

## Compliance Today – April 2019

# The next frontier of opioid enforcement: Civil liability for hospitals

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The opioid epidemic is one of the top enforcement priorities for the U.S. Department of Justice (DOJ). In October 2018, former Attorney General Jeff Sessions referred to the opioid epidemic as the “deadliest drug crisis in American history”<sup>[1]</sup> when he announced DOJ’s plan to counter the issue through increased enforcement of the country’s drug laws. If recent history is a guide, hospitals may soon find themselves in the government’s crosshairs, as the Controlled Substances Act (CSA)<sup>[2]</sup> provides for civil penalties for drug diversion and other recordkeeping violations, and is proving to be a powerful tool in the government’s arsenal.

### The Controlled Substances Act

In recent years, the government has increased its civil enforcement efforts against hospitals and health systems for violations of the CSA, often in record-breaking amounts.<sup>[3]</sup> This article provides an overview of the CSA, examines recent enforcement actions, and offers suggestions on how to mitigate opioid diversion and enforcement risks.

### General structure of the CSA

The CSA is the main federal statute that regulates the lawful production, possession, use, distribution, and importation of certain controlled substances. In general, the CSA establishes a scheduling system in which controlled substances are placed into five categories based on medical use, potential for abuse, and safety or dependence liability. The CSA further states that any individual or entity that handles controlled substances must register with the Drug Enforcement Administration (DEA). Each registrant is subject to detailed recordkeeping, security, and reporting requirements. The purpose of the CSA is to create a “closed system” of distribution, which helps to “ensure that all controlled substances are accounted for from their creation until their dispensing or destruction”<sup>[4]</sup> and to minimize the possibilities of diversion.

### Obligations of the hospitals under the CSA

Under the CSA and relevant regulations, each hospital that is authorized to handle controlled substances must, among other things:

- Maintain complete and accurate inventories and records of all regulated transactions involving controlled substances, which must be made available for inspection by the DEA;<sup>[5]</sup>
  - Have specific security controls and operating procedures in place to guard against theft and diversion;<sup>[6]</sup>
  - Notify the DEA when theft or significant loss happens;<sup>[7]</sup> and
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- Keep a system in place to identify suspicious orders of controlled substances (for hospitals with onsite pharmacies).<sup>[8]</sup>

## Consequences of violating the CSA

The CSA is administered and enforced by the DEA, which is granted the authority to carry out investigations and impose sanctions to ensure that registrants comply with the recordkeeping, security, storage, and reporting requirements. The CSA's civil penalty provisions are the primary tools the DEA uses to hold entities and persons involved in drug diversion accountable. Under the CSA, each violation may incur a civil penalty of up to \$10,000,<sup>[9]</sup> which can lead to millions of dollars in civil fines.

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