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Government Matters

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## McLaren Health Reaches Record \$7.75 Million Settlement with DEA

### MCLAREN HEALTH CARE CORPORATION'S RECORD \$7.75 MILLION SETTLEMENT

Reflecting the Department of Justice's continued priority on opioid diversion and enforcement of controlled substance regulations, the U.S. Attorney's Offices in the Eastern and Western Districts of Michigan jointly announced that McLaren Health Care Corporation (MHCC) agreed to pay a record-breaking \$7,750,000 to resolve allegations that it violated the Controlled Substances Act (CSA) and its implementing regulations. This settlement resulted from a multi-year investigation by the Drug Enforcement Administration (DEA) and is the largest settlement to date involving allegations of drug diversion at a health care system. Matthew Schneider, U.S. Attorney for the Eastern District of Michigan, asserted that MHCC's "internal practices were so deficient that it allowed the diversion of drugs, including opioids."

Headquartered in Grand Blanc, Michigan, McLaren Health operates 15 hospitals in Michigan and Ohio, as well as ambulatory surgery centers, imaging centers, pharmacy services, and Michigan's largest network of cancer centers and providers<sup>1</sup>. DEA's investigation initially focused on allegations that an MHCC subsidiary pharmacy improperly distributed controlled substances to a substance abuse treatment facility that did not possess the required DEA registration. However, as is often the case when an investigation begins with a complaint of a single violation, DEA soon expanded its investigation to include MHCC hospitals and facilities across the state of Michigan.

The USAO's [press release](#) announcing the settlement alleged two pharmacies dispensed Schedule II drugs without written prescriptions and specified the "red flags" that the pharmacies ignored:

- pattern of prescriptions for the same type of drugs, in the same quantities, from the same prescriber;
- prescriptions for excessive quantities of highly-addictive Schedule II drugs;

- repeated early prescription refills;
- significant outlier drug volumes for individual patients and prescribers;
- prescription entries in the names of fake patients; and
- discrepancies between the cash reported and cash collected for controlled substance prescriptions.

In addition, DOJ alleged that other MHCC pharmacies also dispensed controlled substances despite obvious red flags suggesting that the underlying prescriptions were not for a legitimate medical purpose; that MHCC failed to notify DEA of known employee thefts of controlled substances, in violation of the CSA's reporting provisions; and that MHCC's corporate controlled substance policies were not consistent with the CSA and its regulations.<sup>2</sup>

MHCC's settlement is noteworthy not only because it is the largest of its kind but also because it nearly doubles the previous record-setting settlements—in 2018, Effingham Health System agreed to pay \$4.1 million and Michigan Health \$4.3 million to resolve similar allegations.<sup>3</sup>

As part of the settlement, MHCC also agreed to a three-year Memorandum of Agreement with DEA that, at a minimum, requires third-party controlled substance audits, prescribes the system's drug-handling responsibilities, and requires MHCC to institute a broad-based educational program focused on preventing drug diversion.<sup>4</sup> In reaching this settlement, the government acknowledged that MHCC took substantial steps to address problems in its handling of controlled substances in response to DEA's investigation.<sup>5</sup>

#### INCREASED ENFORCEMENT OF CSA

In recent years, as synthetic opioids fueled a surge in overdose deaths and addiction rates, DEA has intensified its focus on hospitals and health care systems as potentially having a role in the opioid epidemic. This settlement confirms that DOJ's continued emphasis on controlled substance regulatory enforcement will not be limited to manufacturers, wholesalers, and retail pharmacies, and will include health care systems, hospitals, and medical practices that store and dispense controlled substances. In announcing the MHCC settlement, U.S. Attorney for the Western District of Michigan Andrew Birge acknowledged that hospitals and health systems provide "critical services to patients" but stressed that they also "carry broader public responsibilities as bulwarks" against drug diversion. Birge also emphasized DOJ's commitment to "hold even the largest providers accountable."<sup>6</sup>

The scrutiny of the controlled substance operations of health systems is not likely to subside and could potentially increase, as the Biden administration has already announced an aggressive plan to "end the opioid crisis," which has only worsened in the shadow of COVID-19.<sup>7</sup> In his plan, President Biden specifically directs the DOJ to "make actions that spurred this crisis a top investigation and, where appropriate, civil and criminal enforcement priority" and directs the DEA to "step up its efforts to identify suspicious shipments and protect communities."<sup>8</sup>

The scale of operations and availability of controlled substances in hospital systems make these entities especially vulnerable to controlled substance diversion, which means hospital systems must be particularly vigilant in complying with their obligations under the CSA. The consequences of failing to prevent diversion can be significant. In addition to penalties and government-mandated controls and systems like those included in the MHCC settlement, DEA may seek to suspend or even revoke the license of a registrant.

King & Spalding's Special Matters practice includes attorneys experienced with the CSA and other controlled substance regulations in hospital settings. We have conducted internal investigations, represented registrants in government investigations, and conducted compliance reviews for a variety of entities to assess the effectiveness of their policies, procedures, and diversion programs as it relates to their regulatory obligations.



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<sup>1</sup> *About McLaren Health Care*, MCLAREN HEALTH CARE CORPORATION, <https://www.mclaren.org/main/about-mclaren-health-care> (last visited Jan. 21, 2021).

<sup>2</sup> Press Release, Dep't of Justice, U.S. Attorney's Office, Eastern District of Michigan, U.S. Attorneys Andrew Birge and Matthew Schneider Announce Record-Setting Drug Diversion Civil Penalty Settlement with McLaren Health Care Corporation (Jan. 19, 2021), <https://www.justice.gov/usao-edmi/pr/us-attorneys-andrew-birge-and-matthew-schneider-announce-record-setting-drug-diversion>.

<sup>3</sup> Press Release, Dep't of Justice, U.S. Attorney's Office, Southern District of Georgia, Southern District of Georgia Announces Largest Hospital Drug Diversion Civil Penalty Settlement in U.S. History (May 16, 2018), <https://www.justice.gov/usao-sdga/pr/southern-district-georgia-announces-largest-hospital-drug-diversion-civil-penalty#:~:text=SAVANNAH%2C%20GA%3A%20In%20the%20nation's,to%20guard%20against%20theft%20and>; Press Release, Drug Enforcement Administration, Record Settlement Reached in University of Michigan Hospital Drug Diversion Civil Penalty Case (Aug. 30, 2018), <https://www.dea.gov/press-releases/2018/08/30/record-settlement-reached-university-michigan-hospital-drug-diversion>.

<sup>4</sup> Press Release, Dep't of Justice, U.S. Attorney's Office, Eastern District of Michigan, *supra* note 1.

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> *The Biden Plan to End the Opioid Crisis*, JOEBIDEN.COM, <https://joebiden.com/opioidcrisis/> (last visited Jan. 21, 2021).

<sup>8</sup> *Id.*