

# CLIENT ALERTS

## DEA Makes Changes in the Process for Reporting Theft or Significant Loss of Controlled Substances

### Client Alert

6.22.2023

Effective July 22, 2023, the U.S. Drug Enforcement Agency (DEA) will no longer accept paper filing from Registrants when reporting the theft or “significant loss” of Controlled Substances.

On June 22, 2023, the DEA published a Final Rule amending the regulations regarding DEA Form 106, which is required for all Registrants to formally report any theft or significant loss of Controlled Substances to the DEA under the Controlled Substances Act (CSA)[1]. While the current regulation required the submission of the DEA 106, it was silent as to the mechanism and timing for doing so. In its Final Rule, the DEA indicated that 99.5% of all DEA 106 submissions were through a secure application on the DEA’s Diversion Control Division’s website, and the remaining .5% were submitted on paper. The Final Rule eliminates paper filing to ensure that the DEA receives *legible* and *timely* submission of the DEA Form 106. With the issuance of its Final Rule, the DEA is mandating that all DEA Form 106 be filed with the Administration electronically. Further, the Final Rule adds a timeframe for submission—within 45 calendar days of discovery of the theft or loss.

This reporting is the second step in the current 2-step process; the first step being an initial report *within one business day*. Notably, despite comments that the one-day reporting requirement should be abolished—claiming it was arbitrary, confusing and redundant—the DEA disagreed and declined to alter the current two-step reporting requirement. Thus, under the Final Rule, Registrants must report thefts or losses of Controlled Substances as follows:

- a preliminary report of all thefts and significant losses must be reported to the Registrant’s local DEA Field Office within one (1) business day of discovery;

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- a DEA Form 106 must be submitted online within 45 calendar days.

The DEA also rejected comments that the term “significant loss” should be defined, noting that the decision is one that is best made by the Registrant based on the specific case and circumstances.

Regarding other comments on a definition of “discover” to assist in determining when the reporting obligations commence, the DEA indicated that it would address that issue in future rulemaking.

While the Final Rule does not make a significant change in a Registrant’s reporting obligations, it provides welcome clarification on the procedure for submitting a DEA Form 106 and serves as a reminder that Registrants need to be vigilant in their efforts to secure their Controlled Substances through internal processes (*i.e.*, accurate inventories/record-keeping, auditing and training on drug diversion, systems for timely reporting and follow-up). Failure to do so can lead to costly penalties and DEA oversight.[2]

Butzel will continue to monitor the DEA reporting process, however if you have questions or would like to discuss the topic, please contact your Butzel health care attorney.

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[1] 21 C.F.R. 1301.74(c) and 1301.76(b).

[2] By way of example, in November 2021, the University of Texas Southwestern Medical Center entered into a Settlement Agreement with the DOJ to resolve allegations of violations of the CSA, agreeing to pay \$4,500,000 and enter into a 3-year Memorandum of Agreement with the DEA.