Drug Enforcement Administration Diversion Control Division Guidance Document

Title: Reporting Theft, Loss, or Missing Sealed Inner Liners from DEA-Registered Authorized Collector Locations

Summary: This guidance document addresses whether a Drug Enforcement Administration (DEA) registrant who is an authorized collector has the responsibility to file a Report of Theft or Loss of Controlled Substances (DEA Form 106) if a sealed inner liner is stolen, lost, or missing from the collector's registered location (or authorized long-term care facility) before the sealed inner liner is picked up for destruction or destroyed on-site.

Activity: Filing DEA Form 106 for Stolen, Lost, or Missing Sealed Inner Liners by DEA Registrants Who are Authorized Collectors

To Whom It Applies: DEA registrants authorized as collectors: manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies.

Question: Who is responsible for <u>filing a DEA Form 106</u> if a sealed inner liner is stolen, lost, or missing from a DEA authorized collector's registered location (or authorized long-term care facility) before the sealed inner liner is picked up for destruction or destroyed on-site?

Answer: All DEA registrants, including DEA-registered authorized collectors, are required to notify the DEA Field Division Office in their area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss; the registrant must also follow up on the written notification by subsequently filing a DEA Form 106 for the theft or significant loss. 21 CFR 1301.74(c); 21 CFR 1301.76(b). 21 CFR 1301.74(c)(1)-(6) and 1301.76(b)(1)-(6) also direct DEA registrants, including DEA authorized collectors, how they may determine whether a loss is significant. See also the Federal Register (FR) Final Rule published by DEA on September 12, 2005, titled Reports by Registrants of Theft or Significant Loss of Controlled Substances, 70 FR 47094.

If a sealed inner liner is stolen, lost, or missing from an authorized collector's registered location (or authorized long-term care facility) before the sealed inner liner is picked up for destruction or destroyed on-site as allowed by 21 CFR 1317.05(c)(2), the authorized collector has the responsibility to both report the theft or loss as well as file a DEA Form 106 for the sealed inner liner. However, the authorized collector does not have the responsibility to file a DEA Form 106 for the actual contents of the liner because an inner liner's contents are not allowed to be sorted or inventoried after being placed in a collection receptacle, and the sealed inner liner may not be opened once it is removed from the collection receptacle. See 21 CFR 1317.60(c); 1317.75(c).

Pursuant to <u>21 CFR 1317.40</u>, DEA has authorized several types of registrants to be collectors after modifying their registration in accordance with <u>21 CFR 1301.51(b)</u>. Authorized

collectors who are DEA registrants are designated as either non-practitioners (i.e., manufacturers, distributors, reverse distributors, and narcotic treatment programs), or practitioners (i.e., hospitals/clinics with an on-site pharmacy and retail pharmacies). 21 CFR 1317.05(c)(2)(iv)-(v). Here, non-practitioner collectors are responsible for filing a DEA Form 106 for the sealed inner liner as directed by 21 CFR 1301.74(c), and practitioner collectors are responsible for filing a DEA Form 106 for the sealed inner liner as directed by 21 CFR 1301.76(b). In addition, DEA-registered authorized collectors must also be in compliance with applicable State, local or tribal laws.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law, regulations, or Department of Justice policies.

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