

POTENTIAL COMPLIANCE PROGRAM EFFECTS OF PROPOSED DEA THEFT REPORTING RULE

On Wednesday, July 29, 2020, the U.S. Department of Justice Drug Enforcement Administration (“DEA”) **proposed a new rule** that would require DEA registrants to electronically report “theft or significant loss” of controlled substances within 15 days of discovery of the circumstances requiring the report (“Proposed Rule”). This proposal is notable as currently there is no formal notification deadline. It does not, however, change the current requirement that the area DEA Field Division Office be notified in writing within one business day of discovery of the loss or theft.

While the Proposed Rule does not address the definition of “significant loss” as many hoped it would, it does have material implications for pharmacy compliance programs in that it highlights the relationship of controlled substance diversion reporting to the 60-day clock for repaying an overpayment that starts upon identification of the overpayment under the False Claims Act, as explained in more detail below. Specifically, both reporting obligations should be coordinated more broadly with Legal and Compliance team members who are involved with organizational compliance programs. Below we provide a brief overview of the Proposed Rule as well as a summary of its practical implications.

BACKGROUND

Under the current rule requiring self-disclosures of theft or significant loss of controlled substances, DEA registrants are already required to:

- Notify, in writing, the DEA Field Division Office in his or her area of any theft or significant loss of any controlled substances within one business day of discovery; and
- Submit a completed DEA Form 106 regarding theft or significant loss to the DEA Field Division Officer in his or her area.

Under the Proposed Rule, however, DEA Form 106 reports identifying the exact nature of the theft or significant loss would be required to be submitted within a defined period of time, namely within 15 days of “discovery.” Thus, if the Proposed Rule is finalized, DEA registrants will still be required to give written notice to their DEA Field Division Office within one business day of discovery and submit a DEA Form 106, but they would then also be required to submit the DEA Form 106 electronically within 15 days of discovery of the theft or significant loss.

COMPLIANCE PROGRAM IMPLICATIONS

The Proposed Rule could have meaningful implications for the pharmacy component of broader compliance programs. More specifically, by tying the 15-day reporting deadline to the date of discovery, organizations could inadvertently start the clock on the 15-day reporting period if an internal compliance review and investigation identifies theft or significant loss. Consider that this issue is analogous to reporting requirements under the 60-Day Rule, which requires providers to report and return overpayments within 60 days of identification of an overpayment. Therefore, the Proposed Rule and the 60-Day Rule each have implications for the internal review and investigation processes under compliance programs. As such, Compliance and Legal stakeholders will need to work closely and coordinate with pharmacy operations team members, particularly if DEA controlled substance inventories/audits are typically conducted by pharmacy team members. Going forward, it may be more appropriate for internal reviews and investigations of controlled substance theft and significant loss to instead be subject to internal controls and oversight that govern False Claims Act investigations handled under compliance programs.

REMAINING QUESTIONS

A few questions remain in light of the Proposed Rule. Since DEA registrants are already required to submit the DEA Form 106 reports upon discovery of theft or significant loss, it is unclear whether the Proposed Rule actually lengthens or decreases the time for reporting. The current standard could be interpreted as requiring contemporaneous reporting or it could be interpreted as requiring reporting within a reasonable time after discovery of the theft or significant loss. Moreover, the question as to the definition of “significant” remains unanswered. A definition of “significant” loss has never been promulgated, making the analysis subjective and dependent on the facts and circumstances of what constitutes a significant loss that would be required to be reported.

TIMELINE

The Proposed Rule's 60-day comment period is now open. If you would like to submit a comment on the Proposed Rule, please note that all comments must be submitted electronically or postmarked no later than **11:59 PM ET on September 28, 2020**.

PRACTICAL TAKEAWAYS

- The Proposed Rule would require electronic reporting by non-practitioner registrants within 15 days of the date of discovery of a theft or significant loss.
- The Proposed Rule does not change the requirement that all DEA registrants provide written notice to their area DEA Field Office of theft or significant loss within one business day of discovery but still could present an organizational risk due to the DEA's commonly strict interpretation of compliance requirements.
- Organizational staff responsible for compliance program implementation should ensure coordination of pharmacy compliance efforts with the overall compliance program structure.
- If finalized, the 15-day deadline for reporting theft and significant loss of controlled substances should be added to any compliance work plan addressing remedial action steps.
- Since there is no regulatory definition of "significant" loss, DEA registrants may consider creating an organizational definition to promote consistent application of the Proposed Rule's reporting requirement.

If you have any questions on the issues discussed in or related to this article, or if you would like assistance in preparing and submitting comments on the Proposed Rule, please contact:

- **Todd Nova** at (414) 721-0464 or tnova@hallrender.com;
- **Scott Taebel** at (414) 721-0445 or staebel@hallrender.com;
- **Katherine Kuchan** at (414) 721-0479 or kkuchan@hallrender.com;
- **Ritu Kaur Cooper** at (202) 370-9584 or rcooper@hallrender.com; or
- Your regular Hall Render attorney.

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