



Billing Code 4410-09-P

**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Part 1305**

**[Docket No. DEA-453]**

**RIN 1117-AB44**

**New Single-Sheet Format for U.S. Official Order Form for Schedule I and II  
Controlled Substances (DEA Form 222)**

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** The Drug Enforcement Administration (DEA) is amending its regulations to implement a new single-sheet format for DEA Form 222, used by DEA registrants to order schedules I and II controlled substances. The rule provides for a two-year transition period, during which the existing triplicate version of the forms may continue to be used. The rule also includes a number of minor procedural changes.

**DATES:** This rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**FOR FURTHER INFORMATION CONTACT:** Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362-8209.

**SUPPLEMENTARY INFORMATION:**

**Legal Authority and Background**

The Controlled Substances Act (CSA) grants the Attorney General authority to promulgate rules and regulations relating to the registration and control of the

manufacture, distribution, and dispensing of controlled substances; maintenance and submission of records and reports; and for the efficient execution of his statutory functions. 21 U.S.C. 821, 827, 871(b). The Attorney General is further authorized by the CSA to promulgate rules and regulations relating to the registration and control of importers and exporters of controlled substances. 21 U.S.C. 958(f). The Attorney General has delegated this authority to the Administrator of the DEA. 28 CFR 0.100(b).

The DEA originally published a notice of proposed rulemaking (NPRM) on this matter in the Federal Register on November 27, 2007. 72 FR 66118. On February 21, 2019, the DEA issued another NPRM, 84 FR 5395, superseding the 2007 NPRM. The DEA now finalizes the 2019 NPRM, with a number of minor changes.

### **Discussion of Comments**

DEA received twelve comments on the 2019 NPRM, copies of which are available online at [www.regulations.gov](http://www.regulations.gov). The commenters included individuals, pharmaceutical distributors, retail pharmacies, pharmaceutical companies, and associations representing retail pharmacies and pharmacists. The DEA thanks all commenters for their thoughtful questions and suggestions, and appreciates their input during the rulemaking process.

Two comments were general statements of support for the rule, with no discussion of the proposed regulatory changes. Another comment stated that adopting “the single-sheet form would make sense only if security measures are in place,” but supported the rule, saying that “all-important concerns have been addressed,” and noting that the rule would result in a net cost savings. Of the remaining comments, most sought clarification of certain provisions in the proposed rule or recommended additional changes. Several comments expressed support for various provisions in the proposed rule. Only one

comment explicitly opposed the rule. The substantive comments received, along with DEA's responses, will be discussed below.

### **Power of Attorney Issues**

*Comment:* Multiple commenters raised issues relating to the proposed changes to the power of attorney (POA) provisions in 21 CFR 1305.05(d). The comments focused on which persons would be authorized to sign a POA, and how POAs may be signed.

Under the current rules, § 1305.05(d) requires that a POA be signed by four people: the person who signed the registrant's most recent application for DEA registration or reregistration, the person to whom the POA is being granted, and two witnesses. The proposed amendment to § 1305.05(d) would require that this first signature be made not by the person who in fact signed the most recent application for DEA registration or reregistration, but instead by any person directly authorized to sign such an application under § 1301.13(j): by the registrant, if an individual; by a partner of the registrant, if a partnership; or by an officer of the registrant, if a corporation, corporate division, association, trust or other entity. Multiple commenters recognized, and supported, that this amendment would allow a broader range of individuals to sign POAs, but expressed concerns that it would not include one type of person currently authorized to sign. Under the existing rules, if, e.g., an officer of a corporation executes a POA under § 1301.13(j) to authorize a non-officer to sign applications for registration and reregistration on behalf of the corporation, and that individual has signed the most recent application, then that individual may also sign a POA under § 1305.05, despite not being an officer of the corporation. Under the proposed change to § 1305.05(d), this person would no longer be authorized to sign a POA. Multiple commenters suggested the DEA update the final rule

to continue to allow persons in this situation to sign POAs in addition to permitting those individuals with expanded authority to sign a POA identified in the proposed § 1305.05(d).

*Response:* Given the significance of Form 222 signature authority, and the potential for diversion when that authority is abused, the DEA deems it appropriate to require an officer, a partner, or the registrant him- or herself to sign POAs under § 1305.05. The DEA appreciates that this change may require some registrants to update their business processes to ensure POAs are signed by the appropriate persons, but POAs are effective until revoked, and registrants would only need to execute a single POA under the new rule to authorize the person who signed the most recent application for registration.

*Comment:* A few of the commenters, who raised concerns about the expanded authority for signing a POA, also requested changes to § 1305.05(d) to allow POAs to be signed electronically as an alternative to a written signature on a hard-copy form. Commenters stated electronic signatures are a secure and traceable method of signing documents, and are already commonly accepted in commercial transactions. Commenters also stated that electronic signature systems are able to accommodate witness signatures, but that given the security features of electronic signatures, witness signatures are not needed when a document is signed electronically.

*Response:* Electronic signatures are a widely accepted form of signature both in the government and the private sector, and the DEA agrees that allowing electronic signatures on POAs under § 1305.05 is a reasonable way of giving registrants more flexibility in the execution process. However, the requirement to have two witness signatures on a POA is essential to preventing diversion, and the DEA does not believe

that electronic signatures are an adequate substitute for that requirement because they do not offer the necessary safeguards against diversion. Requiring two additional parties to confirm the validity of a POA significantly reduces the risk of a fraudulent POA being used to divert controlled substances, or otherwise disrupt the closed system of distribution. Therefore, the witness requirement will be kept in place, but witnesses may sign a POA electronically, if the electronic signature technology used has this capability. This final rule adds § 1305.05(f) to explicitly allow electronic signatures for POAs, but does not make any changes to the witness signature requirement. This final rule also includes some non-substantive changes to that section to improve clarity.

#### **Anonymous Comment**

*Comment:* An anonymous commenter stated that the proposed rule conflicts with the requirements of 21 U.S.C. 828(d)(1) as it requires purchasers to make a copy of a submitted order form “on a form provided by the [A]ttorney [G]eneral.” The commenter stated that DEA should petition Congress to change section 828 before the DEA changes the triplicate form to a single-sheet form. This commenter also stated that, with the DEA no longer providing forms to be used to create copies, the rule would impose costs on registrants, not reduce their costs.

*Response:* The DEA does not interpret the provisions of 21 U.S.C. 828(d)(1) to preclude the single-sheet framework proposed in the NPRM. The language of section 828(d)(1) is broad enough to allow for regulations permitting registrants to create a photocopy of a Form 222, or indeed to create an electronic copy and not retain any paper form at all. Section 828(d)(1) only states that the Attorney General (delegated to the Administrator of the DEA) must issue order forms pursuant to 21 U.S.C. 828(a) and

(c)(2). Section 828(c)(2) requires distributors of controlled substances in schedule I or II to use a form issued by the Administrator and “make or cause to be made a duplicate thereof” on such form. The DEA interprets section 828(d)(1) to mean that the distributor must make a copy; it does not mean that the issued form itself must be a form with carbon copies. Therefore, the DEA does not interpret the proposed rule’s change to the Form 222 to necessitate any changes to section 828.

Regarding the economic impact of the rule, while it does impose certain costs on affected registrants, the DEA estimates it will result in a net cost savings for purchasers, dispensing suppliers, and non-dispensing suppliers of between \$312 and \$336 per entity per year.<sup>1</sup>

**Comment by Healthcare Distribution Alliance (HDA)**

*Comment:* HDA noted that § 1305.13(a) as amended in the proposed rule is not explicit as to when the purchaser must make a copy of the Form 222. HDA stated that they believe the DEA’s intent was for the purchaser to make a copy before submitting the form to a supplier, and that they support the provision under that reading.

*Response:* HDA is correct that under the proposed rule, a purchaser would be required to make a copy of the original Form 222 before submitting it to a supplier. Since the supplier would retain the original for its records, the purchaser would not have an opportunity to create a copy after submitting the original to the supplier. The regulatory text in § 1305.13(a) has been updated in this final rule to make this requirement explicit.

---

<sup>1</sup> More information about the economic impact of this rule can be found in the Regulatory Flexibility Act section, below.

*Comment:* HDA also recommended updating § 1305.13(b) to not require suppliers that are required to report acquisition/disposition transactions to the Automation of Reports and Consolidated Orders System (ARCOS) to create a copy of the original Form 222. As drafted in the proposed rule, § 1305.13(b) required suppliers to “record on the original and a copy their DEA registration number” and other information, regardless of whether the supplier needed to submit a copy of the form to the DEA. By removing “and a copy” from this section, only suppliers who do not report to ARCOS would be required to create a copy of the original, per proposed § 1305.13(d).

*Response:* The DEA agrees that removing “and a copy” from § 1305.13(b) would help clarify that ARCOS-reporting suppliers are not required to make a copy of the original Form 222. This final rule updates § 1305.13(b) accordingly.

*Comment:* Relatedly, HDA commented that while the proposed rule specified that purchasers would be permitted to make an electronic copy of a Form 222 to keep for their records, the proposed rule did not explicitly state whether suppliers could retain the original Form 222 in an electronic form, instead of the paper original itself. HDA suggested the DEA clarify this issue, and allow suppliers to retain the original Form 222 in an electronic form.

*Response:* The proposed rule was clear that under the proposed changes to § 1305.13, suppliers would be required to retain the original of a Form 222, and could not fulfill their recordkeeping responsibilities by retaining a copy, whether paper or electronic. HDA’s comment suggests allowing suppliers to retain the original Form 222 “in an electronic form,” but this amounts to nothing more than creating an electronic copy. The original form is on paper, and so the only way to retain the original is to retain that same

paper form. The new single-sheet Form 222 is designed with multiple security features that would not be preserved in a copy, paper or electronic. Retaining the original forms and making them available for inspection is necessary in order to maintain the closed system of distribution and to prevent diversion. Since the DEA is not changing the requirement that suppliers must retain the original Form 222 for their records, and may not retain a copy, whether paper or electronic, no changes have been made to this provision in this final rule.

*Comment:* HDA's comment also included a suggestion to increase the number of order lines on the form, provided that this could be done without reducing legibility or requiring the form to be larger than 8.5" x 11", and recommended the DEA coordinate with the Food and Drug Administration (FDA) to ensure the single-sheet Form 222 can accommodate any changes to the National Drug Code (NDC) format currently being considered.

*Response:* The new form will include 20 order lines, double the previous number, and will fit on a standard 8.5" x 11" sheet. The DEA is aware of the pending changes to the NDC format, and, although no changes are being made to the NDC field on the new Form 222, the DEA will be monitoring the FDA's rulemaking on the matter, and will update the Form 222 as necessary in the future. Based on the current state of that rulemaking, any changes to the NDC format would only require minor modifications to the single-sheet Form 222.

*Comment:* Finally, HDA offered a number of comments related to the electronic Controlled Substances Ordering System (CSOS).

*Response:* While the DEA appreciates these comments, changes to CSOS are outside the scope of this rulemaking.

**Comment by CVS Health**

*Comment:* CVS Health commented that the DEA should further explain the procedure in 21 CFR 1305.11(c) for signing and dating an electronic requisition for new Form 222, and clarify that signing and dating is not required for electronic requisition requests, but that registrants instead must comply with DEA requirements for using the DEA secured network connection.

*Response:* CVS Health is correct that registrants are not required to sign or date electronic requisition requests made through a DEA secured network connection. Nor are registrants required to provide their address on such requests. Section 1305.11(c) has been updated in this final rule to reflect this.

*Comment:* CVS Health further suggested that, in the regulatory text of the final rule, the DEA explicitly state that purchasers are permitted to retain their copies of Forms 222 as electronic scanned images.

*Response:* The DEA agrees an explicit statement authorizing purchasers to retain electronic copies of Forms 222 would improve clarity, and § 1305.13(a) has been updated in this final rule to include such a statement.

*Comment:* CVS Health also asked how purchasers should record the number of containers and date received from the supplier, if the purchaser has retained an electronic copy of the order form, noting that printing out the electronic copy, filling it out with the receipt information, and rescanning it is a somewhat inefficient process. CVS Health suggested adding a provision to the final rule allowing purchasers to create an electronic

file with the receipt information and “electronically link” this file to the electronic copy of the Form 222, provided that the information is readily retrievable upon request.

*Response:* The DEA appreciates that some registrants’ records systems may process order forms in this way, or in a way that poses a similar inefficiency. However, creating a separate file for order receipt data would significantly complicate the inspection process. With double the number of records for DEA investigators to review during an inspection, this would add additional complexity, and consequently time and expense, to the enforcement process, and risk increasing diversion. Therefore, although requiring the order receipt data to be entered onto the copy of the Form 222 may, in some cases, require purchasers to take additional steps when processing the order, the DEA deems this necessary to prevent diversion and protect the public health and safety.

*Comment:* Finally, CVS Health recommended updating § 1305.17(c) to clarify that the requirement to maintain Forms 222 separately from all other records does not apply when a purchaser stores its copy of a form electronically.

*Response:* Given the nature of electronic records systems, the DEA agrees that electronic copies of Forms 222 do not need to be stored on a different server or electronic system from a registrant’s other records. The requirement to store Forms 222 separately from all other records may be met, for electronic copies, by storing them in such a way that they can be readily retrieved separately from all other records. Purchasers must be able, during an inspection or upon other DEA requests, to readily retrieve their electronic copies of Forms 222, with any related statements or other documents, and without any other records. Section 1305.17(e) has been added in this final rule to make this requirement clear.

**Comment by Costco**

*Comment:* As discussed above, Costco requested changes to § 1305.05(d) to allow POAs to be signed electronically, and to not require witness signatures when a POA is signed electronically.

*Response:* As discussed above, this final rule adds a provision allowing a POA under § 1305.05 to be signed electronically, but retains the requirement that such POAs be signed by two witnesses.

**Comment by National Association of Chain Drug Stores (NACDS)**

*Comment:* NACDS' comment discussed the POA provisions of the proposed rule, but also requested that the final rule allow pharmacies to continue to requisition Forms 222 using Form 222a. NACDS indicated this would be helpful in situations where pharmacies need more forms than allotted or when there is a need beyond the normal demand. NACDS stated that this method of requisition would be in addition to those specified in the proposed rule.

*Response:* While the DEA appreciates the importance of offering registrants multiple options for requisitioning Forms 222, Form 222a has been out of use for some time. The requisition options in the proposed rule – through a DEA secured network connection, by contacting any Division Office, or by contacting the Registration Section through the customer service center – should be sufficiently broad to accommodate the vast majority of registrants, without requiring the time and expense of maintaining an outdated form.

**Comment by Novartis**

*Comment:* After briefly touching on the POA issues discussed above, Novartis' comment asked how many forms could be requisitioned per registration type, and

whether there would be a particular data source (e.g., ARCOS) that would be used to determine that number based on business activity.

*Response:* Currently, registrants are asked to provide a written explanation of need if the number of Forms 222 requested in a given requisition request exceeds a particular number (not made public, for security reasons), unique to each business activity. The proposed rule did not include any changes to the default numbers for each business activity, or how a registrant's business activity is determined for these purposes. This final rule does not make any changes to these policies either, and under the new rules registrants may continue to requisition Forms 222 in the same numbers as under current practice. Registrants will still be asked to provide a written explanation when more than the default number of forms is requested.

*Comment:* Novartis also asked whether the proposed rule would include any change to how Forms 222 are ordered in bulk, and if so, what the new procedure would be.

*Response:* The proposed rule included no substantive changes to the bulk ordering process. The rule gave three ways to requisition order forms – through a DEA secured network connection, by contacting any Division Office, or by contacting the Registration Section through the customer service center – but registrants will provide the same information in the same format as under existing practice.

*Comment:* Novartis sought additional information on the details of the new form, specifically: whether it would be printed on color paper or in color ink; if so, whether a black and white copy would satisfy the purchaser's recordkeeping requirements; what type of paper stock the form would be printed on; and whether a sample of the new form would be made available to registrants. Novartis stated that registrants using electronic

ordering systems will need time to update their systems before adopting the new single-sheet form. Novartis stated it would take six to eight months to update its own system.

*Response:* The new Form 222 will be printed in color on white 8.5" x 11", 24 pound paper stock. A black and white copy of the form is sufficient to meet the purchaser's recordkeeping obligations. A sample of the new form can be obtained by request, using the contact information first provided above, and is included in the information collection request associated with this rulemaking, available on [www.reginfo.gov](http://www.reginfo.gov) under Office of Management and Budget (OMB) Control Number 1117-0010. With respect to registrants needing to update their electronic ordering systems to accommodate the new single-sheet format, the DEA appreciates that it will take time to implement the necessary changes; this is why the proposed rule included a two-year transition period. Registrants may continue to use existing stocks of triplicate Forms 222 while they update their ordering systems, to avoid any disruptions.

**Comment by Kroger Health**

*Comment:* As discussed above, Kroger Health suggested the DEA update § 1305.05(d) to expand the range of people authorized to sign a POA. Kroger Health also suggested changes to § 1305.05 to allow POAs to be signed electronically, and to not require witness signatures when a POA is signed electronically.

*Response:* As discussed above, this final rule retains the requirement that POAs under § 1305.05 be signed by an officer, a partner, or the registrant him- or herself, and does not expand this provision to include the person who signed the most recent application for registration. Additionally, this final rule adds a provision allowing a POA

under § 1305.05 to be signed electronically, but retains the requirement that such POAs be signed by two witnesses.

**Comment by Janssen**

*Comment:* As discussed above, Janssen suggested the DEA update § 1305.05(d) to expand the range of people authorized to sign a POA.

*Response:* As discussed above, this final rule retains the requirement that POAs under § 1305.05 be signed by an officer, a partner, or the registrant him- or herself, and does not expand this provision to include the person who signed the most recent application for registration.

**Comment by American Pharmacists Association (APhA)**

*Comment:* APhA sought clarification whether the handling and recordkeeping for triplicate Forms 222 during the transition period would remain the same as under the current rules, or if any of the proposed changes would apply.

*Response:* In general, for triplicate forms used during the transition period, registrants should continue to use the same handling and recordkeeping procedures they use under the existing rules. The provisions in § 1305.20 are the specific requirements applicable to the use of triplicate Forms 222 during the transition period, and are largely duplicative of the existing rules governing the use of triplicate forms. However, when § 1305.20 is silent as to a particular requirement included in other sections of part 1305, those other sections are controlling. For example, the requirements for signing POAs in § 1305.05 are not superseded by any provision in § 1305.20; therefore, the new rules for who may sign a POA, and how, are applicable to the use of triplicate Forms 222 during the transition period.

*Comment:* APhA recommended the DEA coordinate with the FDA to accommodate any changes to the NDC format.

*Response:* As previously discussed, the DEA is monitoring FDA's rulemaking on this matter, and will update the new single-sheet Form 222 as needed in the future.

*Comment:* APhA stated that the proposed rule would require purchasers to "make a copy (photocopy or scan)" of executed Forms 222 for their records, and would similarly allow "dispensing suppliers" to submit a copy of Form 222 to the DEA by fax or email. However, APhA noted that there were other methods of creating an electronic copies besides scanning. APhA encouraged the DEA to clarify that purchasers and suppliers would not be arbitrarily restricted in how they can create an electronic copy of Forms 222, and that capturing an image of a form using, e.g., a smartphone, would be deemed to meet the recordkeeping requirements of the rule.

*Response:* The DEA agrees registrants should be permitted to make an electronic copy of Forms 222 in any reasonable method, and the regulatory text in the proposed rule did not indicate otherwise. Photocopying and scanning were given in the preamble as two possible methods of creating a copy, but are not the only methods that would be allowed. The proposed changes to the regulatory text in § 1305.13(a) did not restrict registrants to only photocopying or scanning, so no changes are needed in the final rule to give registrants the flexibility APhA suggested.

Also, as is discussed below, the DEA is removing fax as an option for submitting copies of Forms 222 to the DEA. The DEA believes the cost of providing this submission option would outweigh the marginal benefit to the few registrants who would submit copies by fax.

*Comment:* Finally, APhA stated it approves of the DEA’s decision to allow purchasers to retain either the original of the single-sheet Form 222 or a “readily retrievable” copy of the form for their records. APhA stated this flexibility would be more efficient and reduce costs, and encouraged the DEA to keep this provision in the final rule.

*Response:* The terms of the proposed rule would not allow purchasers to retain the original of a Form 222 for their records, and the DEA is not updating these terms in this final rule to allow purchasers to do so. As the proposed amendments to § 1305.13(a) clearly stated, the original of the single-sheet Form 222 must be submitted to the supplier. The purchaser must create a copy of the original form and retain the copy for its records. The purchaser does not have the option of retaining the original. The proposed amendments to § 1305.13(d) clearly stated that suppliers must keep the original of the Form 222 on file. The preamble to the proposed rule also made clear that purchasers would make and retain a copy of the Form 222, and suppliers would retain the original.<sup>2</sup> These requirements have not been changed in this final rule, and therefore no changes to the relevant regulatory text have been made.

### **Changes in the Final Rule**

This final rule makes a number of substantive changes to the provisions of the proposed rule, as well as some non-substantive corrections and style edits to improve clarity. Regulatory text referring to registrants as “he or she,” “him or her,” or in similar

---

<sup>2</sup> 84 FR 5395 at 5397 (Feb. 21, 2019) (“[purchasers] would be required to complete and retain a copy of the form and send the original to their supplier for filling. The supplier would be required to record certain information related to the filling on the original and retain such original”).

ways has been updated to reflect that purchasers may be corporate entities. The substantive changes to the regulatory text are listed below.

**Section 1305.05**

As discussed in the comment analysis section, above, § 1305.05(f) has been added to permit electronic signatures on POAs executed under that section. The witness requirement remains in place, but witnesses are permitted to sign a POA electronically.

This final rule also includes some non-substantive changes to § 1305.05(d) to improve clarity.

**Section 1305.11**

As discussed in the comment analysis section, above, § 1305.11(c) has been updated to reflect that registrants are not required to sign or date Form 222 requisition requests, or to provide their address with such requests.

**Section 1305.13**

As discussed in the comment analysis section, above, § 1305.13(a) has been updated to make explicit that purchasers must make a copy of the original Form 222 for their records before forwarding the original to the supplier, and that purchasers may retain either paper or electronic copies of Forms 222 for their records.

As discussed in the comment responses, above, § 1305.13(b) has been updated to not require ARCOS-reporting suppliers to create and fill out copies of Forms 222 in addition to the originals.

Section 1305.13(d) has been updated to remove fax as one of the options for submitting copies of completed Forms 222 to the DEA. On further review, the DEA believes the cost of providing this submission option would outweigh the marginal

benefit to the few registrants who would submit copies by fax. Even if fax submission were permitted, the DEA believes that the vast majority of registrants would use the other options available – mail and email. Removing fax submissions as an option will simplify the processing of Form 222 copies for DEA, though excepted cost savings of this change are minimal.

#### **Section 1305.17**

As discussed in the comment responses, above, § 1305.17(e) has been added in this final rule to clarify that the requirement to maintain copies of Forms 222 separately from all other records may be met, for electronic copies, by storing them in such a way that they are readily retrievable separately from all other records.

Additionally, newly added § 1305.17(e) also includes a provision allowing electronic copies of Forms 222 to be stored at a location different from the registered location, provided such forms are readily retrievable at the registered location upon request. This will give purchasers more flexibility in utilizing electronic records systems while still ensuring the inspection process is not unduly hindered by complex recordkeeping arrangements.

#### **Section 1305.18**

Section 1305.18 has been updated to properly reflect the requirements of § 1301.52(c), which directs registrants discontinuing business activities with respect to controlled substances to return all unexecuted Forms 222 to the Registration Section at DEA headquarters. Section 1305.18 currently states that unused Forms 222 should be returned to the nearest DEA office. This final rule resolves this conflict by updating § 1305.18 to require registrants to return all unused Forms 222 to the Registration Section.

The current mailing address for the Registration Section may be found in 21 CFR 1321.01.

### **Section 1305.20**

Section 1305.20(h) has been updated to provide that unused triplicate Forms 222 should be returned to the Registration Section at DEA headquarters. This matches the new language in § 1305.18, and resolves the conflict with § 1301.52(c).

The introductory text to § 1305.20 has been updated to make clear that even if registrants still have a supply of triplicate Forms 222 available after the two-year transition period, they must switch to using the new single-sheet Form 222 at that point.

### **Regulatory Analysis**

The DEA conducted a regulatory analysis of the final rule to determine how its provisions will impact registrants and the DEA. The results of this analysis are outlined below.

*Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 13771 (Reducing Regulation and Controlling Regulatory Costs)*

This final rule was developed in accordance with the principles of Executive Orders 12866, 13563 and 13771. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866.

Executive Order 12866 classifies a “significant regulatory action,” requiring review by OMB, as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

1. The DEA expects that this regulatory action will not have an annual effect on the economy of \$100 million or more in at least one year and therefore is not an economically significant regulatory action. DEA’s analysis finds that this final rule will result in an annual cost-savings of \$25.9 million; approximately \$22.1 million to purchasers (persons executing DEA Form 222s) primarily due to efficiencies gained from having more lines per form, anticipated reduction of instances of form failure, allowing the use of a printer, and general ease of use; approximately \$0.2 million to non-dispensing suppliers (manufacturers and distributors) due to the elimination of the requirement that registrants mail copies of their completed order forms to their DEA field office; \$2.9 million to dispensing suppliers due to having the option to scan and email completed order forms; and \$0.8 million to the DEA from reduction in cost of forms production, postage, and equipment maintenance.

2. This regulatory action is not likely to result in a rule that may create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

3. This regulatory action is not likely to result in a rule that may materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof.

4. This regulatory action is not likely to result in a rule that may raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

This final rule is estimated to have a total cost savings of \$25.9 million. Although this final rule is not a significant regulatory action under Executive Order 12866, this final rule is expected to be an Executive Order 13771 deregulatory action.

An economic analysis of this rule can be found in the rulemaking docket at <https://www.regulations.gov>.

*Executive Order 12988, Civil Justice Reform*

This final rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

*Executive Order 13132, Federalism*

This final rule does not have federalism implications warranting the application of Executive Order 13132. The final rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

*Executive Order 13175, Consultation and Coordination with Indian Tribal Governments*

This final rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities between the Federal Government and Indian tribes.

*Regulatory Flexibility Act*

The Administrator hereby certifies that this final rule has been drafted, in accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 605(b)), and by approving it, certifies that this rule will not have a significant economic impact upon a substantial number of small entities.

In accordance with the RFA, the DEA evaluated the impact of this rule on small entities. The DEA is amending its regulations to implement a new single-sheet format for order forms (DEA Form 222) which are issued by the DEA to DEA registrants to allow them to order schedule I and/or II controlled substances. The DEA is also making a number of minor procedural changes, including, among other things, who can issue the power of attorney that is required for others to sign DEA Form 222. This final rule affects all parties (purchaser and suppliers) to transactions where a DEA Form 222 is used.

Based on its records, the DEA estimates that 71,481 entities are affected by this rule, which consists of 336 manufacturers, 378 distributors, 31,887 pharmacies, 7,980 hospitals and clinics and 30,900 practitioners. The DEA estimates that 65,984 (92.3%) of the total 71,481 affected entities are small entities (312 manufacturers, 364 distributors, 31,217 pharmacies, 3,716 hospitals and clinics and 30,375 practitioners). The estimated

economic impact varies for purchasers and suppliers, and among the suppliers, dispensing suppliers and non-dispensing suppliers.

“Purchasers” are registrants (primarily pharmacies, practitioners, hospitals and clinics) who execute DEA Form 222 to order schedules I and II controlled substances. The use of the new single sheet form will require purchasers to make a copy (paper or electronic) prior to submission to a supplier at an estimated cost of \$0.22 per form, or a total of \$734,646 per year. However, some cost savings are expected due to efficiencies gained from the new form. Key advantages include: 1) Reduction in number of forms executed due to increased number of lines per form, 2) reduction in form failure due to upgraded high-quality secure paper (fewer incidences of tears, carbon not copying through, improper tear of perforated edges, etc.), and 3) increased efficiency in completing the form due to ability to use a computer printer to fill the form (in addition to the existing allowable methods of typewriter, pen, or indelible pencil). Purchasers, as a group, are anticipated to save \$22,794,750, for a net savings of \$22,060,104, or \$312 per entity.

“Dispensing suppliers” are individual or institutional practitioners (e.g. physicians, pharmacies, hospitals, clinics, etc.) that are registered to dispense a controlled substance and may also distribute (without being registered to distribute) a quantity of such substance to another practitioner using a DEA Form 222. The final rule will allow the dispensing supplier to submit their copy of the order form to the DEA via email, as an alternative to submitting it by mail. Assuming dispensers will opt for the less costly scan and email method, based on an estimated 17,480 dispensing suppliers, the DEA estimates the dispensing suppliers, as a group, will save \$2,861,977 per year or \$164 per supplier.

“Non-dispensing suppliers” are persons registered with the DEA as manufacturers or distributors of controlled substances listed in schedules I or II. The final rule and new form will remove the requirement to ship their copies of the received order forms to their DEA field office at the end of each month. The DEA estimates, by removing this requirement, the non-dispensing suppliers, as a group will save \$239,657 per year, or \$336 per entity.

In summary, the final rule is estimated to save purchasers, dispensing suppliers, and non-dispensing suppliers, \$312, \$164, and \$336 per entity per year, respectively. The DEA uses 3% of annual revenue as threshold for “significant economic impact.” The annual revenue at which \$312, \$164, and \$336 is 3% equates to \$10,400, \$5,467, and \$11,200, respectively. The DEA estimates the annual revenues of purchasers, dispensing suppliers, and non-dispensing suppliers are greater than \$10,400, \$5,467, and \$11,200, respectively, resulting in an economic impact of less than 3% of annual revenue.

Therefore, the DEA’s evaluation of economic impact by size category indicates that the rule will not have a significant economic impact on a substantial number of small entities.

#### *Unfunded Mandates Reform Act of 1995*

This final rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532.

#### *Paperwork Reduction Act of 1995*

Pursuant to section 3507(d) of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), the DEA has identified the following collections of information related to this final rule. A person is not required to respond to a collection of information unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be obtained at <http://www.reginfo.gov/public/do/PRAMain>.

*A. Collections of Information Associated with the Final Rule*

*Title:* U.S. Official Order Forms for Schedules I & II Controlled Substances (Accountable Forms), Order Form Requisition

*OMB Control Number:* 1117-0010

*Form Number:* DEA-222

The DEA Form 222 provides the DEA with oversight and control over the distribution of schedules I and II controlled substances. The form is the only document that can authorize the distribution of schedules I and II controlled substances within the closed system of distribution. The DEA is amending its regulations to implement a new single-sheet format for order forms (DEA Form 222) which are issued by DEA to DEA registrants to allow them to order schedule I and/or II controlled substances. Currently, the DEA Form 222 is a triplicate form with interleaved carbon paper.

The new single-sheet format is expected to lower labor burden due to efficiencies gained from having more lines per form, anticipated reduction of instances of form failure, allowing the use of a printer, and general ease of use. Additionally, this rule removes the requirement for ARCOS-reporting suppliers to mail completed order forms to the DEA field offices. Finally, this rule will also allow suppliers that do not report to

ARCOS (generally dispensers who distribute) to submit completed order forms to DEA headquarters via mail or email.

DEA registrants will be allowed to exhaust their supply of the current forms as part of the transition to using the new single-sheet form. When a registrant's supply of triplicate forms is depleted, the DEA will issue the registrant the new single-sheet forms. This rule includes a "sunset date" – a date after which use of the triplicate forms will not be allowed – of October 30, 2021.

This rule does not impact those who use the electronic equivalent order form. Since the proposed rule, the DEA has adjusted its methodology to estimate the amount of online responses relative to paper responses to account for the additional ordering lines included on the new paper form. As a result, the estimated number of online responses has decreased, but the average burden per response has increased, so the total annual hour burden estimate remains the same. The DEA now estimates the following number of respondents and burden associated with this collection of information (which includes DEA Form 222 and the electronic equivalent):

- Number of respondents: 125,435
- Frequency of response: 42.7 per respondent per year (average)
- Number of responses: 5,350,000 (3,300,000 paper DEA Form 222; 2,050,000 electronic equivalent)
- Burden per response: \$0.1925
- Total annual hour burden: 1,030,000

Since this rule eliminates the requirement that suppliers mail completed DEA Forms 222 to their local DEA field offices, the cost burden associated with that requirement is

also eliminated. However, this rule requires purchasers to make copies of the new single-sheet Form 222 before submitting the original to the supplier; the DEA estimates this printing/copying will have a cost burden of \$130,350.

If you need a copy of the information collection instrument(s) with instructions or additional information, please contact the Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

Any additional comments on this collection of information may be sent in writing to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to OMB Control Number 1117-0010.

#### *Congressional Review Act*

This final rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. This final rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets. Accordingly, this final rule is not subject to the reporting requirements under the CRA.

#### **List of Subjects in 21 CFR Part 1305**

Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set forth above, the DEA amends 21 CFR part 1305 as follows:

**PART 1305—ORDERS FOR SCHEDULE I AND II CONTROLLED  
SUBSTANCES**

1. The authority citation for part 1305 continues to read as follows:

**Authority:** 21 U.S.C. 821, 828, 871(b), unless otherwise noted.

2. Amend § 1305.05 by revising paragraph (d) and adding paragraph (f) to read as follows:

**§ 1305.05 Power of attorney.**

\* \* \* \* \*

(d) A power of attorney must be executed by:

(1) The registrant, if an individual; a partner of the registrant, if a partnership; or an officer of the registrant, if a corporation, corporate division, association, trust or other entity;

(2) The person to whom the power of attorney is being granted; and

(3) Two witnesses.

\* \* \* \* \*

(f) A power of attorney executed under this section may be signed electronically, by any or all of the persons required to sign.

3. Revise § 1305.11 to read as follows:

**§ 1305.11 Procedure for obtaining DEA Forms 222.**

(a) DEA Forms 222 are issued in mailing envelopes containing a predetermined number of forms based on the business activity of the registrant, each form consisting of one single-sheet. A limit, which is based on the business activity of the registrant, will be imposed on the number of DEA Forms 222 that will be furnished upon a requisition for

order forms unless additional forms are specifically requested and a reasonable need for such additional forms is shown.

(b) Any person with an active registration that is authorized to order schedule I and II controlled substances is entitled to obtain a DEA Form 222, which will be supplied at any time after the DEA registration is granted. Any person holding a registration authorizing the person to obtain a DEA Form 222 may requisition the forms through a DEA secured network connection or by contacting any Division Office or the Registration Section of the Administration through the customer service center.

(c) Each requisition must show the name, address, and registration number of the registrant and the number of DEA Forms 222 desired.

(d) DEA Forms 222 will have an order form number and be issued with the name, address and registration number of the registrant, the authorized activity, and schedules of the registrant. This information cannot be altered or changed by the registrant; the registrant must report any errors to the local Division Office or the Registration Section of the Administration to modify the registration.

4. Amend § 1305.12 by revising paragraph (a) to read as follows:

**§ 1305.12 Procedure for executing DEA Forms 222.**

(a) A purchaser must prepare and execute a DEA Form 222 by use of a typewriter, computer printer, pen, or indelible pencil.

\* \* \* \* \*

5. Amend § 1305.13 by revising paragraphs (a), (b), (d), and (e) to read as follows:

**§ 1305.13 Procedure for filling DEA Forms 222.**

(a) A purchaser must make a copy of the original DEA Form 222 for its records and then submit the original to the supplier. The copy retained by the purchaser may be in paper or electronic form.

(b) 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 and the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the DEA Form 222. No DEA Form 222 is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (f) of this section.

\* \* \* \* \*

(d) The supplier must retain the original DEA Form 222 for the supplier's files in accordance with §1305.17(c). Any supplier who is not required to report acquisition/disposition transactions to the Automation of Reports and Consolidated Orders System (ARCOS) under § 1304.33(c) (such as a practitioner) must make and submit a copy of the original DEA Form 222 to DEA, either by mail to the Registration Section, or by email to [DEA.Orderforms@usdoj.gov](mailto:DEA.Orderforms@usdoj.gov). The copy must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, the copy must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires.

(e) The purchaser must record on its copy of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser.

\* \* \* \* \*

6. Amend § 1305.14 by revising the first two sentences of paragraph (a) and paragraph (b) to read as follows:

**§ 1305.14 Procedure for endorsing DEA Forms 222.**

(a) A DEA Form 222, made out to any supplier who cannot fill all or a part of the order within the time limitation set forth in § 1305.13, may be endorsed to another supplier for filling. The endorsement must be made only by the supplier to whom the DEA Form 222 was first made, must state (in the spaces provided in Part 3 on the original DEA Form 222) the DEA number of the second supplier, and must be signed and dated by a person authorized to obtain and execute DEA Forms 222 on behalf of the first supplier. \* \* \*

(b) Distributions made on endorsed DEA Forms 222 must be reported by the second supplier in the same manner as all other distributions.

7. Amend § 1305.15 by revising paragraphs (b) and (d) to read as follows:

**§ 1305.15 Unaccepted and defective DEA Forms 222.**

\* \* \* \* \*

(b) If a DEA Form 222 cannot be filled for any reason under this section, the supplier must return the original DEA Form 222 to the purchaser with a statement as to the reason (e.g. illegible or altered).

\* \* \* \* \*

(d) When a purchaser receives an unaccepted order, the original DEA Form 222 and the statement must be retained in the files of the purchaser in accordance with § 1305.17.

A defective DEA Form 222 may not be corrected; it must be replaced by a new DEA Form 222 for the order to be filled.

8. Amend § 1305.16 by revising paragraphs (a) and (d) to read as follows:

**§ 1305.16 Lost and stolen DEA Forms 222.**

(a) If a purchaser ascertains that an unfilled DEA Form 222 has been lost, the purchaser must execute another and attach a statement containing the order form number and date of the lost form, and stating that the goods covered by the first DEA Form 222 were not received through loss of that DEA Form 222. A copy of the second form and a copy of the statement must be retained with a copy of the DEA Form 222 first executed. A copy of the statement must be attached to a copy of the second DEA Form 222 sent to the supplier. If the first DEA Form 222 is subsequently received by the supplier to whom it was directed, the supplier must mark upon the face “Not accepted” and return the original DEA Form 222 to the purchaser, who must attach it to the statement.

\* \* \* \* \*

(d) If any DEA Forms 222 are lost or stolen, and the purchaser is unable to state the order form numbers of the DEA Forms 222, the purchaser must report, in lieu of numbers of the forms, the date or approximate date of issuance.

\* \* \* \* \*

9. Amend § 1305.17 by revising paragraphs (a), (b), and (c) and adding paragraph (e) to read as follows:

**§ 1305.17 Preservation of DEA Forms 222.**

(a) The purchaser must retain a copy of each executed DEA Form 222 and all copies of unaccepted or defective forms with each statement attached.

(b) The supplier must retain the original of each DEA Form 222 that it has filled.

(c) DEA Forms 222 must be maintained separately from all other records of the registrant. DEA Forms 222 are required to be kept available for inspection for a period of two years. If a purchaser has several registered locations, the purchaser must retain a copy of the executed DEA Form 222 and any attached statements or other related documents (not including unexecuted DEA Forms 222, which may be kept elsewhere under § 1305.12(e)), at the registered location printed on the DEA Form 222.

\* \* \* \* \*

(e) Electronic copies of DEA Forms 222 will be deemed to be maintained separately from all other records of the registrant, for the purposes of this section, if such copies are readily retrievable separately from all other records. Electronic copies of DEA Forms 222 may be stored on a system at a location different from the registered location, provided such copies are readily retrievable at the registered location.

10. Revise § 1305.18 to read as follows:

**§ 1305.18 Return of unused DEA Forms 222.**

If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes the name or address as shown on the purchaser's registration) or is suspended or revoked under § 1301.36 of this chapter for all Schedule I and II controlled substances for which the purchaser is registered, the purchaser must return all unused DEA Forms 222 to the Registration Section.

11. Amend § 1305.19 by revising paragraph (a) to read as follows:

**§ 1305.19 Cancellation and voiding of DEA Forms 222.**

(a) A purchaser may cancel part or all of an order on a DEA Form 222 by notifying the supplier in writing of the cancellation. The supplier must indicate the cancellation on the original DEA Form 222 sent by the purchaser by drawing a line through the canceled items and printing “canceled” in the space provided for the number of items shipped.

\* \* \* \* \*

12. Add § 1305.20 to read as follows:

**§ 1305.20 Transition provisions allowing continued use of existing stocks of triplicate DEA Forms 222.**

Registrants may continue to use existing stocks of the triplicate DEA Form 222 until October 30, 2021. In any case, as soon as a registrant’s supply of triplicate DEA Forms 222 is exhausted, the registrant must use the new single-sheet DEA Form 222. The provisions of this part are applicable to the use of triplicate forms, except for the specific rules as provided in this section.

(a) *Procedure for obtaining triplicate DEA Forms 222.* The DEA will no longer issue triplicate forms. Triplicate DEA Forms 222 will not be accepted after October 30, 2021.

(b) *Procedure for executing triplicate DEA Forms 222.* (1) A purchaser must prepare and execute a triplicate DEA Form 222 simultaneously by means of interleaved carbon sheets that are part of the triplicate DEA Form 222. Triplicate DEA Form 222 must be prepared by use of a typewriter, pen, or indelible pencil.

(2) Only one item may be entered on each numbered line. An item must consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance. The number of lines completed must be noted on that

form at the bottom of the form, in the space provided. Triplicate DEA Forms 222 for carfentanil, etorphine hydrochloride, and diprenorphine must contain only these substances.

(3) The name and address of the supplier from whom the controlled substances are being ordered must be entered on the form. Only one supplier may be listed on any form.

(4) Each triplicate DEA Form 222 must be signed and dated by a person authorized to sign an application for registration or a person granted power of attorney to sign a DEA Form 222 under § 1305.05. The name of the purchaser, if different from the individual signing the DEA Form 222, must also be inserted in the signature space.

(5) Unexecuted DEA Forms 222 may be kept and may be executed at a location other than the registered location printed on the form, provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of the location by any officer authorized to make inspections, or to enforce, any Federal, State, or local law regarding controlled substances.

(c) *Procedure for filling triplicate DEA Forms 222.* (1) A purchaser must submit Copy 1 and Copy 2 of the triplicate DEA Form 222 to the supplier and retain Copy 3 in the purchaser's files.

(2) A supplier may fill the order, if possible and if the supplier desires to do so, and must record on Copies 1 and 2 the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the triplicate DEA Form 222.

No triplicate DEA Form 222 is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (c)(6) of this section.

(3) The controlled substances must be shipped only to the purchaser and the location printed by the Administration on the triplicate DEA Form 222, except as specified in paragraph (c)(6) of this section.

(4) The supplier must retain Copy 1 of the triplicate DEA Form 222 for his or her files in accordance with paragraph (g)(3) of this section and forward Copy 2 to the Special Agent in Charge of the Drug Enforcement Administration in the area in which the supplier is located. Copy 2 must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, Copy 2 must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires.

(5) The purchaser must record on Copy 3 of the triplicate DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser.

(6) DEA triplicate Forms 222 submitted by registered procurement officers of the Defense Supply Center of the Defense Logistics Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the triplicate DEA Form 222, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

(d) *Procedure for endorsing triplicate DEA Forms 222.* (1) A triplicate DEA Form 222, made out to any supplier who cannot fill all or a part of the order within the time

limitation set forth in paragraph (c) of this section, may be endorsed to another supplier for filling. The endorsement must be made only by the supplier to whom the triplicate DEA Form 222 was first made, must state (in the spaces provided on the reverse sides of Copies 1 and 2 of the triplicate DEA Form 222) the name and address of the second supplier, and must be signed by a person authorized to obtain and execute triplicate DEA Forms 222 on behalf of the first supplier. The first supplier may not fill any part of an order on an endorsed form. The second supplier may fill the order, if possible and if the supplier desires to do so, in accordance with paragraphs (c)(2) through (4) of this section, including shipping all substances directly to the purchaser.

(2) Distributions made on endorsed triplicate DEA Forms 222 must be reported by the second supplier in the same manner as all other distributions.

(e) *Unaccepted and defective triplicate DEA Forms 222.* (1) A triplicate DEA Form 222 must not be filled if either of the following apply:

- (i) The order is not complete, legible, or properly prepared, executed, or endorsed.
- (ii) The order shows any alteration, erasure, or change of any description.

(2) If a triplicate DEA Form 222 cannot be filled for any reason under this section, the supplier must return Copies 1 and 2 to the purchaser with a statement as to the reason (e.g. illegible or altered).

(3) A supplier may for any reason refuse to accept any order and if a supplier refuses to accept the order, a statement that the order is not accepted is sufficient for purposes of this paragraph.

(4) When a purchaser receives an unaccepted order, Copies 1 and 2 of the triplicate DEA Form 222 and the statement must be attached to Copy 3 and retained in the files of

the purchaser in accordance with paragraph (g) of this section. A defective triplicate DEA Form 222 may not be corrected; it must be replaced by a new triplicate DEA Form 222 for the order to be filled.

(f) *Lost and stolen triplicate DEA Forms 222.* (1) If a purchaser ascertains that an unfilled triplicate DEA Form 222 has been lost, the purchaser must execute another in triplicate and attach a statement containing the serial number and date of the lost form, and stating that the goods covered by the first triplicate DEA Form 222 were not received through loss of that triplicate DEA Form 222. Copy 3 of the second form and a copy of the statement must be retained with Copy 3 of the triplicate DEA Form 222 first executed. A copy of the statement must be attached to Copies 1 and 2 of the second triplicate DEA Form 222 sent to the supplier. If the first triplicate DEA Form 222 is subsequently received by the supplier to whom it was directed, the supplier must mark upon the face "Not accepted" and return Copies 1 and 2 to the purchaser, who must attach it to Copy 3 and the statement. However, if the registrant no longer can use triplicate forms, then the registrant shall proceed by issuing a new single-sheet form in accordance with §1305.16.

(2) Whenever any used or unused triplicate DEA Forms 222 are stolen or lost (other than in the course of transmission) by any purchaser or supplier, the purchaser or supplier must immediately upon discovery of the theft or loss, report the theft or loss to the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located, stating the serial number of each form stolen or lost.

(3) If the theft or loss includes any original triplicate DEA Forms 222 received from purchasers and the supplier is unable to state the serial numbers of the triplicate DEA Forms 222, the supplier must report the date or approximate date of receipt and the names and addresses of the purchasers.

(4) If an entire book of triplicate DEA Forms 222 is lost or stolen, and the purchaser is unable to state the serial numbers of the triplicate DEA Forms 222 in the book, the purchaser must report, in lieu of the numbers of the forms contained in the book, the date or approximate date of issuance.

(5) If any unused triplicate DEA Form 222 reported stolen or lost is subsequently recovered or found, the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located must immediately be notified.

(g) *Preservation of triplicate DEA Forms 222.* (1) The purchaser must retain Copy 3 of each executed triplicate DEA Form 222 and all copies of unaccepted or defective forms with each statement attached.

(2) The supplier must retain Copy 1 of each triplicate DEA Form 222 that it has filled.

(3) Triplicate DEA Forms 222 must be maintained separately from all other records of the registrant. Triplicate DEA Forms 222 are required to be kept available for inspection for a period of two years. If a purchaser has several registered locations, the purchaser must retain Copy 3 of the executed triplicate DEA Form 222 and any attached statements or other related documents (not including unexecuted triplicate DEA Forms

222, which may be kept elsewhere under paragraph (b)(5) of this section), at the registered location printed on the triplicate DEA Form 222.

(4) The supplier of thiafentanil, carfentanil, etorphine hydrochloride, and diprenorphine must maintain triplicate DEA Forms 222 for these substances separately from all other DEA triplicate Forms 222 and records required to be maintained by the registrant.

(h) *Return of unused triplicate DEA Forms 222.* If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes the name or address as shown on the purchaser's registration) or is suspended or revoked under §1301.36 of this chapter for all schedule I and II controlled substances for which the purchaser is registered, the purchaser must return all unused triplicate DEA Forms 222 to the Registration Section.

(i) *Cancellation and voiding of triplicate DEA Forms 222.* (1) A purchaser may cancel part or all of an order on a triplicate DEA Form 222 by notifying the supplier in writing of the cancellation. The supplier must indicate the cancellation on Copies 1 and 2 of the triplicate DEA Form 222 by drawing a line through the canceled items and printing “canceled” in the space provided for the number of items shipped.

(2) A supplier may void part or all of an order on a triplicate DEA Form 222 by notifying the purchaser in writing of the voiding. The supplier must indicate the voiding in the manner prescribed for cancellation in paragraph (i)(1) of this section.

Date: September 23, 2019.

---

Uttam Dhillon,  
*Acting Administrator.*

[FR Doc. 2019-21021 Filed: 9/27/2019 8:45 am; Publication Date: 9/30/2019]