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Hospital Pays \$4.5M to Settle CSA Case; Two Nurses Died From Overdoses

By Nina Youngstrom

The deaths of two hospital nurses from overdoses of drugs allegedly diverted from the University of Texas Southwestern Medical Center (UTSW) played a part in its \$4.5 million settlement for allegedly violating the Controlled Substances Act, the U.S. Attorney's Office for the Northern District of Texas said Nov. 30.^[1] This is the second largest settlement in the nation involving drug diversion at a hospital and requires "extensive" corrective action, the U.S. attorney's office said.

Drug diversion is a universal problem, and the opportunities may have multiplied as the COVID-19 pandemic took hold, experts say.^[2] For example, to conserve personal protective equipment (PPE), nurses could access automated dispensing cabinets (ADCs) containing narcotics without their fingerprint to avoid taking off their glove. And the stressful work environment and lack of in-person addiction services has made health care workers more vulnerable to drug diversion while attention to the problem has waned.

The alleged diversion at UTSW, however, preceded the pandemic. According to the settlement, which is available on the U.S. attorney's website, the allegations center on UTSW's William P. Clements Jr. University Hospital and Zale Lipshy Pavilion, which are in Dallas.^[3]

In a statement of covered conduct included with the settlement, the United States alleges that UTSW's recordkeeping violations included failure to properly document dispensing and wasting of controlled substances and failure to tell the Drug Enforcement Administration (DEA) timely of significant loss or theft of controlled substances. "Theft and diversion occurred at Clements University Hospital and Zale Lipshy Pavilion as a result of UTSW's failure to maintain effective controls and procedures to guard against the theft and diversion of controlled substances," the statement of covered conduct alleged. For example, in December 2016, a UTSW nurse overdosed on diverted drugs and died at the UTSW William P. Clements Jr. Hospital. In April 2018, another UTSW nurse met the same fate. They were found in different Clements bathrooms, the U.S. attorney's office said in a news release.

UTSW Did Compliance Review Beforehand

Another attachment to the settlement that's a memorandum of agreement with the DEA spells out its findings and UTSW's remediation. For example, DEA alleges that diversion investigators in September 2019 identified recordkeeping violations. Among other things, there was a failure to maintain complete and accurate records and readily retrievable records; failure to address an employee's suspected diversion; and failure to maintain effective controls to prevent theft and diversion of controlled substances.

UTSW agreed to a series of compliance reforms. For example, UTSW will hire an external auditor to do unannounced audits of controlled substances dispensed by the Pyxis machines, with an audit emphasis on fentanyl. Deficiencies will be resolved in 30 days and reported to the DEA.

UTSW didn't admit liability in the settlement. In a statement, UTSW said, "As noted in today's settlement agreement with the DOJ/DEA, prior to learning about their investigation, UTSW conducted a comprehensive compliance review of its controlled substances safeguards and procedures and invested significant resources to enhance these processes, including hiring additional staff, acquiring advanced technology and software, and implementing physical security controls like lockboxes and tamper-resistant IV tubing. In response to, and in collaboration with the DOJ/DEA's investigation, UTSW has continued to strengthen its handling of controlled substances, including the formation of a Controlled Substance Investigation Team and the installation of security cameras to deter diversion of these substances within its facilities."

UTSW added that it's committed to meeting legal and ethical obligations in all its operations. The U.S. attorney noted in its news release that "UTSW cooperated with the DEA's investigation. After the agency launched its probe into the medical center's compliance program in December 2018, UTSW began working with the DEA to address deficiencies and strengthen its controls for handling controlled substances. A number of changes were instituted well before the settlement agreement was signed."

1 Department of Justice, U.S. Attorney's Office for the Northern District of Texas, "UT Southwestern to Pay \$4.5 Million to Resolve Alleged Controlled Substance Act Violations That Permitted Drug Diversion by Staff," news release, November 30, 2021, <https://bit.ly/3dbtZ4a>.

2 Nina Youngstrom, "Drug Diversion Monitoring Took a Hit in Pandemic; Consider High-Level Utilization Reports," *Report on Medicare Compliance* 30, no. 17 (May 3, 2021), <https://bit.ly/2ZS7yOq>.

3 United States v. University of Texas Southwestern Medical Center, settlement agreement, accessed December 2, 2021, <https://bit.ly/3IitRhk>.

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