> Proposal: 84 Fed. Reg. 5395 (February 21, 2019); Final: 84 FR 51368 (Sept. 30, 2019)

<sup>2</sup> 86 Fed. Reg. page 38231 col. 1.

Comments by HDA on the DEA Direct Final Rule:  
Clarification Regarding the Supplier's DEA Registration Number  
on the Single-Sheet DEA Form 222  
Docket No. DEA-662

Thus, HDA agrees with the following language inserted into the final rule, which explains this clarification:

A supplier may fill the order, if possible and if the supplier desires to do so, and must record on the original DEA Form 222 its DEA registration number (if not previously entered by the purchaser) and the number of commercial or bulk containers furnished on each item and the date on which containers are shipped to the purchaser.<sup>3</sup>

HDA requests that DEA retain the direct final rule, with this language, intact. We add that we urge DEA to refrain from withdrawing the direct final rule because we believe the clarification is useful, is in keeping with the responsibilities of both DEA and registrants and will not result in security risks or other potentially adverse consequences.

## **CONCLUSION**

In summary, HDA and its members understand the need to transition from the three-part carbon copy to the single-sheet DEA Form 222 and appreciate the clarification provided in the direct final rule. We agree with the new language in § 1305.13(b) and urge DEA to retain this section as written.

If you have any questions, please contact me at 703-885-0240 or [aducca@hda.org](mailto:aducca@hda.org).

Sincerely,



Anita T. Ducca  
Senior Vice President, Regulatory Affairs

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<sup>3</sup> § 1305.13(b), 86 FR 38232 Col. 2.