

## DEA's Drug Diversion Focus Underscores Importance of Controlled Substances Compliance and Audit Programs

Late last year, a former nurse at a plastic surgery center was [sentenced to a year and a day in prison](#) for diverting and tampering with doses of Demerol. *U.S. v. Gibson*, No. 2:09-cr-00148 (W.D.Wash. Nov. 6, 2009). Last month, a federal judge [imposed a 30-year jail term](#) on a former surgery technician who diverted and tampered with Fentanyl, and infected at least 18 patients with Hepatitis C in the process. *U.S. v. Parker*, No. 1:09-cr-00332 (D.Colo. Feb. 24, 2010). These cases underscore how seriously the government takes individual provider diversion of controlled substances (CS).

However, health care organizations of all sizes should recognize that they, too, are at risk even for more "routine" CS losses or diversions at their facilities. Last month, Cardinal Health Pharmacy Services, LLC agreed to [pay \\$1 million to settle an investigation](#) into missing drugs at two of its hospital-based pharmacies. See Press Release, U.S. Department of Justice, "Two Tulsa Pharmacies Penalized for Missing Prescription Drugs" (Feb. 19, 2010).

The federal Drug Enforcement Administration (DEA) maintains "drug diversion" squads dedicated to CS loss/diversion audits and investigations; its wedge into this area is the Controlled Substance Act (CSA). Designed to strictly regulate the handling of controlled substances, the CSA mandates record keeping requirements for organizations that participate in the lawful manufacture, delivery and distribution of controlled substances. See 21 U.S.C § 827; 21 C.F.R. § 1304.28.

**Neither bad intent nor knowledge is required for CSA liability.** Rather, substantial civil exposure exists for health care organizations which *negligently* keep inaccurate records of CS storage, use or wasting. The statute carries a \$10,000-per-violation maximum civil penalty, 21 U.S.C. § 842(a)(5), and federal prosecutors may argue that a "violation" exists for every inaccurate inventory, every inaccurate page in an inventory or even every individual pill or dose not accounted for in the inventory. The financial and reputational consequences of inaccurate CS record-keeping can be enormous.

Health care organizations should implement robust CS training and internal controls as well as regular audit programs to: (a) ensure that CS policies are being followed; (b) detect losses and CS usage outliers; and (c) trigger prompt remedial action should a loss or diversion occur. Effective compliance and audit programs are also essential to demonstrate good faith and help to negate the government's hindsight views of negligence and liability under the CSA.

If you have any questions about this E-Flash, or need for assistance in evaluating or developing your organization's compliance and audit programs, please contact Post & Schell attorney Ronald H. Levine at [rlevine@postschell.com](mailto:rlevine@postschell.com) or (215) 587-1071, or Ross G. Currie at [rcurrie@postschell.com](mailto:rcurrie@postschell.com) or (215) 587-1134.

*The attorneys of Post & Schell's Health Law and White Collar, Compliance & Risk Management groups provide compliance, regulatory, and litigation counseling to health care clients, including hospitals, health systems, and pharmaceutical companies.*

**Disclaimer:** This E-Flash does not offer specific legal advice, nor does it create an attorney-client relationship. You should not reach any legal conclusions based on the information contained in this E-Flash without first seeking the advice of counsel.