CHAPMAN LAW GROUP
Health Care Attorneys

BALANCING
PAIN TREATMENT SYMPTOM MANAGEMENT AND LEGAL RESPONSIBILITIES

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GOALS

- History of the Controlled Substance Act
- Federal Standard
- Michigan State Standard
- Practical Considerations
- Questions

A BRIEF HISTORY OF THE CSA

Harrison Narcotics Act, Controlled Substances Act, Origin of the DEA

21 U.S.C. 801 ET. SEQ.

The Controlled Substances Act

21 U.S.C. 801 ET. SEQ.

- "Only licensed medical practitioners who are registered with the DEA are authorized to prescribe controlled substances listed in Schedules II-V to patients; such prescriptions may only be issued by a practitioner who is acting in the usual course of his professional practice, and for a legitimate medical purpose." 21 U.S.C. 801 et. seq.
- The person issuing a prescription which is not issued in the usual course of professional treatment shall be subject "to the penalties provided for violations of the provisions of law related to controlled substances." 21 C.F.R. 1306.04(a).

Seems simple enough, right?

UNITED STATES V. MOORE, 423 U.S. 122 (1975)

Can physicians be prosecuted for prescribing controlled substances?

Is there a valid physician-patient relationship?

UNITED STATES V. MOORE, 423 U.S. 122 (1975)

- "…he gave inadequate physical examinations or none at all. He ignored the results of the tests he did make. He did not give methadone at the clinic and took no precautions against its misuse and diversion. He did not regulate the dosage at all, prescribing as much and as frequently as the patient demanded. He did not charge for medical services rendered, but graduated his fee according to the number of tablets desired. In practical effect, he acted as a large-scale 'pusher' not as a physician."
- SCOTUS upheld the conviction and said a physician can be prosecuted when their actions "fall outside of professional practice"

UNITED STATES v. VOLKMAN, 797 F.3D 377 (6TH CIR. 2015)

Is the physician acting in the usual course of practice?

What is the standard for criminal culpability in patient death cases?

United States v. Volkman (2015)

FACTS

- Pain Management Physician w/ Ph.D. in Pharmacology educated at University of Chicago
- Board certified in Emergency Medicine and AAPM Diplomat
- Cash-only clinic with dispensary
- Over twenty patient deaths attributed to his practice

UNITED STATES v. VOLKMAN

- Volkman on appeal argued *(1)* the CSA 21 U.S.C. 841 only applies to "conventional drug trafficking", and *(2)* there was no causation to suggest he was responsible for patient deaths.
- Court rejected "conventional drug trafficking" argument and reiterated the *U.S. v. Moore* standard which was a "broad approach" to the "not for a legitimate medical practice" standard, including where a physician deliberately ignored signs of diversion.
- Court held a physician is still responsible for patient death where patient took 60 oxycodone in one day.

RUAN v. UNITED STATES, ___US___; 142 S. Ct. 2370; 213 L. Ed. 2d 706 (2022)

What is the standard for criminal culpability in prescribing controlled substances?

Did the physician knowingly or intentionally act in an unauthorized manner?

Ruan v. United States (2022)

FACTS

- 2 Physicians were accused of running "pill mills" and were convicted of violating CSA with 20+ year jail sentences for prescribing in an unauthorized manner.
- Their attorneys argued that they were convicted based on a negligence standard, not a criminal standard of having "mens rea" or conscious wrongdoing.
- Appealed all the way to the U.S. Supreme Court which ruled in June of 2022 unanimously for the physicians and vacated their convictions.

RUAN v. UNITED STATES

- U.S. Supreme Court ruled that "after a defendant produces evidence that he or she was authorized to dispense controlled substances, the **Government** must prove beyond a reasonable doubt that the defendant knew that he or she was acting in an unauthorized manner, or intended to do so."
- In other words, physicians are not criminally liable if their prescribing is not in accord with medical standards or guidelines if they believed they were helping their patients. Only if they knowingly or intentionally acted in an unauthorized manner can they be guilty of a criminal violation of the CSA.
- This is a landmark decision for both physicians practicing pain management and their patients and CLG was proud to file an amicus brief in support of one of the defendants.

Deconstructing the Legal Standard for Successful Compliance:

Treatment and Symptom Management Concerns

- Whether adequate physical exams were conducted;
- Whether tests were conducted;
- Regulation of the dosage of narcotics;
- Terms and method of payment;
- If a complete medical history was taken;
- Whether informed consent was given;
- Prescriptions issued for use by one patient but used for another;
- Admissions by patients that drugs would be used for a nonmedical purpose;
- Falsification of patient records;
- Number of prescriptions written in a short amount of time.

21 C.F.R. 1306.04

"A PRESCRIPTION MUST BE ISSUED FOR A LEGITIMATE MEDICAL PURPOSE BY AN INDIVIDUAL PRACTITIONER ACTING IN THE USUAL COURSE OF HIS PROFESSIONAL PRACTICE. THE RESPONSIBILITY FOR THE PROPER PRESCRIBING AND DISPENSING OF CONTROLLED SUBSTANCES IS UPON THE PRESCRIBING PRACTITIONER…"

DEA "RED FLAGS"

THE FOLLOWING MAY SHOW LACK OF LEGITIMATE MEDICAL PURPOSE:

- Paying cash despite having insurance
- Requesting CII medication
- The "triangle" is too great a distance
- Has received "the trinity"
- Requesting pain medication from a provider outside of his/her specialty
- Groups of patients travel together
- Resistant to alternative treatment
- Discloses allergies to non-opioid medications
- Doctor shopping
- Urinalysis test is inconsistent

ELEMENTS OF A VALID PRESCRIPTION 21 C.F.R. 1306.05

- Date of issue
- Patients name and address
- Practitioner's name, address, and DEA registration number
- Drug name, strength dosage, and quantity
- Direction for use
- **diagnosis
- **post fill instruction if necessary

MICHIGAN STANDARDS

YOU MUST FOLLOW THE MOST STRINGENT STANDARD APPLICABLE

MCL 333.7402

- Pertains to unlawful drug transactions.
- Except as authorized by the public health code, a person shall not unlawfully deliver a controlled substance.

MCL 333.7405

- Shall not dispense, distribute or prescribe in violation of MCL 333.7333.

MCL 333.7333

- A practitioner must:
  - prescribe in the regular course of professional treatment
  - to or for an individual who is under treatment by the practitioner
  - For a pathology or condition other than physical or psychological dependence upon or addiction to a controlled substance
- A pharmacist shall not fill a prescription where the following are present:
  - No doctor patient relationship
  - Pattern prescribing
  - Quantities unusual for specialty or board certification
  - Unusual dosages
  - Unusual geographic distances

MCL 333.7333
PRESCRIPTION REQUIREMENTS

Quantity of controlled substances (written and numerical)

Post dating is not allowed

Electronic prescribing is governed by MCL 333.17754a for all controlled and non-controlled substances, unless exempt or subject to waiver. Controls can still be orally prescribed (called in)

A practitioner may issue more than one Schedule II on a single form

Schedule II must not be filled more than 90 days after the date the prescription was issued

Schedule III and IV must not be filled or refilled without specific refill instructions or later than 6 months after prescription was issued

ACUTE PAIN: MCL 333.7333

- As of July 1, 2018, if a prescriber is treating a patient for acute pain, the prescriber shall not prescribe the patient more than a seven-day supply of an opioid within a seven-day period.
- "Acute Pain" means pain that is a normal, predicted psychological response to a noxious chemical or a thermal or mechanical stimulus and is typically associated with invasive procedures, trauma, and disease and usually lasts for a limited amount of time.

MAPS

MICHIGAN AUTOMATED PRESCRIPTION SYSTEM

- MAPS is the Michigan Automated Prescription System, which is Michigan's prescription monitoring program used to track controlled substances to assess patient risk and prevent drug abuse and diversion at the prescriber, pharmacy, and patient levels.
- Beginning June 1, 2018, MCL 333.7303a required all licensed prescribers to register with MAPS and to obtain and review a report of a patient's CS history from MAPS before prescribing any schedule 2-5 controlled substance in excess of a 3-day supply.
- LARA's Drug Monitoring Section reviews MAPS data to identify outliers and determine if there is a need for investigation or disciplinary action.
- The eye in the sky sees all and the bill will come due eventually.

HOW THE **STANDARD OF CARE** IS DETERMINED

- Michigan Guidelines for the Use of Controlled Substances for the Treatment of Pain (2009)
- FSMB Guidelines for the Chronic Use of Opioid Analgesics (2017)
- Responsible Opioid Prescribing, Scott Fishman (2007)
- CDC Clinical Practice Guidelines for Prescribing Opiates for Pain – Revised (November 4, 2022)

PRACTICAL CONSIDERATIONS – WHAT DO THE MICHIGAN GUIDELINES REQUIRE?

- Evaluation of the Patient
- Treatment Plan
- Informed Consent and Agreement for Treatment
- Periodic Review
- Consultation
- Medical Records
- Compliance with CS Laws and Regulations

MEDICAL RECORDS REQUIREMENTS

- Copies of the signed informed consent and treatment agreement.
- • The patient's medical history.
- • Results of the physical examination and all laboratory tests.
- • Results of the risk assessment, including results of any screening instruments used.
- • A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity).

MEDICAL RECORDS REQUIREMENTS CONT'D

- • Instructions to the patient, including discussions of risks and benefits with the patient and any significant others.
- • Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement.
- • Notes on evaluations by and consultations with specialists.
- • Results of queries to MAPS.
- • Any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors.
- • Authorization for release of information to other treatment providers.

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