

Coping with the Fallout of the Opioid Crisis

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The staggering emotional and economic repercussions of the prescription opioid epidemic continue to play out on the national stage. More than 40 percent of all U.S. opioid overdose deaths in 2016 involved a prescription opioid, with more than 46 people dying every day from such overdoses. Notwithstanding the substantial loss of lives and lingering emotional turmoil for families and communities in general, there is another dimension to the opioid epidemic that is ramping up and will have a significant impact on our society.

Lawsuits targeting the healthcare industry are being filed at every level of the court system, brought by cities, counties, states, labor unions, and Native American tribes. Over one thousand lawsuits relating to the opioid crisis have been joined together in multidistrict litigation (MDL), a special procedure wherein federal civil cases from around the country that share one or more questions of fact are transferred to one court for purposes of efficiency and economy. One judge manages the litigation during the pretrial and discovery process rather than having multiple judges across the country hear similar pretrial motions and preside over similar discovery disputes, which saves the parties time and money.

In the Opioid MDL, plaintiffs allege that "the manufacturers of prescription opioids grossly misrepresented the risks of long-term use of those drugs for persons with chronic pain, and distributors failed to properly monitor suspicious orders of those prescription drugs--all of which contributed to the current opioid epidemic." U.S. District Judge Dan Polster in Cleveland, Ohio is overseeing the MDL, and will preside over pretrial motions, discovery proceedings and settlement conferences. If a trial is

necessary, the cases will be sent back to the original court where they were first filed for trial. The potential aggregate costs of this litigation are staggering, and if it turns out to be anything like the tobacco industry litigation in the 1990s, the costs will reach into the billions. Individual plaintiffs alleging medical malpractice have also filed lawsuits against physicians, pharmacists and healthcare organizations. The largest verdict to date has come from a St. Louis jury that awarded \$17.6 million to a couple who brought a case against the husband's doctor and the doctor's employer for overprescribing opioid pain medication. The jury found that the defendants breached the standard of care by providing "chronic opioid" therapy between 2008 and 2012, causing the patient who had complained initially of lower back pain to become drug dependent. The most shocking aspect of the verdict is that, of the \$17.6 million, \$15 million was awarded in punitive damages.

America's Drug Problem

Treating acute and chronic pain has long been one of the most complex challenges in the healthcare arena. In this context, opioids like morphine were providential. The drug triggers the release of endorphins—the brain's "feel good" neurotransmitters—diminishing perceptions of pain while augmenting feelings of well-being.

In 2001, the Joint Commission released its Pain Management Standards, which broadcast the idea of pain as a "fifth vital sign." Under the impression that much pain was undertreated, the standards required healthcare providers to ask patients about their pain levels. Consequently, the rate of opioid prescriptions grew and peaked in 2012, when 255 million opioid prescriptions were written. This translated into an eye-opening prescribing rate of 81.3 prescriptions per 100 people.³

In response to this alarming rate, several national organizations like the Centers for Disease Control and Prevention, The Joint Commission and The Centers for Medicare and Medicaid began releasing revised standards addressing pain management and opioid use in 2016. The revised standards recommended reduced opioid dosage and duration and expanded safety precautions to include "all patients," rather than just to those who are deemed "high risk." Broader use of technological advances such as state prescription drug monitoring programs was also encouraged. In 2017, the rate of prescriptions fell to 58.7 per 100 people—an improvement, but still alarming. In 16 U.S.

counties, so many opioid prescriptions were dispensed that there was one prescription for every single person in those counties.⁴

The U.S. government is taking action to halt the epidemic, providing increased funding to ferret out instances of opioid-related fraud. In June 2018, the U.S. Department of Justice filed charges against 601 people, including doctors, for illegally prescribing and distributing opioid painkillers, resulting in more than \$2 billion in healthcare fraud losses.⁵

We are also starting to see health plans and pharmaceutical benefit managers take a more active role in combating opioid addiction. Health insurers are announcing changes to their list of covered drugs, removing OxyContin in some states and mandating "non-crushable" medications in others. Furthermore, retail pharmacy CVS Health Corporation announced plans to limit opioid prescriptions to 7 days or less for certain patients with acute pain who haven't previously taken an opioid painkiller, compared to the 20-day or more prescriptions they previously had filled.⁶

Identify, Investigate, Intervene

Given the potential for hospital and physician liability within healthcare organizations, a multi-pronged approach that involves opioid risk awareness, education and training, action and monitoring is advisable. In launching a risk mitigation strategy, healthcare entities should consider the value of forming an opioid task force.

Led by a clinical professional and staffed with physicians, nurses, pharmacists, and other patient support personnel, the task force's objectives are to collect and analyze prescription data, identify and assess opioid-related risks, and create the means to manage these exposures to limit liability— and to do so without adversely affecting the hospital's greater purpose of providing compassionate and consistent care. This crucial risk mitigation strategy begins with the need to educate clinicians, staff, and especially patients about the potential misuse and abuse of opioid medications. Various steps can be taken to limit the use of such prescription medications where feasible, and to monitor patient usage and dosages over time.

Tracking patients after their release from the hospital to discern their pain levels is part of this process. In some cases, a multimodal pain plan involving short-term use of opioids followed by longer-term doses of non-narcotic medications like NSAIDS or

Acetaminophen may be warranted. The use of alternative pain management treatments like physical therapy or nerve blocks may also be utilized.

Establishing targets for reducing opioid prescriptions and then measuring related progress is vital to the success of the opioid task force. In this regard, prescription monitoring can help discern inappropriate prescribing by physicians and pharmacists and will support efforts aimed at minimizing instances of drug diversion. Healthcare organizations should also educate staff on recognizing signs of diversion and implement a zero-tolerance policy with clear procedures for evaluating and addressing suspected and identified instances of drug diversion.

Risk Transfer

Healthcare insurance brokers play a vital role in assisting organizations with their opioid risk transfer strategies. Evaluating insurance coverages can be complicated, given recent policy language changes that relate to opioids. A wide range of insurance policies that could involve opioid-related claims, including life sciences, product liability, general liability, excess casualty, directors and officers, life and health, workers compensation and professional liability, are being scrutinized and will likely see additional changes going forward. These changes vary by line of business and by insurance carrier, making it imperative that the parties involved have a clear understanding of what is and is not covered.

Insurer specialists and attorneys also can make recommendations regarding a healthcare organization's opioid policies and procedures to enhance risk mitigation by providing guidance on best practices, such as documenting staff education and training activities, creating plans on how opiates are managed by hospital pharmacies, and even documenting patient care. The use of predictive data analytics and machine learning tools may also become significant resources in identifying and tracking high-risk patients and overuse of prescription opioids in a patient population. The goal should be to expand the ability to examine data throughout the broader healthcare industry, rather than limit the focus to prescription use within a specific facility, system or physician office.

A Multifaceted Response

The effects of opioid addiction are devastating on a personal level, but the significant ramifications for the healthcare industry cannot be taken lightly. Healthcare organizations across the country are working to keep up with changing standards and guidelines, and to protect themselves from litigation stemming from opioid-related exposures.

Drawing on multiple resources to help address the vulnerabilities that opioids present will enable organizations to develop a multi-faceted approach to combatting the epidemic. Creating an opioid task force composed of diverse medical professionals with various perspectives can assist in achieving a unified goal of reducing patients' dependency on opioids while providing consistent and compassionate care. Evaluating insurance policies can further protect healthcare organizations from the uncertain liabilities arising from the opioid epidemic.

Sadly, the opioid crisis is far from over, and in terms of the legal fallout from the number of prescription opioids distributed over the last decade... I fear that we have only seen the tip of the iceberg.

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Footnotes

⁴ Ibid

charges-against-601-individuals-responsible-over ⁶ Dow Jones News. "CVS Health moves to limit access to opioid painkillers,"

September 21, 2017.

¹ U.S. Centers for Disease Control and Prevention, "Opioid Prescription Opioid Data" https://www.cdc.gov/drugoverdose/data/prescribing.html

² MDL 2804 National Prescription Opiate Litigation Description. United States District Court Northern District of Ohio. http://www.ohnd.uscourts.gov/mdl-2804 ³ U.S. Centers for Disease Control and Prevention, "Changes in Opioid Prescribing Practices" https://www.cdc.gov/drugoverdose/data/prescribing.html

⁵ U.S. Department of Justice. "National Health Care Fraud Takedown Results in Charges Against 601 individuals," June 28, 2018. https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-