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 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 makes a Finding that there has been a Theft or Significant Loss of a Controlled Substance, it must, within one business day of the date the Finding is made, send an Initial DEA Report to the Local DEA Office. If, at the conclusion of the Facility’s investigation, the Finding is the same, the Facility must file a DEA Form 106.

In addition, a Theft must be reported to local law enforcement and, if state law requires it, any Theft or Significant Loss must be reported to the applicable state agencies within the appropriate timeframes.

DEFINITIONS:

“Theft” means that a person has stolen a Controlled Substance at the Facility. Evidence that a Theft has occurred could include the confession of an employee that he or she has diverted Controlled Substances; a video recording of such diversion; a credible eyewitness to it; or similar concrete evidence that would make a reasonable person believe that it is highly probable that a Controlled Substance has been stolen.

“Significant Loss” means that 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 that either (a) the quantity lost is greater than one Purchased Unit or (b) there is a pattern of losses associated with a particular employee(s).

“Controlled Substances” has the meaning set forth in 21 C.F.R. §§ 802(6), 812, as amended from time to time.

“DEA” means the U.S. Drug Enforcement Administration.

“DEA Form 106” means the official DEA Form 106 (Report of Theft or Loss of Controlled Substances), submitted through the DEA’s online submission system.
**DEPARTMENT:** Clinical Services Group  
**POLICY DESCRIPTION:** DEA and State Controlled Substance Diversion and Loss Reporting Policy

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**APPROVED BY:** Ethics and Compliance Policy Committee

“**Finding**” means that the CEO of the Facility has determined that a Theft or a Significant Loss has occurred. If the CEO is not the DEA Registrant, the CEO shall consult with the Registrant prior to making the determination.

“**Initial DEA Report**” means a short written notification, sent by fax or e-mail, stating that a 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. A template Initial DEA Report is included as Appendix A. If the Facility later determines that its Finding was incorrect and that there had not been a Theft or Significant Loss, the Facility must send a short written follow-up to the Local DEA Office, by fax or e-mail, stating that the Facility’s Finding of Theft or Significant Loss was not substantiated. A template follow-up report is included as Appendix B.

“**Local DEA Office**” means the DEA Field Division Office in the area in which the Facility is located. The contact information for the Local DEA Office is available on Atlas Connect.

“**Purchased Unit**” means the unit of measure in which the Controlled Substance is purchased by the Facility. For example, the Purchased Unit for hydrocodone is 100.

**REFERENCES:**

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

11/2017
Appendix A - Template Initial DEA Report

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 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 has been 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 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 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 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 Report (No 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 [theft / significant loss] of a controlled substance(s). After further investigation, [Facility] has located the controlled substance(s) and has determined that no [theft or significant loss] 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].