



DEPARTMENT: Clinical Operations Group	POLICY DESCRIPTION: DEA and State Controlled Substance Diversion and Loss Reporting Policy
PAGE: 1 of 2	REPLACES POLICY DATED: 1/1/18, 10/1/20
EFFECTIVE DATE: July 24, 2023	REFERENCE NUMBER: COG.MM.006 (formerly CSG.MM.006)
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: This Controlled Substance Diversion and Loss Reporting Policy applies to all Affiliates of HCA Healthcare, Inc. that hold a DEA registration to handle Controlled Substances (each such Affiliate is referred to as a “Facility”).

PURPOSE: To require appropriate reporting to the U.S. Drug Enforcement Administration (DEA) and State Agencies of any Theft or Significant Loss of a Controlled Substance.

POLICY:

If a Facility discovers there is reasonable suspicion of a potential Theft or Significant Loss of a Controlled Substance (“Discovery”), the DEA Registrant shall ensure the Local DEA Field Office is notified in writing (“Initial DEA Notification”) within **one business day of the date of Discovery**.

If, at the completion of the investigation, the Facility’s Medication Diversion Team (“MDT”) concludes that Theft or Significant Loss is highly probable or confirmed (“Final Determination”), the DEA Registrant shall ensure that a DEA Form 106 is submitted electronically through the DEA’s online system **within 45 calendar days of the date of Discovery**.

If, at the completion of the investigation, the MDT does **not** conclude that Theft or Significant Loss is highly probable or confirmed, the DEA Registrant shall ensure that a short written Follow-up DEA Notification is sent to the Local Field DEA Office **within 45 calendar days of the date of Discovery**, stating that the Facility’s reasonable suspicion of Theft or Significant Loss was not substantiated.

In addition, a Final Determination of Theft shall be reported to local law enforcement and, if state law requires it, any Theft or Significant Loss shall be reported to the applicable state agencies within the appropriate timeframes specified by the state agency.

DEFINITIONS:

Controlled Substances: Any medication or other substance identified in 21 C.F.R. §§ 802(6), 812, as schedules II-V (including IIN and IIN), as amended from time to time.

DEA: The U.S. Drug Enforcement Administration.

DEA Form 106: The official DEA Form 106 (Report of Theft or Loss of Controlled Substances), submitted through the DEA’s Diversion Control Division secure network application. The DEA will not accept paper/email/fax submissions of the DEA Form 106. *In the event of technical issues with the network application, the DEA Registrant should report the issues by calling the DEA Help Center at 1-800-882-9539.*

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Discovery: The Facility initiates an active investigation upon discovering information that raises a reasonable suspicion of a potential Theft or Significant Loss of a Controlled Substance.

Follow-up DEA Notification: A short written statement consistent with Appendix B, sent by fax or email to the Local DEA Field Office, stating that the Facility’s reasonable suspicion of Theft or Significant Loss was not substantiated and that a DEA Form 106 will not be submitted.

Final Determination: The MDT of the Facility concludes it is highly probable or confirmed that a Theft or a Significant Loss has occurred.

Initial DEA Notification: A short written statement consistent with Appendix A, sent by fax or e-mail to the Local DEA Field Office, stating that the potential Theft or Significant Loss of a particular Controlled Substance has been discovered and that a DEA Form 106 will be submitted, if warranted, once the Facility’s investigation is complete.

Local DEA Field Office: The DEA Field Division Office in the area in which the Facility is located.

Facility Medication Diversion Team: Each facility is required to have a multidisciplinary Medication Diversion Team (“MDT”) that is charged with developing a coordinated and systematic approach to prevent, detect and report medication diversion.

Purchased Unit: Unit of measure in which the Controlled Substance is purchased by the Facility. For example, the Purchased Unit for hydrocodone is 100.

Theft: It is highly probable that a person has stolen a Controlled Substance from the Facility. A Finding of Theft requires actual, real or specific evidence, either direct or circumstantial, that would make a reasonable person believe that theft is highly probable. In deciding whether a theft has occurred, the Facility should consider all of the available evidence and, when viewed as a whole, determine if the evidence would make a reasonable person believe that it is highly probable that a Controlled Substance has been stolen.

Significant Loss: The standard of Theft has not been met, but it is clear that a Controlled Substance cannot be accounted for, even after reasonable efforts have been taken to find it, and that loss is “Significant.” For purposes of this policy, “Significant” means either (a) the quantity lost is greater than one Purchased Unit or (b) there is a pattern of losses associated with a particular workforce member.

REFERENCES:

1. Controlled Substance Monitoring Policy, [COG.MM.001](#)
2. Reporting Compliance Issues and Occurrences to the Corporate Office Policy, [EC.025](#)

Appendix A - Template Initial DEA Notification

Theft Example

[Facility letterhead, if sent by Fax]

Dear DEA:

I am writing on behalf of [Facility] to inform you about the discovery on [insert date] of a potential theft of a controlled substance(s). Specifically, [Facility] has discovered that [insert issue, for example, at least 6 oxycodone pills] were stolen by [name of diverter], a [insert position] employed by [Facility]. The employee has been suspended pending the outcome of our investigation. Local law enforcement will be notified and a DEA Form 106, if warranted, will be submitted once the investigation is complete. We are submitting this notification within one business day of discovery of the potential theft as required by 21 C.F.R. § 1301.76. Please let me know if you have any questions.

Regards,

[DEA Registrant]

Significant Loss Example

[Facility letterhead, if sent by Fax]

Dear DEA:

I am writing on behalf of [Facility] to inform you about the discovery on [insert date] of a potential significant loss of a controlled substance(s). Specifically, [Facility] has discovered that [insert issue, for example, two boxes of fentanyl patches were ordered and received into pharmacy inventory], but are now unaccounted for. A DEA Form 106, if warranted, will be submitted once our investigation is complete. We are submitting this notification within one business day of discovery of the potential significant loss as required by 21 C.F.R. § 1301.76. Please let me know if you have any questions.

Regards,

[DEA Registrant]

Appendix B – Follow-up DEA Notification (No Theft or Significant Loss)

[Facility letterhead, if sent by Fax]

Dear DEA:

I am writing to follow up on the initial report submitted by [Facility] on [insert date] regarding a potential [theft / significant loss] of a controlled substance(s). After further investigation, [Facility] has determined that no [theft or significant loss] of a controlled substance occurred. Thus, no DEA Form 106 will be submitted. Please let me know if you have any questions.

Regards,

[DEA Registrant]

Attachment: original written notice dated [insert date].