HDA
Healthcare Distribution Alliance

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http://www.regulations.gov, Docket No. DEA 501

May 14, 2020

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

RE: Registration and Reregistration Fees for Controlled Substance and List I Chemical Registrants; RIN 1117-AB51/Docket No. DEA 501, 85 Fed. Reg. 14810 (March 16, 2020)

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 "*Registration and Reregistration Fees for Controlled Substance and List I Chemical Registrants Docket*" ("proposed rule" or "proposal") RIN 1117-AB51/Docket No. DEA 501, 85 Fed. Reg. 14810 (March 16, 2020)

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.

BACKGROUND

HDA members act as both purchasers and suppliers of controlled substances and list I chemicals regulated under the Controlled Substances Act (CSA) and, therefore, are subject to the registration and reregistration requirements and associated fees.

HDA notes that all wholesale distribution facilities are experiencing unique challenges, including financial challenges, as they contend with the increased demand for products associated with meeting the healthcare needs of patients during the current coronavirus pandemic outbreak. However, we recognize that DEA's responsibilities have changed since the last fee schedule revision in 2012. We particularly note that several new Acts of Congress have expanded the responsibilities and scope of the Diversion Control Program (DCP). HDA has supported many of these new Congressional mandates described in the preamble, and, therefore, also recognizes that meeting these new requirements will add to the resource needs of the Agency.

Below we share a few perspectives on the proposed rule, and hope they help inform DEA's decision making as the Agency moves to establish a final rule.

COMMENTS

1. HDA Agrees with the Proposed Methodology for the New Fee Calculation

The proposed rule provides a useful explanation of the three alternative methodologies to calculate the new registration fees. These include a "Flat Fee Option" a "Past-Based Option" and a "Weighted-Ratio Option."[1] For the following reasons, HDA agrees with DEA's selection of the Weighted-Ratio Method:

- As the preamble states: "DEA is authorized to charge reasonable fees relating to the registration and control of the manufacture, distribution, dispensing, import, and export of controlled substances and listed chemicals. 21 U.S.C. 821 and 958(f)."[2] Of the three potential calculation methodologies, HDA believes that the proposed increase achieved by the Weighted-Ratio Method, from $1,523 to $1,850, per year, per wholesale distributor registrant, *i.e*., an increase of $327, is the most "reasonable."

- The Weighted-Ratio method is the same method DEA used for previous increases. While there have been changes in the underlying abuse and misuse circumstances over time, the form and number of specific products with abuse potential, as well as in DEA's congressionally mandated responsibilities, the Agency's core mission and goals have essentially remained the same. Thus, we believe it is appropriate for DEA to base the 2020 fee increase on the same methodology used historically.

- The Weighted-Ratio method results in an equivalent across the board increase of 21 percent for all DEA registrants whether they are wholesale distributors, manufacturers, dispensers, or others. HDA believes that since all supply chain trading partners share a responsibility for helping to avoid the misuse/abuse of the controlled substances and other products that DEA regulates, adopting a method that applies an equivalent increase to all registrants is "reasonable."

2. HDA Agrees with the Proposal to Grant Registration Fee Refunds Under Certain Circumstances.

The proposal includes a provision to provide a refund of the registration fees under certain circumstances. As explained on Page 14821, col. 1 of the preamble:

> DEA proposes amending 21 CFR 1301.13(e) and 1309.12(b) to codify existing practices of the issuance of refunds by DEA for applicant registration fees. Generally, registration fees are not refundable. This regulation was implemented when registration fees were nominal. Now that registration fees have been increasing, DEA recognizes that the

[1] *See*: The preamble discussion begins with the Proposed Methodology for New Fee Calculation, 85 Fed. Reg. 14825 (March 16, 2020) col. 1.
[2] See: 85 Fed. Reg. 14812 (March 16, 2020) col. 1.

> issuance of refunds in limited circumstances is warranted… such as: Applicant error, DEA error, and death of a registrant within the first year of the three-year registration cycle…

HDA appreciates DEA's acknowledgement that there will be a certain amount of "honest errors" either on the part of the registrant or on DEA's part. Thus, we agree with this part of the proposal and encourage DEA to include §§ 1301.13(e) and 1309.12(b) in the final rule.

3. HDA Urges DEA to Eliminate the Duplicative Registration Requirement

HDA has previously noted the duplicative nature of the registration requirement established under 21 CFR part 1309. Specifically, wholesale distributors who possess and distribute both controlled substances and certain iodine products must apply, and pay registration fees, for two separate registrations, even though they are storing and distributing by way of a single warehouse for both products. As we explained in further detail in the attached HDA letter of August 14, 2017 to Mr. Robert Hinchman, Senior Counsel, Office of Legal Policy (OLP):

> Under current regulatory requirements, a wholesale distributor that handles schedules II, III, IV, and V controlled substances and products containing the listed chemicals ephedrine and pseudoephedrine, may do so under a single DEA controlled substance registration. However, if the same wholesale distribution facility handles a 7 percent iodine solution in order to distribute such product to a customer, that distributor must obtain a separate listed chemical registration from DEA. HDA finds the requirement to be redundant and unnecessary.[3]

HDA was hoping that our previous request for DEA to amend 1309 to waive the chemical registration requirements of those wholesale distributors who are also registered as controlled substance handlers would have been addressed in this proposed rule. Such a waiver makes sense for a number of reasons. Including,

- As HDA further noted in its 2017 letter "this requirement for duplicative registrations impacts [wholesale distributors'] inventory and invoicing systems, adding implementation costs that are not necessary to realize the benefit of regulation. Including a listed chemical registration number in records, and maintaining records for that registration separately from the records linked to the controlled substance registration, requires additional database complexity."[4] Not only is the wholesale distributor subject to two registration fees, they experience further financial burdens resulting from managing this additional data base complexity.

- The Agency's own internal IT systems must retain records of two sets of registration numbers, where one would be sufficient to identify a single location. Thus, we suspect that while there would be an initial cost to change internal IT systems so that the Agency could appropriately maintain its registrant

[3] Letter from HDA to Robert Hinchman, Senior Counsel, Office of Legal Policy (OLP) U.S. Department of Justice, August 14, 2017, Re: Request for Public Comment: Enforcing the Regulatory Reform Agenda; Department of Justice Task Force on Regulatory Reform Under E.O. 13777.
[4] *Ibid*, page 8.

records, longer term, the agency would realize a cost savings for decreasing the total amount of required recordkeeping DEA itself must undergo.

- Currently, DEA conducts inspections based on a facility's registration or registrations. This results in a single facility undergoing two separate DEA inspections if that same facility stores both controlled substances and the covered iodine products. By waiving the duplicative registration requirement, DEA could achieve a potential cost savings and increased efficiencies by consolidating these inspections. Wholesale distributors would similarly benefit from the increased efficiencies.

- Some wholesale distributors have limited the number of facilities in which they will stock iodine products to avoid the duplicative registration fees, tracking two sets of registration numbers, and other tasks associated with the dual registration requirements. This creates unnecessary, artificial market restrictions. It also reduces distribution efficiencies since such products may, for example, have to be transported over longer distances, at additional time and expense, to reach the customers who have ordered them, if a warehouse located physically closer to the customer does not stock them to avoid the extra registration fees and other burdens.

- HDA sees it as "unfair" to make a single facility registering with a single federal agency pay two registration fees to do so.

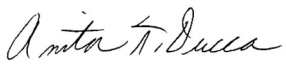
We emphasize that there is no security risk by making such a change. DEA will still know the locations of those warehouses storing both controlled substances and listed chemicals, including the iodine products mentioned above. This notification could be accomplished by requiring a registrant who is applying for a controlled substances registration, to also check a box, or otherwise indicate, that the facility is one that stores/handles both types of products. Moreover, as noted above, these registrants will still experience DEA inspections. Inspections would only be different in that they would be consolidated.

Should DEA be unable to eliminate the duplicative registration requirement under this rulemaking, HDA urges the agency to do so under a separate proceeding.

CONCLUSION

HDA and its wholesale distributor members appreciate the opportunity to share our views with the DEA. If you have any questions, please contact me at 703-885-0240 or at aducca@hda.org.

Sincerely,



Anita T. Ducca
Senior Vice President, Regulatory Affairs

Attachment