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Opioid Litigation Landslide – Are Physicians and Hospitals the Next Targets?

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Our nation is beset by an opioid epidemic that is colossal in scope and devastating in effect. The human and economic toll of this plague is stunning. Every day, more than 100 Americans die from an opioid overdose.[i] Some economists estimate that the opioid crisis has cost the U.S. economy more than $1 trillion since 2001 and is on pace to cost an additional $500 billion through 2020.[ii] As bad as it is today, it is unlikely that the crisis has peaked. The opioid epidemic is spreading to all corners of the country, horrifyingly potent drugs are cheaper and more readily available than ever, and the death toll rises, year-by-year.

Our society did not reach this unhappy place overnight – the opioid crisis has been at least a generation in the making. There is little question but that the profligate use of opioid pain relievers contributed mightily to the epidemic. A few familiar data points tell the story:

- About a quarter of patients prescribed opioids for chronic pain do not use them as directed.[iii]
- Roughly 4 out of 5 heroin users first abused prescription opioids.[iv]
- United States citizens consume about 80% of the world supply of oxycodone and almost all of the supply of hydrocodone.

As predictably as night follows day, lawyers and their clients have engaged the legal system to assign responsibility and recover monetary damages for the carnage wrought by the opioid epidemic. The damages potential is staggering and should cause serious concern for any potential defendant. Opioid litigation modeled largely on the tobacco lawsuits of the 1990's, has grown exponentially over the last few years. State and local governments initially targeted pharmaceutical manufacturers. In the next wave of litigation, distributors such as McKesson and Cardinal have been sued. In 2017, more than 250 state and local governments filed opioid suits against organizations throughout the opioid supply chain, including manufacturers, wholesalers and distributors. The immutable laws of litigation economics suggests that plaintiffs will continue to look down the opioid distribution chain for new targets.

This means that physicians, hospitals and clinics may well be next. Indeed, the next wave of opioid litigation is already building. A number of cities in West Virginia have sued the Joint Commission (formerly known as the Joint Commission on the Accreditation of Health Care Organizations, or JCAHO) for allegedly spreading misinformation about the dangers of prescription opioids and thereby contributing to the current crisis. There are a growing number of lawsuits filed against hospitals, clinics, medical groups, and individual physicians for allegedly negligent opioid prescribing practices. The suits typically allege that a physician was negligent, or worse, by unnecessarily prescribing opioids, overprescribing, or continuing to treat the patient with opioids for too long. Hospitals allegedly failed to effectively monitor or regulate their physicians' prescribing practices, thereby contributing to addiction and all of its dire consequences.

There is every reason to believe that this trend will continue. Indeed, the United States Department of Justice has signaled that it will increasingly target physicians for overprescribing opioids. Attorney General Jeff Sessions, speaking in Louisville, Kentucky, recently attributed much of the current crisis to the overprescription of opioid pain relievers.[v] He promised that the Department of Justice would pursue physicians who overprescribed more aggressively, and noted that a number of new federal prosecutors have been hired around the country who will focus exclusively on prosecuting healthcare providers who improperly prescribe opioids. Attorney General Sessions also touted the Department's increasing use of data mining to identify outliers as targets for investigation. The investigation could yield DEA administrative actions, False Claims Act suits, or criminal prosecutions.

Physicians and hospitals should, of course, strive to improve prescribing practices because it is the right thing to do for patients. Aside from the constant drive for quality improvement, physicians and hospitals should take concrete steps to protect themselves from the building wave of opioid litigation. There are a number of such steps that should be considered and implemented where appropriate. Physician groups and hospitals should:

- Require thorough and regular training for all opioid prescribers. Hospitals should require such training for employed physicians and those working in their facilities.

- Ensure that monitoring and testing for appropriate opioid prescribing practices is an integral and properly resourced component of every compliance program. Each jurisdiction will likely have its own standards for opioid management and the compliance program must ensure adherence to those rules by all of the organization's practitioners.

- Develop a comprehensive screening tool consistently used to identify patients who may have a genetic or social predisposition for opioid addiction, or who have struggled with such issues in the past.

- Develop quality metrics related to opioid prescribing practices. Mine the data to identify and counsel outliers. View your data through the government's eyes. Physicians and hospitals should assume that the government is engaged in extensive data mining to find outliers among opioid prescribers. If the first notice of a problem is from the government, trouble has arrived.

- Adopt a consistent and effective patient education program related to opioids and the potential for addiction.

- Design and implement a protocol for patient intervention for those suspected of developing a dependency or addiction.

Perhaps most importantly, hospitals and physician groups should adopt evidence-based best practices for the prescription and management of opioids. While a number of tools are available, the Center for Disease Control and Prevention ("CDC") Guidelines for Prescribing Opioids for Chronic Pain is an excellent resource. The guidelines are summarized as follows:

1. **OPIOIDS ARE NOT FIRST-LINE THERAPY.** Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risk to the patient. If opioids are used, they should be combined with non-pharmacologic therapy and non-opioid pharmacologic therapy, as appropriate.

2. **ESTABLISH GOALS FOR PAIN AND FUNCTION.** Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh the risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

3. **DISCUSS RISKS AND BENEFITS.** Before starting and periodically during opioid therapy, clinicians should discuss with patients the known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

4. **USE IMMEDIATE-RELEASE OPIOIDS WHEN STARTING.** When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long acting opioids.

5. **USE THE LOWEST EFFECTIVE DOSE.** When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to more than 50 morphine milligram equivalents per day, and should avoid increasing dosage to 90 morphine milligram equivalents per day, or carefully justify a decision to titrate dosage to more than 90 morphine milligram equivalents per day.

6. **PRESCRIBE SHORT DURATIONS FOR ACUTE PAIN.** Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of an immediate-release opioid and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.

7. **EVALUATE BENEFITS AND HARMS FREQUENTLY.** Clinicians should evaluate the benefits and harms with patients within one to four weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every three months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosage or to taper and discontinue opioids.

8. **USE STRATEGIES TO MITIGATE RISK.** Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering

offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (more than 50 morphine milligram equivalents per day), or current benzodiazepine use, are present.

9. **REVIEW PDMP DATA.** Clinicians should review the patient's history of controlled substance prescriptions using state Prescription Drug Monitoring Programs (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him/her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every three months.

10. **USE URINE DRUG TESTING.** When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

11. **AVOID CONCURRENT OPIOID AND BENZODIAZEPINE PRESCRIBING.** Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

12. **OFFER TREATMENT FOR OPIOID USE DISORDER.** Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

There may be disagreement among practitioners concerning the clinical value of the CDC Guidelines. It is clear, however, that a defendant in opioid litigation would have considerable difficulty in persuading a judge or jury that guidelines from such a respected organization are reasonably ignored.

There is no assurance that opioid prescribing physicians and hospitals won't be sued in today's rapidly developing litigation environment. They can, however, through the adoption and rigorous implementation of common sense policies ensure that they have a defense. Indeed, such policies will likely yield better clinical outcomes while discouraging any plaintiff's attorneys who might be lurking around the litigation corner.

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i. CDC/NCHS, National Vital Statistics System, mortality. U.S. Department of Health and Human Services, CDC; 2017.

ii. Altarum; economic toll of opioid crisis in U.S. exceeded $1 trillion since 2001. February 13, 2018.

iii. Vowles, K.E., McEntee, M.L., Jones, P.S., Forhe, T., May, J.P., Vangoes, D.N. Rates of opioid misuse, abuse, and addiction and chronic pain: a systematic review and data synthesis. Pain. 2015.

iv. Muhuri, P.K., Gfroerer, J.C., Davies, M.C. Associations of non-medical pain reliever use and initiation of heroin use in the United States. CBHSQ data review, August 2013

v. Louisville Business First, January 30, 2018.

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