

New DEA Rules and Explanations for Reporting Thefts or Losses of Controlled Substances

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What should a pharmacy do now when a theft, or significant loss, of controlled substances is discovered?

A new revision to Drug Enforcement Administration rules specifies when it must be notified of a theft or significant loss of a controlled substance, as well as what makes a loss "significant." The new rule is final, and it becomes effective on September 12, 2005. *

WHEN. Under the previous rule, notice of a theft or loss was required to be given to the DEA "upon discovery." This left some to wonder whether that meant at the very moment of discovery. Still others felt giving notice within a week, or even 10 or so days, was timely.

Leaving no room for doubt now, the new rule specifies a registrant must give notice "within one business day" of discovery, and adds that it must be written. This deadline can be met only if notice is faxed. With such a specific time limit, registrants would be well advised to keep a receipt with the date of fax transmission.

SIGNIFICANT. After first admitting there is no single objective standard that can be used by all registrants to determine whether a loss is "significant," the rule now lists six factors a registrant should consider in the course of deciding whether a loss it has discovered is significant and thus notice must be given and Form 106 filed.

Some of those factors are: The specific controlled substance involved; the actual quantity lost; whether the loss can be attributed to unique activities that take place in manufacturing or compounding activities. Regardless, the DEA points out any unexplained loss should be reviewed within the context of a registrant's business activity, and, when in doubt "registrants should err on the side of caution" and alert the DEA and law enforcement.

FORM 106 REPORT. This DEA report must still be filed, but submitting it "is not immediately necessary." Form 106 requires that a registrant provide specific circumstances and detail concerning the names and quantities of controlled substances involved, and other data. When the details are not immediately known at the time of discovery, however, the registrant is to make efforts to determine those facts. It should do so, the DEA suggests, both by conducting its own internal inventories and investigations and by enlisting the aid of law enforcement resources, if necessary.

Once the circumstances surrounding the theft or loss are clear, then Form 106 should be submitted. The DEA recognizes some time may elapse between the date of initial notification and conclusion of an investigation. If an investigation takes more than two months, however, it suggests that a registrant should provide updates to the DEA.

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Prompt and timely initial notification, and eventually filing Form 106, is not something to be treated lightly. The DEA explicitly states in this final rule, as it has done often in the past, that it considers this prompt notification part of a good-faith effort by registrants to maintain effective controls against diversion – a duty it reminds registrants is imposed on them by other parts of its regulations.

* See 70 *Federal Register* 47094, August 12, 2005.