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LEGAL MEDICINE

2021 Pain Management: Legal Aspects

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This article presents some of the recent developments in pain management laws, rules and regulations of the United States, at both the federal and state levels, and the impact of the COVID-19 pandemic on pain management policies and practice.

In 2011, the Institute of Medicine released a report[1] entitled "Relieving Pain in America" alerting Congress and the American public to the enormity of this growing public health epidemic. The report noted that:

(a) Chronic pain is one of the most prevalent and costly health conditions in America;
(b) Once pain becomes chronic, it can cause changes in the brain, spinal cord and peripheral nerves of the nervous system and become a distinct chronic disease in itself, and
(c) Called for a coordinated national effort to transform how the U.S. society understands and approaches pain management and prevention.

In 2013, the U.S. Centers for Disease Control and Prevention (CDC) recognized opioid-related deaths as an epidemic.[2] Since then, pain-related policies have been adopted and amended at an unprecedented rate. For example, from 2016 to 2018, more than 500 statutes, regulations, and guidelines were adopted at the state and federal levels pertaining to pain-related opioid use. More recently, newer statutes include limits on opioid prescribing, mandatory utilization of prescription drug monitoring programs, mandatory continuing education related to the treatment of pain, and policy changes associated with electronic medical records and telemedicine (telehealth) during the COVID-19 pandemic.

In 2019, nearly 50,000 people in the United States died from opioid-involved overdoses. The CDC stated that "The misuse of and addiction to opioids - including prescription pain relievers, heroin, and synthetic opioids such as fentanyl - is a serious national crisis that affects public health as well as social and economic welfare."[3]

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CENTURY OLD U.S. WAR ON DRUGS

In the U.S., the so-called *War on Drugs*, is over 100 years old.[4] In 2011, this author noted that "Doctors are concerned that prescribing opioid analgesics in chronic pain treatment is accompanied by an unacceptable risk of unwarranted prosecution. Doctors are fearful of the standards through which physicians are targeted and prosecuted. Some medical professionals regard criminalization of medical practice as a consequence of Prohibition law which represents an error in social policy that distorts medical standards." Sanbar also stated that in the U.S., law enforcement efforts to prevent diversion and abuse of opioid analgesics are important and necessary, but they should not be so restrictive as to interfere with medical practice and patient care resulting in under-treatment of pain. A balanced approach is necessary to resolve these two co-occurring serious public health problems.

Pain management policies should aim at a balanced approach to prescribing opioids. Administrative regulation includes the comprehensive Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategy (REMS) for opioid medications.[5]

In 2018, the U.S. Department of Justice created a task force to address illegal practices in the prescription drug pipeline. It focused on manufacturers, distributors, doctors, pain management clinics, and pharmacies, some of whom were sued successfully by federal and state attorneys general. There have been some solutions to the opioid crisis by federal, state and local governments, medical organizations, consumer advocates and the public. Notably, t**herapeutic Jurisprudence by Drug Treatment Courts has reduced** incarceration through treatment of drug abusers, and consequently decreasing the cost of incarceration.[7]

LIMITS ON PRESCRIBING OPIOIDS

Ten years ago, the CDC stated that overdoses from prescription pain medications [hydrocodone (Vicodin), methadone, oxycodone (OxyContin), oxymorphone (Opana), morphine, codeine, and heroin) had reached epidemic levels. The CDC opined that prescriptions with fewer days' supply would minimize the num-

ber of pills available for unintentional or intentional diversion. On the other hand, critics have noted that limiting prescriptions of opioids could help some individuals, but it might destabilize other patients and also promote the use of addictive drugs, such as heroin, cocaine, fentanyl and other drugs.

Five years later, in 2016, the CDC issued guidelines which recommended that physicians limit opioid prescriptions for acute (or short-term) pain to no more than a seven-day supply.[8] The CDC guidelines stated that for acute pain, a three-day supply of opioids would often be sufficient, and that supplies greater than seven days were rarely needed.

Massachusetts became the first state to enact legislation in 2016 to limit the initial supply of opioid painkillers prescribed by doctors. As of April 2021, 36 states had implemented policies or guidelines setting limits on the amounts of opioids that doctors may prescribe: (a) 24 states set opioid prescription limits through legislation, (b) Two states set opioid limits through executive orders, and (c) 10 states authorized another organization to set limits or guidelines. The initial limit on opioid prescribing is for seven days for adults. For minors, the limit is seven days total. Five states apply opioid limits only to Medicaid recipients. And two states require doctors to prescribe the lowest effective dose without setting pill or day limit for opioid prescriptions.[9]

In 2018, Oklahoma established limits on prescription opioids.[10] Oklahoma doctors are allowed to initially prescribe only a week's worth of opioid drugs at the lowest dose. Before prescribing another seven days, doctors have to meet with their patient to make sure they are not at risk for abuse or addiction. If more opioid is needed, further pain management options need to be discussed. ***Exemptions*** to this law include patients who are receiving (a) active treatment of cancer, (b) in hospice, (c) those receiving palliative care, or (d) residents in a long-term care facility. The law also mandates that doctors receive an extra hour of continuing education in pain management or in opioid abuse and addiction before renewing their license.

OPIOID WORKGROUP (OWB), BOARD OF SCIENTIFIC COUNSELORS (BSC), NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL (NCIPC), CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

In 2019, the CDC established the OWB, as a workgroup of the BSC/NCIPC, to review and update the CDC Guideline for Prescribing Opioids for Chronic Pain —United States, 2016. The latter provided twelve recommendations for prescribing opioid pain medications for outpatients aged ≥18 years in primary care settings.[11] The CDC recommendations focused on the use of opioids in treating chronic pain (defined as pain lasting longer than 3 months or past the time of normal tissue healing). The 2016 CDC Guideline was not intended for use in active cancer treatment, palliative care, or end-of-life care. The updated guideline is anticipated to be released in late 2021.

2021 CHANGES IN THE SUPPORT ACT[12]

In April of 2018, Congress amended the Support Act to require all U.S.-based health facilities to adopt electronic prescribing of controlled substances (EPCS) for all regulated substances covered in Medicare Part D**.** The purpose of using EPCS is to reduce opioid abuse, drug diversion, and drug fraud. As of January 2021, prescription of controlled substances must be transmitted via compliant electronic prescribing software.

The Support Act also includes the following: (1) Treatment for people suffering from opioid addiction; (2) Enrollees in Medicare must undergo opioid screening; (3) EPCS for all substances classified in schedule II - V; (4) Children's Health Insurance Program (CHIP) should cover substance abuse and mental health; and (5) CMS should educate all Medicare beneficiaries.

Effective January 1, 2021, the new EPCS system requires the adoption of the following techniques to mitigate the risk of unqualified or quack doctors prescribing controlled substances: **(1) Identity proofing** of the identity of the prescriber of the schedule ll-V drugs; (2) **Digital signature** to authenticate the prescription; (3) **Two-factor authentication** which helps in verifying the credibility of the prescriber; and (4) **Regular monitoring** by the Drug Enforcement Administration (DEA). Monitoring of opioid use will be enabled, and DEA may require well-audited reports on the prescription of regulated substances in health facilities.

The Support Act will not only help patients addicted to heroin or opioid access viable treatment programs, but also offer pain management alternatives to the patients. It should reduce prescription errors; diminish fraudulent (forged) prescriptions; enhance efficiency and interoperability, thereby allowing seamless exchanging and use of data from one system to another in a healthcare setup; and proper clinical alerts about drugs.

PAIN POLICIES AND PRACTICE CHANGES DURING COVID-19 PANDEMIC

During the COVID-19 pandemic, *temporary* policy changes were made at the federal and state levels. Clinic were closed, surgeries were postponed, lab work was delayed, and clinicians were learning how to treat a new coronavirus disorder. They were confused over which medical services were considered *essential*. As a consequence, there was an explosion in the utilization of telemedicine (telehealth) in hopes of providing the highest quality pain care to their patients. It is important to emphasize that the federal and most of the state policy changes made during the COVID-19 pandemic were issued as *temporary*.

In 2020, pain management physicians, who were already confused from the decade-long sweeping policy changes in laws, rules, regulations and guidelines, have had to contend with the reality of treating an already vulnerable patient population during a pandemic. New pain management policies had to be implemented on an emergency basis to reduce transmission of COVID-19, which had the unfortunate effect of impeding the standard of pain management. For example,

(1) Federally Qualified Health Centers (FQHCs)[13] are community-based health care providers that receive funds from

the HRSA Health Center Program to provide primary care services in underserved areas. They collectively serve around 30 million uninsured and underinsured patients. During the COVD-19 pandemic, FQHCs experienced significant problems in treating patients in their pain program." They had to limit their in-clinic offerings, cancel acupuncture, group visits, and postponed starting their yoga therapies.

(2) Prior to the COVID-19 pandemic, the Interdisciplinary Pain Management Centers at Madigan Army Medical Center[14] offered traditional interventional pain management services and non-interventional pain therapies. During 2020, it was closed to routine patient care for months.

Patients with pain were adversely affected. In March 2020, Jay[15] reported that nearly 30% of patients with pain who responded to a *Practical Pain Management* poll were experiencing trouble having a prescription refilled, and 20% of the responders were having trouble reaching their physician for follow-up.

Another survey of patients by the US Pain Foundation showed that 63% were experiencing increased pain, and 77% were experiencing barriers to medical care.[16]

In November 2020, the AMA strongly urged legislators, regulators, and governors to remove barriers to pain treatment to help ensure that patients with pain were able to access the treatments prescribed by their physician while reducing travel and unnecessary exposure to potential infection.[17]

TELEMEDICINE (TELEHEALTH) POLICY CHANGES

COVID-19 stay-at-home orders and clinic restrictions and closures were promptly countered by increased utilization of telemedicine. For example, UnitedHealthcare reported that utilization of telemedicine (telehealth) went from 0.1% of patients to 40% in their Medicare population.[18]

The utilization of telemedicine by providers of pain management and the patients during the COVID-19 pandemic was facilitated by the prompt, albeit *temporary*, federal government actions. For example,

(1) The CMS (Centers for Medicare and Medicaid Services) improved access to telemedicine health by increasing reimbursements to match person-to-person visits, and by paying for initial visits with a new clinician conducted by telemedicine. (2) The DEA (Drug Enforcement Administration)[19] responded to the COVID-19 public health emergency by helping DEA-registered practitioners to comprehend how they may and may not prescribe controlled substances without having to interact in-person with their patients.

The DEA has also allowed registered clinicians to prescribe controlled substances via telemedicine to patients in states where they are not registered, and also facilitated the prescribing of emergency Schedule II controlled substances orally, as opposed to written or electronic only. The actions by the DEA allowing clinicians to prescribe controlled substances based on a telemedicine visit does not override state laws that prohibit such prescribing.

The Federation of State Medical Boards listed the 41 U.S. States and Territories Modifying Requirements for Telehealth in Response to COVID-19; Oklahoma had COVID-19 Pandemic Emergency Rules in April 2020, and an Amended Executive Order in July 2020 offering broad credentialing privileges.[20] The Oklahoma order expired April 11, 2021.

Telemedicine has come a long way during the COVID-19 pandemic. Many clinicians were forced to implement virtual care. It becomes important to compare the efficacy of telemedicine to the standard in-person pain management. Patients have generally been pleased with telemedicine and desire to continue using virtual services after the pandemic abates for sundry reasons, such as availability of specialized care, convenience, less travel and waiting in a doctor's office as well as cost.

CONCLUSION

Clinicians who provide pain management are no strangers to federal and state laws that govern the prescribing of controlled substances, especially opioids. The clinicians must keep up with the constantly changing laws, rules and regulations in pain management. The use of telemedicine as an adjunct to traditional in-person visits may well become the new standard for medical care in the foreseeable future, including pain management.

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