



Healthcare Distribution Alliance

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<http://www.regulations.gov>, Docket No. DEA-574  
September 28, 2020

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

**RE: Notice of Proposed Rulemaking: [Reporting of Theft or Significant Loss of Controlled Substances](#), [85 Fed. Reg. 45547 (July 29, 2020)] Docket No. DEA-574**

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 “Reporting of Theft or Significant Loss of Controlled Substances” (“proposed rule” or “proposal”) [85 Fed. Reg. 45547 (July 29, 2020)] Docket No. DEA-574.

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**

Currently, a DEA registrant is required to notify DEA’s Field Division Office in his or her area, in writing, of any theft or significant loss of any controlled substances within one business day upon discovery of such theft or loss. The registrant is also required to submit a DEA Form 106 (“Form 106”, or “the Form”) on which the registrant enters additional information such as the specific controlled substance and the quantity lost.<sup>1</sup>

However, the current regulations are silent on whether the registrant must submit the Form in paper (hard copy) and the actual submission method (*e.g.*, mail, hand delivery, electronic). Therefore, registrants currently have a choice of methods. Additionally, the regulations do not stipulate a time frame by which the registrant is expected to submit the form.

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<sup>1</sup> 21 CFR 1301.76(b).

The proposal does not include changes to other requirements, including the requirement to notify the DEA Field Division Office in their area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery. Additionally, we understand that DEA is not proposing any changes to the information (*i.e.*, data fields) contained in the Form.

Thus, the rule proposes to clarify, and standardize, the provisions that remain somewhat ambiguous, by specifying “a 15-day calendar period for submitting a complete and accurate DEA Form 106.” Additionally, submissions must be electronic: “all DEA Form 106 submissions must go through the secure online database, and physical copies will no longer be accepted.”<sup>2</sup>

Below, HDA shares its perspectives on the proposed rule, in the hope they will help inform DEA’s decision making as the Agency moves to establish a final rule.

## **COMMENTS**

HDA believes DEA’s probable purpose in establishing provisions for providing the Form electronically and with a submission deadline, is to modernize its own data and information management processes. Thus, we have no objection to the proposal’s underlying concepts.

However, as we explain below, we believe certain modifications to the specific requirements would be appropriate. We also point out that certain circumstances may arise that potentially make compliance difficult, if not impossible, and urge DEA to further clarify how to handle such circumstances. Our recommendations are intended to improve our wholesale distributor members’ ability to comply, without compromising, and likely improving, the Agency’s ability to perform its own responsibilities for follow-up and possible further action regarding the theft/loss notices it receives.

### **1. Registrants may encounter instances where electronic submission is not possible.**

Many, if not most, wholesale distributors currently rely primarily on the electronic means for completing DEA Form 106, as this generally represents the most efficient submission method. Thus, establishing a requirement to submit the Form electronically, for the most part, will have minimal impact on our wholesale distributor members. However, there is a concern about the DEA Diversion Control Division’s secure network application (the “database” or “network application”) that accepts the electronic Forms.

Specifically, the database to which registrants would be required to submit the Form includes a field for the registrant to provide the stolen/lost drug product’s National Drug Code (NDC) to help identify the exact product(s) in question. Unfortunately, this database is not always up to date. On occasion, the drug product NDC is missing from the database. Thus, a registrant will fill out the electronic Form and submit it to the database, but when the database does not include the submitted

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<sup>2</sup> 85 Fed. Reg. 45549 Col. 1.

NDC, it will not find a match between the NDC in the registrant's submission and the NDC in the database. Consequently, the network application will reject the item due to the missing NDC.

Currently, if such a rejection occurs, a wholesale distributor registrant would typically complete a paper version of the Form, and submit the hard copy to DEA by mail, facsimile or creating a scanned duplicate copy that is e-mailed to the DEA Field Office. While not as convenient as the electronic submission, the registrant will still meet its regulatory obligations via a hard copy. Moreover, because there is currently no regulatory deadline, a possible delay in the submission is not considered a violation of the regulation.

However, if the rule is finalized as proposed, the option to provide a hard copy of the Form is no longer allowed. But, if the database does not contain an NDC, that item will be rejected, and the registrant will be unable to comply with the regulation through no fault of his or her own. This situation could be exacerbated were DEA to retain the relatively short (15-day) deadline for an electronic submission.<sup>3</sup> A registrant might inform DEA that his/her submission was rejected due to the NDC mismatch and request that DEA correct the NDC in its database. However, if DEA is unable to do so in time for the registrant to meet the 15-day deadline, the registrant would still be out of compliance, again, through no fault of their own.

On a separate but related concern, it is also possible for the network application to be "down" for reasons totally unrelated to the registrant's activities (*e.g.*, a several-day power outage; the database is inaccessible to allow for system changes; a natural disaster) making it impossible for the registrant to submit the Form electronically. Yet, the rule, as proposed, does not include a contingency plan for such potential occurrences.

Given the above, we urge DEA to recognize the need to plan for the infrequent, but still possible, instances where a registrant is unable to submit the Form, or an item on the Form, electronically. By planning for such instances, DEA will still obtain the information it needs. Moreover, it could do so without overly burdening its own staff to respond to unanticipated "emergency" requests for help from registrants attempting to comply but are unable to do so (particularly likely if the electronic submission requirement is coupled with a short-term deadline). Simultaneously, it would provide wholesale distributors with some flexibility in how they may report when they face unforeseen electronic submission obstacles.

We believe there are several options for amending the regulation to address these concerns. Those we have identified include:

- DEA could allow the continued use of the hard copy of DEA Form 106, if/when extenuating circumstances warrant. To explain further, DEA could still require registrants to submit the Form electronically. However, the rule would also allow use of the hard copy, clarifying that the hard copy is a last resort and only to be used in instances where an electronic submission is not possible, such as in those instances noted above.

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<sup>3</sup> We provide further context on the impacts of the 15-day submission requirement later in comment point #2 below.

- Grant a “grace period” allowing additional time to file the Form if an electronic submission is not possible within the final rule’s submission deadline. During the grace period, DEA would take appropriate measures, potentially including: correct the NDC(s) in the database, remedy the underlying reason for the database’s inaccessibility, or monitor actions that are not in its control such as may occur during a power outage. DEA would also establish a mechanism for the registrant to notify the Agency that it was unable to submit the Form electronically. The Agency, in turn, would notify the registrant when the database is ready to accept the submission, once the NDC or other problem is resolved. When the Agency notifies the registrant, we believe it would also be appropriate for DEA to allow a brief, but reasonable, time period for the registrant to submit the Form, particularly if a final rule’s submission deadline has passed.
- To address the problem of rejecting an item when an NDC does not “match,” revise the electronic DEA Form 106 (or the network application) to allow for submission, despite the lack of a match. For example, the Form could include a field for the registrant to specify the rejected item, and to indicate that the item was rejected because the NDC is not up to date in the database. That way, DEA would still have an electronic submission, would also have immediate notification that an NDC was missing and therefore causing a mismatch, and the registrant would remain in compliance. The Field Office, or other appropriate DEA official, could follow up with the registrant to resolve the issue.
- Allow the wholesale distributor to contact the local DEA Field Office, explain that they were unable to submit the Form electronically, and request alternative guidance. The DEA Field Office could work with the registrant to establish an alternative mechanism for fulfilling its regulatory obligation, and the timing for doing so. While flexibility will likely be necessary, HDA encourages and would appreciate as much consistency among the directives provided across Field Office as could be achieved.

HDA suggests that it would be slightly preferable to adopt the last option. Unique and/or unforeseen situations may arise where an additional or alternative arrangement, even beyond the first three options described above, may be desirable both for the registrant and for DEA. Thus, the most suitable solution may be to work with the local DEA Field Office on establishing an appropriate submission arrangement. We encourage DEA, however, to strive for the optimum balance between allowing the flexibility needed to address these unique or unforeseen situations against allowing as little variability as possible across the multiple DEA Field Offices charged with overseeing these submissions.

HDA notes that our members would work with any of the contingency plans described above and we are also open to DEA’s own suggestions for situations where the electronic submission cannot be accomplished within a regulatory deadline.

## **2. HDA urges extending the proposed 15-day calendar time frame to submit DEA Form 106.**

Currently, it is typical for local DEA field offices to provide guidance to HDA members on appropriate time frames/deadlines for submitting the Form. These time directives may vary widely across the Field Offices, or can be vague (e.g., submit it “as soon as you complete an investigation”).

Thus, it appears to us that DEA's proposal to "set a 15-day calendar period for submitting a complete and accurate DEA Form 106..."<sup>4</sup> after theft or significant loss identification, is an attempt to establish a standardized, predictable deadline and to signal that submission of a well-considered report is an important responsibility for registrants.

HDA believes that a single, consistent time frame could be beneficial for wholesale distributors. For example, the regulatory deadline would enable those who have warehouses in multiple locations and/or whose product shipments move across multiple state and DEA Field Office jurisdictions, to standardize their own internal processes for preparing and submitting the Forms.

However, while wholesale distributors would make every effort to submit its Forms within a DEA-established time frame, 15 calendar days is very short. Moreover, ensuring that each submission is "complete and accurate," within that time frame adds to their challenges because complete and accurate information may simply be unavailable within a 15-calendar day-time frame.

Should DEA finalize a rule containing a specified submission deadline, we encourage an extension of that deadline to a minimum of 30 days after the initial determination that there was a theft or significant loss. HDA believes there are many reasons for extending the proposed 15-day deadline. They include:

- When a theft or significant loss occurs, the wholesale distributor would, of course, notify the local Field Office (as described in § 1301.76(b)) but they also begin an investigation. Such investigations can involve contacting, seeking information from, and coordinating information exchanges across multiple parties (*e.g.*, local law enforcement, a trucking/delivery service company, the manufacturer, the wholesale distributor's customer(s), and others). Realistically, such notifications and coordination can require considerable time to achieve.
- Wholesale distributors may also request that these entities participate in the investigation. This may involve, for example, identifying potentially involved employees and questioning them for such important information as the location of a delivery truck during a suspected theft, or about possible unusual activity near the vehicle or delivery site. The wholesale distributor might also ask these contacts to perform laborious records searches. Again, such activities may be time-consuming. Moreover, these contacts may not be able to respond immediately due to other, equally important, activities such as a dispenser who is deeply involved in patient care responsibilities.
- Often a report is filed where a change or correction must be made later, because, for example, the carrier or a customer finds a product that was thought to be lost or stolen. Frequently, this occurs after a 15-day time frame. Thus, a shorter reporting time frame is more likely to result in DEA receiving a greater volume of unnecessary 106 Forms. In order to manage and follow-up on them, DEA may need to divert its own resources or staff from other duties or increase resource allocations to handle more reports, and subsequent revisions, that could have been avoided by allowing a longer reporting time frame.

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<sup>4</sup> 85 Fed. Reg. 45549, Col. 1.

- Many state or local regulatory authorities require registrants to notify them if/when a registrant submits the Form 106 to DEA and provide follow-up information if the registrant notifies DEA of a correction or change to the original Form's information. Since a short reporting time frame would likely increase the number of unnecessary Form 106 submissions to DEA as well as increase the number of amendments if new information is identified over time, there would be a corresponding increase in unnecessary state/local notifications. State and local authorities would likely find that they, too, must dedicate additional resources to manage and follow-up on an increased number of notifications that are later determined to be unwarranted. As a result, a short reporting deadline would potentially add yet another unnecessary resource demand for non-federal regulatory authorities and registrants.

In sum, for these reasons, we encourage DEA to extend the proposed DEA Form 106 submission deadline to a minimum of 30 days.

### **3. Recommendations for Amending Form 106.**

Although we understand DEA does not propose changes to the Form 106 itself, HDA recommends that the Agency consider doing so. We believe our recommendations, below, will be particularly important if "complete and accurate" electronic submissions become mandatory.

First, the electronic version of Form 106 is cumbersome to use when there have been large quantities of thefts or losses. To complete DEA Form 106 when large numbers of products are involved, the registrant must manually enter the product information into the Form, one item at a time.

One resolution to this time consuming, manual task would be to provide a way for the registrant to upload a spreadsheet or a list of NDC numbers. We believe this would save considerable time and would allow the distributor to concentrate resources on the investigation rather than on the manual data entry. HDA is open to other methods DEA may wish to pursue for simplifying electronic reporting when large numbers of products are involved and encourages DEA to reach out to registrants to discuss their electronic submission needs before finalizing an electronic submission requirement.

Second, the registrant must indicate the "Type of Theft or Loss" on the Form by checking a box for one of eight types of occurrences, including: Break-in/Burglary, Employee Theft (or Suspected), Hijacking of Transport Vehicle, Packaging Discrepancy, Robbery, Customer Theft (or Non Employee), Loss in Transit, Disaster (fire, weather, etc.)

While these types may occur, there may be other instances where the theft or loss does not fit well into any of these categories. Moreover, there have been occasions where the expectations or information needs of the DEA staff reviewing completed Forms may differ from the wholesale distributors' interpretations of what the Type of Theft or Loss categories represent.

Given the above, wholesale distributors are concerned that they may misunderstand the Agency's intentions and inadvertently complete a Form incorrectly. As a result, their report may not meet the Agency's expectation for an "accurate" submission. Further, DEA may not necessarily receive information that could be important for its own review and investigation purposes.

Thus, as long as DEA is changing this regulation, HDA suggests that the Agency consider reevaluating DEA Form 106. Updating both the information it requests as well as the directions for completing it, as noted above, would benefit all parties, including DEA, which would be more likely to receive the information needed to assess the impact of reported thefts and losses.

Moreover, we believe it is incumbent upon DEA to revise the Form and provide additional guidance should the final rule stipulate that the information submitted must be “complete and accurate.” Certain changes would be particularly important as it is sometimes not possible to align the “Type of Theft or Loss” options allowed on the Form with the theft or loss that has occurred. Further, it is likely that criminals’ tactics have changed over time, and the way that information about thefts is noted on the Form should be modified accordingly.

HDA offers the following initial suggestions:

- Prior versions of the Form included a check box that allowed the registrant to designate “Other” as an additional Type of Theft or Loss category. However, “Other” has been eliminated and is no longer offered as an option that registrants may check. In anticipation of a final rule that includes the specification that the submitted Form must be “complete and accurate” HDA urges DEA to reinstitute the category of “Other” into the Form. This category would allow for accurate reporting of potential theft or loss incidents that do not fit the current response options.
- We encourage DEA to create a guidance document that could be placed on the Agency’s website or included with the electronic Form 106. We envision that such a guidance would explain to registrants exactly how to complete the Form and its fields and clarify DEA’s interpretation of each Type of Theft or Loss. The guidance could also include information on compliance procedures in the event that the electronic version is not operable. In this way, a guidance would help enable
  - consistency among registrants’ interpretations of the Form’s fields,
  - a greater level of accuracy,
  - saving DEA staff resources by reducing the amount of questions DEA officials receive from individual registrants attempting to complete the Form, and
  - minimizing the need for time-consuming corrections later on.

Should DEA choose to consider further modifications, HDA would be more than happy to provide input and collaborate on development of possible changes. We also encourage seeking input from other supply chain members, including dispensers and manufacturers, and, of course, consideration of DEA’s own experiences with investigating thefts and losses.

## **CONCLUSION**

HDA would like to conclude by stating that we understand the need for DEA to update its reporting requirements by compelling electronic submission of DEA Form 106. We also believe

that establishing a submission deadline is an appropriate step to take to help clarify ambiguities about the requirements for submitting the Form.

However, we urge DEA:

- To establish a contingency plan in the event that the database rejects an item in the registrant's electronic submission, or if a registrant is unable to access or submit the Form electronically, and
- Allow more time for submitting Form 106 than the proposed 15-calendar days; HDA recommends a minimum of 30 days after initial identification of the theft or significant loss.

HDA also wishes to reinforce our offer to work with the Agency on identifying additional technical and other modifications to the database or the Form, should the Agency agree to pursue them.

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

Sincerely,



Anita T. Ducca  
Senior Vice President, Regulatory Affairs