LHA IMPACT LAWBRIEF

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Headlines:

- **Recent Regulatory Efforts to Address the Opioid Addiction Crisis and What Hospitals Can Do Now**

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- Nov. 1 LAPS PSO - Event Analysis: Applying the Principles of Patient Safety Science and High Reliability (Baton Rouge)
- Nov. 3 Health Law Symposium (Baton Rouge)
- Nov. 7 Legal Issues Concerning Employees with Psychiatric Illnesses (Webinar)
- Nov. 8 Medical Staff Leadership Credentialing and Privileging Workshop (Baton Rouge)
- Nov. 9 MHCNO - Leading UR Practices from Access to Exit (New Orleans)
- Nov. 10 LACHE Fall Meeting with Face-to-Face Qualified Education (Baton Rouge)

Articles:

Recent Regulatory Efforts to Address the Opioid Addiction Crisis and What Hospitals Can Do Now
By: Emily Black Grey

The increase in the prescription of opioids is startling. Reports on the "opioid crisis" appear in the daily news. This article provides an overview of key statistics that show historical trends, a summary of recent regulatory efforts to address the epidemic, and the role of hospitals in addressing the crisis. The end of this article also provides a list of actions hospitals can take to reduce the risk liability for allegations related to opioid over-prescription.

First, The Bad News
Between 1999 and 2015, the amount of opioids prescribed per person **tripled**. By 2015, Americans were being prescribed enough opioids for every American to be medicated 24/7 for three weeks. Louisiana is one of eight states in the country where more prescriptions have been written for opioid pain pills than there are people in the state. The rates of opioid prescribing are important because, not surprisingly, the rates of opioid overdose deaths have been shown to closely track these prescribing rates.

The current statistics tell a harrowing tale of the tremendous cost of the opioid crisis in the form of economic losses, a corresponding heroin epidemic and in deaths. First, from a purely financial perspective, it is estimated that in a single year, prescription opioid misuse and overdose cost the United States more than $78 billion for substance abuse treatment, criminal justice, productivity losses and increased healthcare expenses. Additionally, clinicians and law enforcement recognize that the overuse of

opioids has, in turn, contributed to a heroin epidemic. As one physician explained: "up to 80 percent of the heroin users we see started off on prescription opioids." (*See* John W. Mitchell, *Opioids: Addressing the Epidemic.* Healthcare Journal of Baton Rouge, (July/August 2017) at p. 33, quoting Stephen Mette, MD, Chief Medical Officer at the University of Arkansas for Medical Sciences.)

The Good News: Wide-ranging Regulatory Efforts

For a number of years, regulators took little action to address the problem of overprescribing of opioid pain medications. Fortunately, now federal and state regulators are aligning on these new guidelines and requirements, which can be helpful tools for hospitals on the front lines of the battle against opioid abuse.

CDC Guidelines

In March 2016, the CDC published Guidelines for Prescribing Opioids for Chronic Pain (CDC Guidelines). While the *CDC Guidelines* have no force of law, the document has been foundational for much of the state and federal legislative activity. The guidelines are also for hospitals developing policies for opioid prescribing. Key points from the *CDC Guidelines* include:

- Indication: Opioids are not first-line or routine therapy for chronic pain.
- Initial Prescription Decision: Before starting opioid therapy, clinicians should establish treatment goals; discuss with patients known risks and realistic benefits of opioid therapy; and clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to safety.
- Prescribe lowest effective dose and no more than needed: When opioids are started, clinicians should prescribe the lowest effective dose. Clinicians should reassess evidence of individual benefits and risks when increasing dosage to > 50 MME/day, and avoid increasing dosage to > 90 MME/day or carefully justify such a decision. When opioids are needed for acute pain, prescribe no more than needed (3 days or less is often sufficient, rarely more than 7 days will be needed).
- Monitoring and follow-up: Clinicians should evaluate benefits and harms with patients within 1-4 weeks of starting opioid therapy for chronic pain or dose escalation; clinicians should evaluate benefits and harms with patients every three (3) months or more frequently. If benefits do not outweigh harms, clinicians should taper and discontinue.
- Use available risk mitigation tools: Check Prescription Drug Monitoring Program (PDMPs) for high doses and prescriptions from other providers.

The Center for Medicare and Medicaid Services (CMS) published an Opioid Misuse Strategy, which identified four priority areas of focus in CMS' efforts to combat opioid misuse and promote treatment and recovery supports: (1) implement more effective person-centered and population-based strategies to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion; (2) expand naloxone use, distribution, and access, when clinically appropriate; (3) expand screening, diagnosis, and treatment of opioid use disorders with an emphasis on increasing access to medication-assisted treatment; and (4) increase the use of evidence-based practices for acute and chronic pain management.

Additionally, CMS has worked to update the Hospital Consumer Assessment of Hospitals and Providers (HCAHPS) surveys to address concerns about questions relating to pain management, as indicated in its final rule issued on Aug. 14, 2017. HCAHPS scores are based on patient surveys and impact quality reporting programs and hospital reimbursement. The current HCAHPS questions relating to pain management are:

- Q12: During this hospital stay, did you need medicine for pain?
- Q13: During this hospital stay, was your pain well controlled?
- Q14: During this hospital stay, how often did the hospital staff do everything they could to help you with your pain?

Amid criticism that the pain management questions had the potential to incentivize more aggressive pain management protocols, which in turn could lead to the over-prescription of pain medication, CMS has updated the pain management questions as follows:

- Q12: During this hospital stay, did you have any pain?
- Q13: During this hospital stay, how often did hospital staff talk with you about how much pain you had?
- Q14: During this hospital stay, how often did hospital staff talk with you about how to treat your pain?

The new questions will be used starting in January 2018 and will be included in public reporting in 2019, appearing on the Hospital Compare website beginning in October 2018. It will be used for payment determinations starting in FY 2019.

Finally, CMS has worked to align Medicare plans, including Part D, with the *CDC Guidelines*.

The United States Drug Enforcement Administration (DEA) has grown more aggressive in taking administrative and criminal action against physicians and pharmacists. DEA is charged with enforcing the Controlled Substances Act (CSA), 21 U.S.C. 801 *et seq*., and accompanying regulations, which prohibit practitioners from dispensing controlled substances except "for a legitimate medical purpose" and "in the usual course of professional practice." Practitioners who fail to comply with the CSA and accompanying regulations are subject to administrative action, including revocation of their DEA registration, and can be criminally prosecuted if they knowingly or intentionally prescribe not for a legitimate medical purpose or outside the usual course of professional practice. DEA, which also regulates manufacturers of controlled substances, has additionally proposed cutting the amount of controlled substances to be manufactured in 2018 by 20 percent compared to 2017. *See* Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2018, 82 Fed. Reg. 36830-34.

The United States Department of Justice (DOJ) has also vigorously prosecuted opioid over-prescribers under the CSA, as well as under federal fraud and abuse statutes. On July 13, 2017, Attorney General Sessions and U.S. Department of Health and Human Services (HHS) Secretary Tom Price announced the largest ever healthcare fraud enforcement action, which included 120 defendants charged for their roles in prescribing and distributing opioids. The focus of the enforcement was on billing for medically-unnecessary drugs.

The HHS Office of Inspector General (OIG) has released a Data Brief, Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing, which identified about 400 prescribers with questionable opioid prescribing patterns. OIG identified the prescribers by (1) identifying beneficiaries receiving extreme amounts of opioids (> 240 mg daily MED for 12 months, (2) identifying beneficiaries who appear to be doctor shopping, and (3) identifying the prescribers who ordered opioids for the highest numbers of beneficiaries at serious risk. The Data Brief observes that nurse practitioners and physician assistants make up about one third of the prescribers with questionable prescribing patterns for beneficiaries at serious risk.

State Activity

Louisiana has numerous initiatives intended to roll back the epidemic, including the use of the state Prescription Monitoring Program (PMP), setting parameters for prescribing activity, and identifying and disciplining or prosecuting individuals and companies responsible for overprescribing.

In 2010, the Louisiana Board of Pharmacy created and implemented PMP in an effort to assist physicians and the DEA in identifying patients who are "doctor shopping" among other things. The PMP is an electronic database that tracks prescribing and dispensing of controlled substances and can serve as an essential resource for prescribers. While widespread, PMPs vary in effectiveness, primarily because their use is not mandatory in every state. Louisiana has one of the more comprehensive state mandates and requires that all prescribers check the PMP prior to initially prescribing any opioid to a patient and must

access the PMP and review the patient's record at least every 90 days if the course of treatment continues.

The Louisiana Legislature has recently enacted several new provisions to address the opioid crisis as follows:

- Act 82 of the 2017 Regular Legislative Session has imposed quantity limits on initial opioid prescriptions for acute pain. Specifically, La. R.S. 40:978 was amended to require that when issuing a first-time opioid prescription for outpatient use to a patient with an acute condition, a medical practitioner shall not issue a prescription for more than a seven-day supply. The new legislation also addresses instances where, in the professional medical judgment of a medical practitioner, more than a seven-day supply of an opioid is required (1) to treat the adult or minor patient's acute medical condition, (2) for the treatment of chronic pain management, (3) for pain associated with a cancer diagnosis, or (4) for palliative care. In those situations, the practitioner can issue a prescription for the quantity needed to treat the patient's acute medical condition or pain;" however, that condition must be documented in the patient's medical record along with an indication that a non-opioid alternative was not appropriate to address the medical condition. The new legislation also requires that prior to issuing a prescription for an opioid, a medical practitioner must (1) consult with the patient regarding the quantity of the opioid and the patient's option to fill the prescription in a lesser quantity and (2) inform the patient of the risks associated with the opioid prescribed.

- Act 88 of the 2017 Legislative Session established the Advisory Council on Heroin and Opioid Prevention and Education (See La. R.S. 49:219.5). The task of the council is to develop an Interagency Heroin and Opioid Coordination Plan and its membership will include representatives from the Louisiana Department of Health, the Department of Children and Family Services and others. The council is allowed to solicit input and guidance from stakeholders including the state Pharmacy Board, Board of Medical Examiners, Board of Nursing, Medical Society, Nurses Association, Association of Nurse Practitioners, Ambulance Alliance, Association of Health Plans and others.

- Act 76 of the 2017 Legislative Session modified La. R.S. 40:973 to require that prescribers who receive a Controlled Dangerous Substance license from the Board of Pharmacy are automatically registered as a participant in the PMP. Additionally, as noted above, the new legislation updated La. R.S. 40:978 to limit the prescription of opioids (consistent with the limitations listed in the first bullet point above) and to specify that the "the profession licensing board that regulates the prescriber" such as Louisiana State Board of Medical Examiners (LSBME) is responsible for enforcement. This act further imposed mandatory continuing education requirements for all practitioners with authority to prescribe controlled substances in Louisiana. Each such practitioner must obtain three (3) credit hours of continuing education to include drug diversion training, best practice prescribing of controlled substances, appropriate treatment for addiction, and any other matters deemed appropriate by the board. Successful completion of this requirement once satisfies the requirement in full.

The Louisiana State Board of Medical Examiners has released guidance related to these recent legislative changes. The guidance advises physicians of the updates that are effective immediately relating to participation in the PMP and mandatory review of the PMP before prescribing an opioid. The other updates are effective Jan. 1, 2018 and include the three (3) hours of mandatory training on drug diversion, best practice prescribing of controlled substances, and appropriate treatment for addiction. The LSBME is currently working to develop the required CME to be completed in 2018 in advance of renewal in 2019.

Finally, the Louisiana Attorney General's Office has joined with forty other attorneys general in a national investigation of the companies responsible for manufacturing and distributing the majority of the nation's opioids, recently serving Civil Investigative Demands and information demand letters as part of their coordinated effort.

Private Sector Activity
Even the private sector appears to be joining efforts to limit access to prescription opioid medications. On Sept. 21, 2017, CVS announced that beginning in February 2018, it would limit opioid prescriptions to seven days or less for certain patients with acute pain who hadn't previously taken an opioid prescription. It will also limit patients with chronic pain to a maximum daily dose of 90 morphine milligram equivalents.

The Role of Hospitals
Hospitals play an important role in developing policies and processes to protect patients. Focused rules and guidelines from the various sources discussed above are aligning to provide directives to hospitals as they work to prevent the over-prescription of opioids as well as opioid misuse and abuse.

Even for hospitals, the risks associated with over-prescription of opioids can be significant. Hospitals can face allegations of negligent hiring, retention, training or supervision. They can be subject to allegations of vicarious liability in the form of responsibility for actions taken by employees or regulatory liability for failure to report theft, loss, diversion or unprofessional conduct. The following are some key actions hospitals can take to minimize their risk:

- Hospitals should require that their physicians and practitioners be educated on the issues in accordance with the new state mandates.

- Hospitals should be alert and attentive to the changing standard of care, ensuring its physicians and practitioners comply with newly-enacted legal limits on opioid prescriptions.

- Hospitals can look to the CDC Guidelines which, while voluntary, help direct additional parameters for initial prescriptions, dosages and monitoring. Along with state law requirements, these guidelines can serve as the basis for the implementation of hospital policies relating to opioid prescriptions.

- The PMP should be used to its fullest extent as an important tool to inform medical judgment and help identify patients with opioid problems, including those who may be doctor-shopping. Hospitals should ensure prescribers are compliant with Louisiana laws that mandate review of the PMP before prescribing opioids.

- Hospitals can look to legal limits on prescriptions, payment limits from private and government payors, and dosage limits imposed by pharmacies like CVS as additional support to bolster their policies that limit opioid prescriptions.

The available tools can help hospitals in implementing policies to fight the opioid crisis, can provide hospitals with the opportunity to support physicians in the battle against the opioid crisis, and can help hospitals to continue providing excellent care to their patients, preventing those patients from becoming another heartbreaking statistic.

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