MIRROR, MIRROR Documentation of Patient History and Treatment Plans

(Part I of the 3-part Looking Glass Series)

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Disclosures

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Background and Reasons for MDL05, MDL06, and MDL07

- Recent published case decisions and board orders reflect an enhanced battle between medical experts over controlled substance prescribing and medical record documentation of the practitioner-patient relationship.

- Recent DEA cases (Pompy (MDL05) and Kahn-Jaffrey (MDL06), as well as two medical licensing board cases (Florida and Maryland) stand out for their enhanced focus on the detail needed in the medical record, as well as a list of “do’s” and “don’ts” for demonstrating a valid controlled substance prescription and adherence to the “prescribing standards of care.”
- CASE SOURCES AVAILABLE IN HANDOUTS FOR THESE COURSES!

Background and Reasons for MDL05, MDL06, and MDL07

- The COVID-19 public health emergency brings yet additional focus on medical record documentation because of what may be viewed as a temporary “permission slip” from DEA to use telemedicine for controlled substance prescribing. MDL07.

- Practitioners should reflect on current work-flow and documentation of the practitioner-patient relationship and strive to improve documentation of the prescriber’s rationale and patient’s response to the treatment plan.

- **SOURCES:** DEA Handout on Prescribing Controlled Substances During the COVID-19 PHE. Sources cited within MDL07.

Subject Matter Covered by MDL05, MDL06, MDL07 and Course Flow

- **MDL-05 – Patient History and Treatment Plans.**
- **MDL-06 – Risk Evaluation and Updating Informed Consents and Treatment Agreements.**
- **MDL-07 – Periodic Review and Other Strategies During the COVID Era.**
    - Each course builds upon the previous course.
- The intent of all three courses is to provide insight into “what” the DEA and licensing boards expect in terms of provider action and documentation when controlled medication is part of the chronic pain management treatment plan.
- Each course uses case-derived suggestions on “how” practitioners may evolve medical record documentation with individualized care notes and clear summaries of prescriber rationale

Learning Objectives

1. Review DEA and Licensing Board positions on what constitutes a valid prescription for a controlled substance.

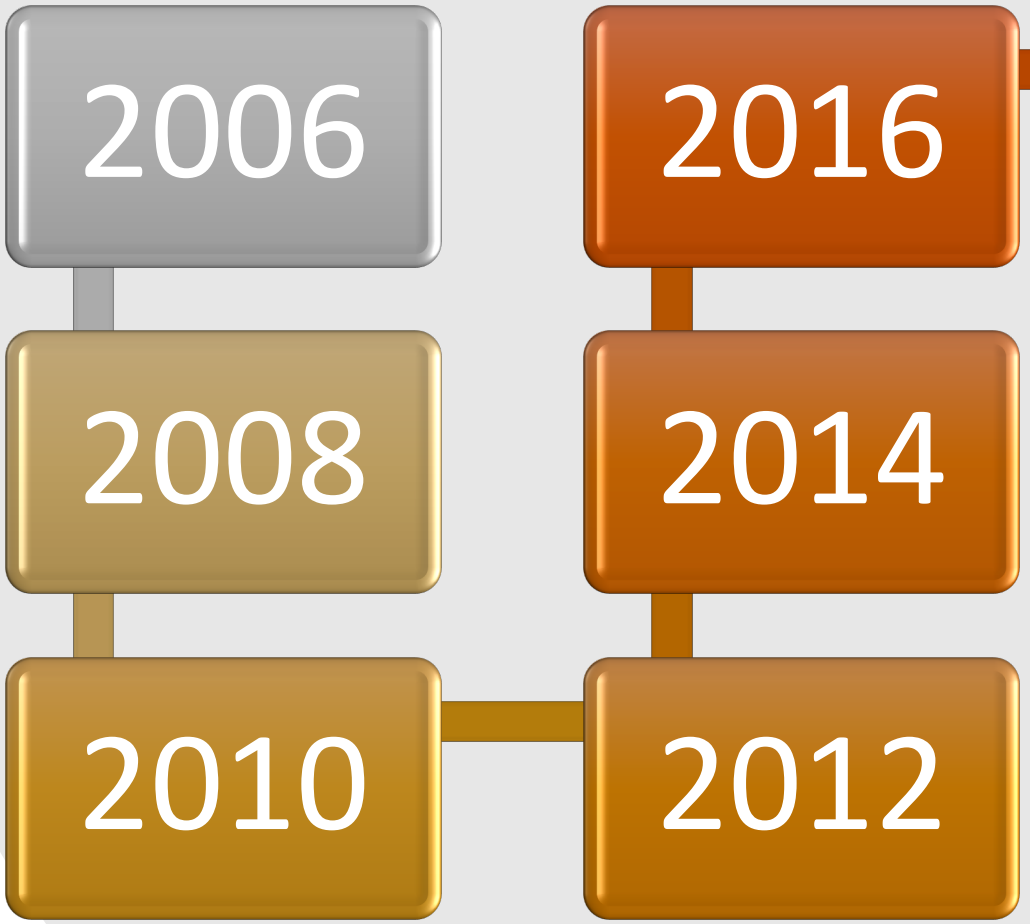
2. Using the DEA‘s findings in Pompy, and the Maryland Physician’s Board findings in the Quainoo Consent Order, this information will permit attendees to explain how DEA and Licensing Boards evaluate history, physical examination, and treatment plans, and serve to illustrate documentation failures that may contribute to administrative sanctions (loss of DEA Registration; loss of professional license).

3. Identify steps practitioners should take to evaluate their own documentation and make updates to reflect an evolving and ongoing commitment to compliant controlled substance prescribing and quality pain care.

Reflections

Mirror, mirror

Development of “Standards of Care” for Chronic Opioid Therapy and Valid Controlled Substance Rxs



DEA LEGAL REQUIREMENTS REMAIN CONSTANT:
Legitimate Medical Purpose and Usual Course of Professional Practice, with Reasonable Steps to Prevent Abuse and Diversion

CLINICAL STANDARDS OF CARE ARE DYNAMIC AND INFLUENCED BY MULTIPLE SOURCES; DEA DECISIONS MORE FREQUENTLY CAPTURE UPDATED EXPRESSIONS OF THE “PRESCRIBING STANDARD OF CARE”:
Board Guidelines and Rules, Professional Society Position Statements and Guidance Documents, and Government Agency Guidelines

Looking Glass Year - 2006

"Moreover, as a condition of being a DEA registrant, a physician who prescribes controlled substances has an obligation to take reasonable measures to prevent diversion. [21 U.S.C. 823(f)]."

"The overwhelming majority of physicians in the United States who prescribe controlled substances do, in fact, exercise the appropriate degree of medical supervision—as part of their routine practice during office visits—to minimize the likelihood of diversion or abuse."

"Again, each patient's situation is unique, and the nature and degree of physician oversight should be tailored accordingly, based on the physician's sound medical judgment and consistent with established medical standards."

SOURCE: DEA Final Policy Statement, Notice, FR Doc E6-14517 [Federal Register: September 6, 2006 (Volume 71, Number 172)] [Notices] [Page 52715-52723] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr06se06-137], Available online at https://www.deadiversion.usdoj.gov/fed_regs/notices/2006/fr09062.htm.

Looking Glass Year - 2006

"When adequate documentation exists in the medical record, the risk of civil, criminal, or administrative action being taken by the DEA against a physician *for prescribing opioids* for a chronic pain patient is small."

SOURCE: Jung, B. and Reidenberg, M., *The Risk of Action by the Drug Enforcement Administration Against Physicians Prescribing Opioids for Pain,* Pain Medicine, Volume 7, No. 4, 2006

Looking Glass Year - 2019

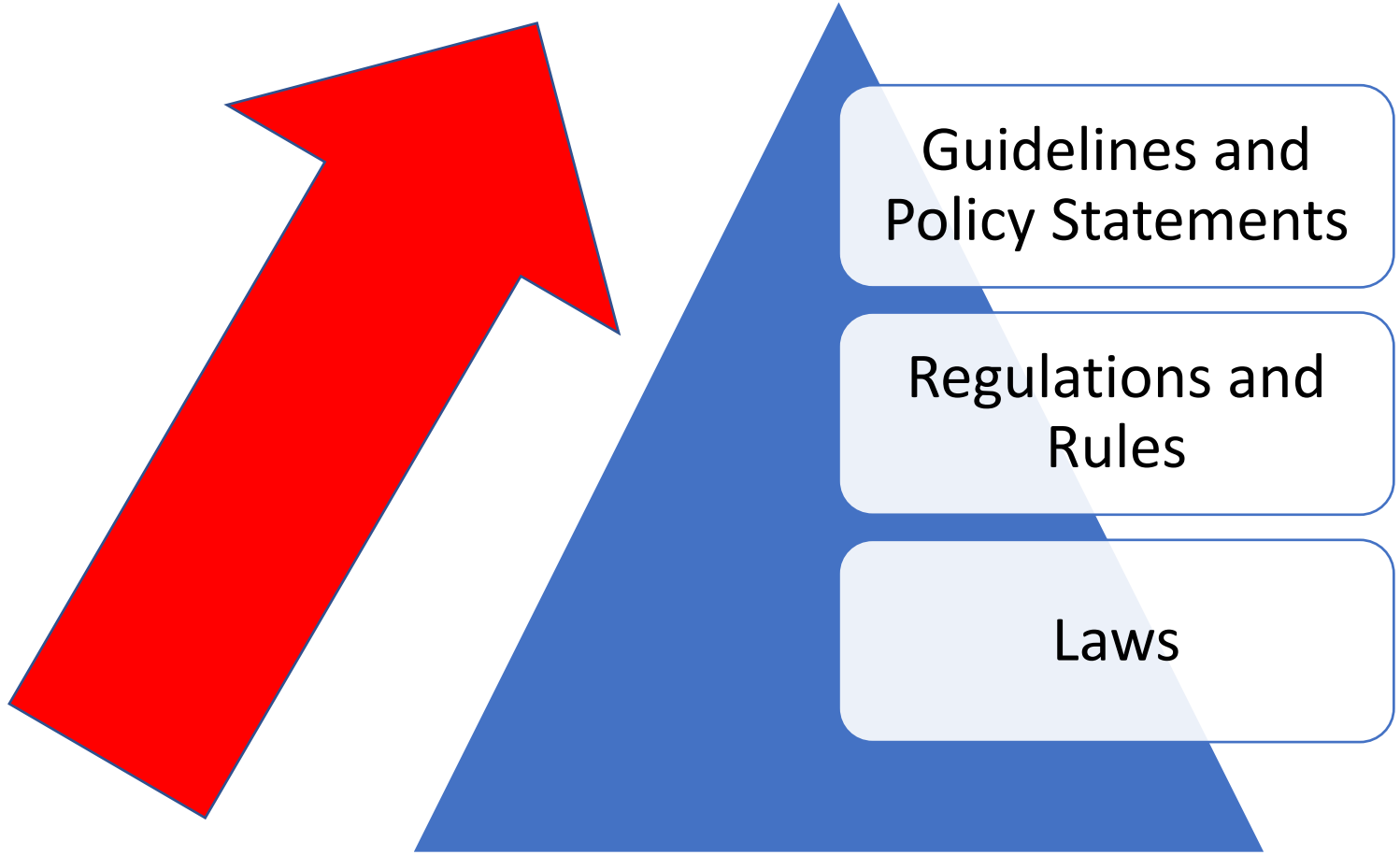
"A physician may not expect to vindicate himself through oral representations at the hearing about his compliance with the standard of care that were not documented in appropriately maintained medical records."

SOURCE: *DEA Decision and Order in the Case of Lesly Pompy*, MD, Vol. 84 Fed. Reg., No 208, Monday, October 28, 2019, pp. 57749, 577**60.**

Basic Legal Framework

Focus on chronic pain management and the legal/regulatory framework for establishing a valid controlled substance prescription.

The Basic Legal/Regulatory Framework Governing Controlled Substance Prescribing



Federal Requirements for a Valid Controlled Substance Prescription

SOURCE: 21 CFR 1306.04, available online at https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_04.htm and as further linked within the DEA website.

U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEM

DIVERSION CONTROL

Diversion Control Division

HOME | REGISTRATION | REPORTING | RESOURCES

RESOURCES > Title 21 Code of Federal Regulations > Part 1306 > 1306.04

Title 21 Code of Federal Regulations

PART 1306 — PRESCRIPTIONS

GENERAL INFORMATION

§1306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective 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, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (**21 U.S.C. 829**) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in **§1301.28** of this chapter.

[36 FR 7799, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 37986, Oct. 25, 1974; 70 FR 36343, June 23, 2005]

*NOTICE: This is an unofficial version. An official version of this publication may be obtained directly from the **Government Publishing Office** (GPO).*

But what does 21 CFR 1306.04 really mean?

Legitimate Medical Purpose

- Establishing and documenting one or more generally recognized indications for the use of the controlled drug, which in turn is based on sound clinical judgment and documentation demonstrating the prescriber's performance of a history, physical examination appropriate to the pain complaint/condition, review of diagnostic information and orders for appropriate diagnostic and imaging studies to achieve a diagnosis/working diagnosis.

Usual Course of Professional Practice

- A valid physician-patient relationship exists.
- The relationship was created and maintained according to standards set forth by the professional licensing board and guidance from related professional and regulatory resources.
- The prescriber acts within the usual course of professional practice when he/she prescribes within the established boundaries and explains his/her decision-making/reasoning for treatment of the individual patient.
- Individual "elements" of Usual Course of Professional Practice set forth in later slides.

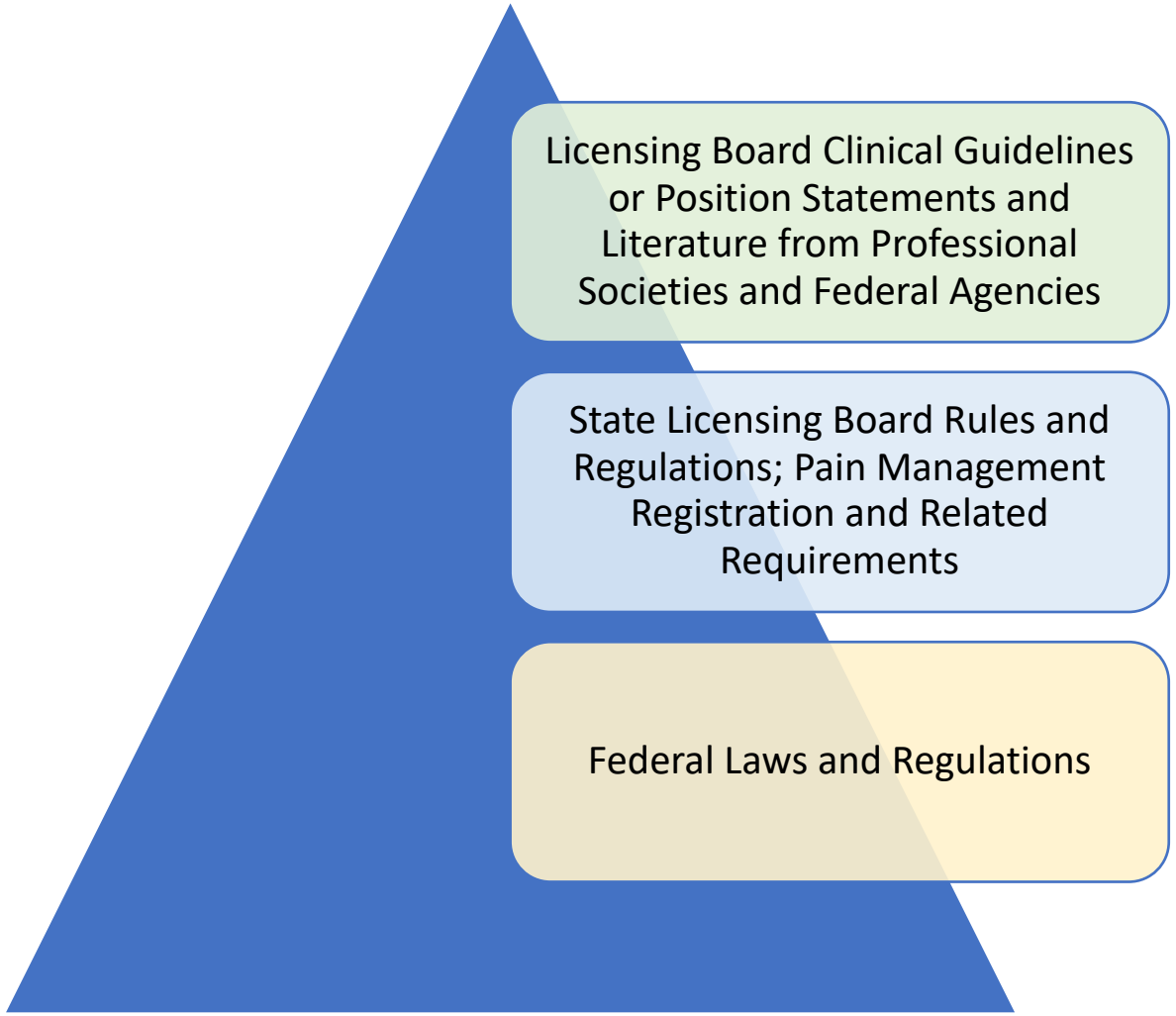
Reasonable Steps to Prevent Abuse and Diversion

- The prescriber must do those things established by the professional licensing board and related agencies that minimizes the potential for harm to the patient and the public.
- The prescriber must evaluate risks at the beginning of the relationship (prior to prescribing controlled medications) and throughout the relationship.
- The nature and frequency of the "reasonable steps" is guided by state law and standard of care material/resources.

SOURCE: Pompy Decision and Order (2019); Kahn-Jaffrey Decision and Order (2020); These are in the handouts for these courses.

Common Sources

Used by DEA and Licensing Boards, and medical experts, to identify the “standard of care” and to determine whether a prescriber issued a controlled substance prescription for a “legitimate medical purpose” while acting in the “usual course of professional practice.”



Visualizing How Federal and State Board "Prescribing Standards" Work Together

DEA Requirements for a Valid CS Rx

- Legitimate Medical Purpose
- Usual Course of Professional Practice
- Reasonable Steps to Prevent Abuse and Diversion

Licensing Board Requirements for Appropriate Prescribing of Opioids

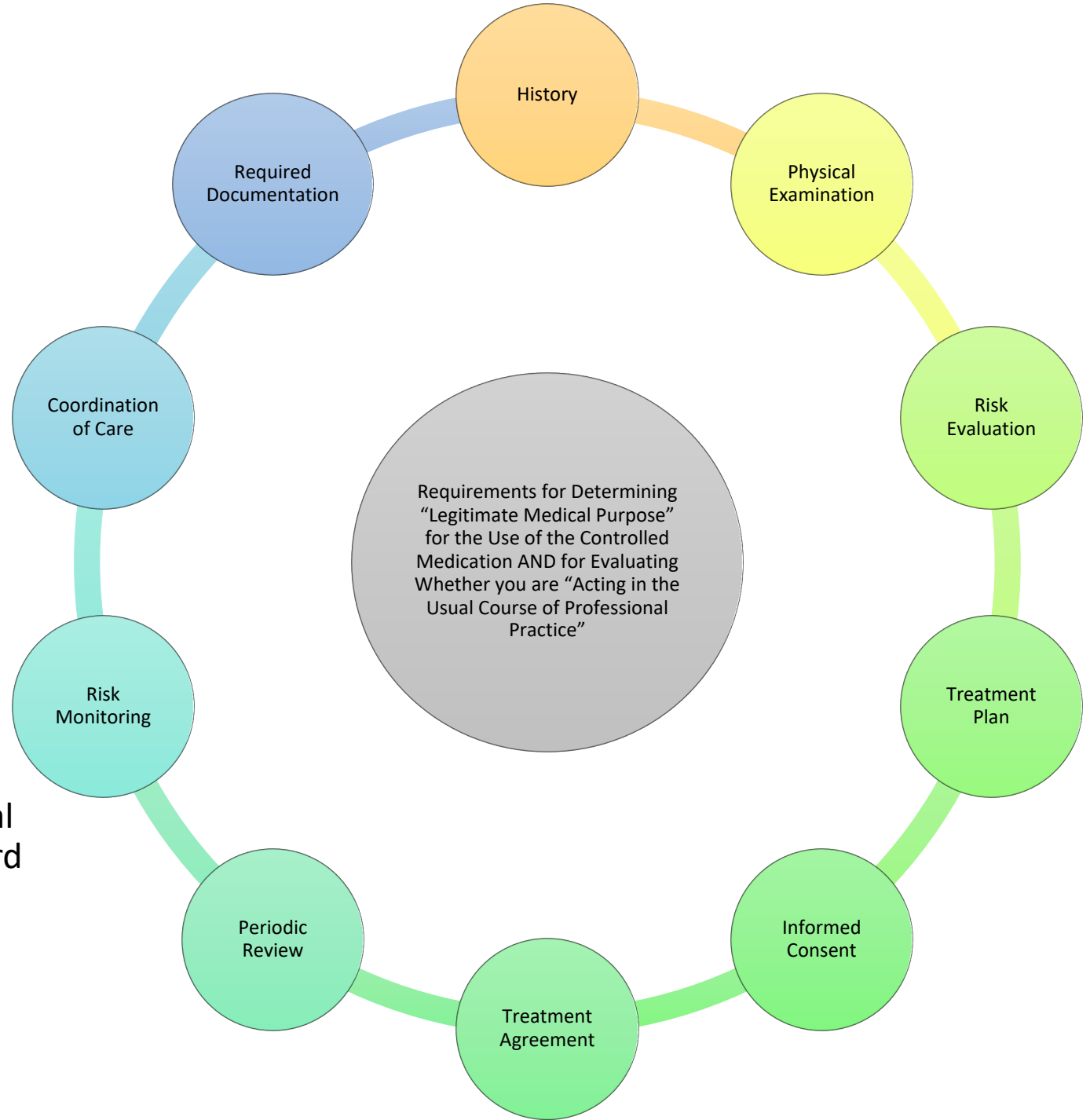
SOURCE: 21 CFR 1306.04; DEA Decision and Order in Pompy (2019) and Kahn—Jaffrey (2020); Various State Licensing Board Materials, including the overall Federation of State Medical Boards (FSMB) Model Policy (2017), available online at https://www.fsmb.org/siteassets/advocacy/policies/opioid_guidelines_as_adopted_april-2017_final.pdf.

The “Backbone” of Most Current Board Guidelines/Rules

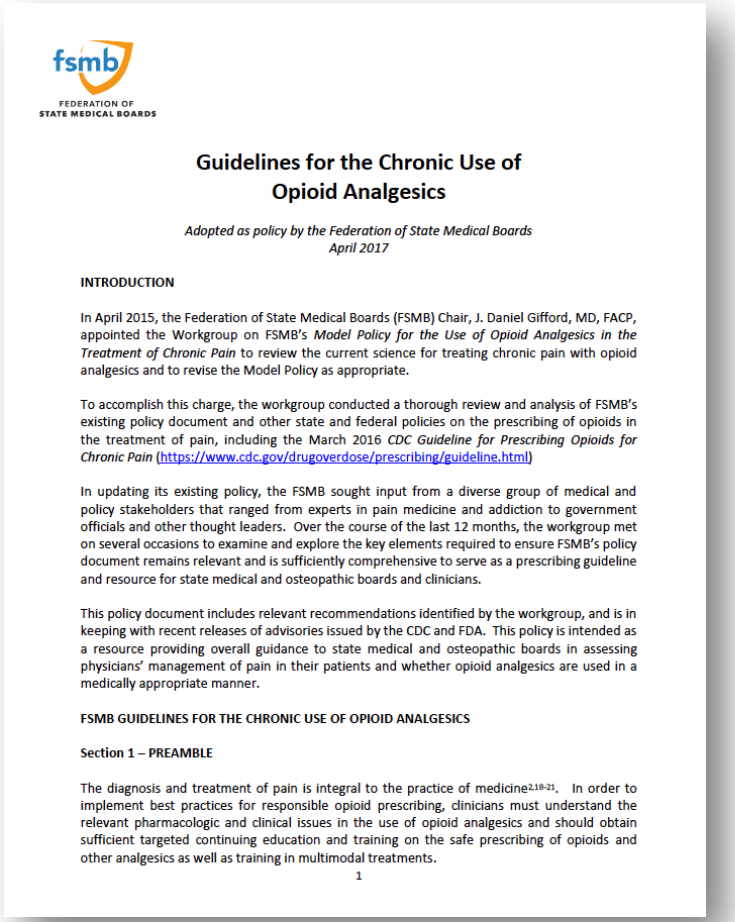
Action and Documentation Domains in Chronic Pain Management

These are basic headers. There are required and suggested actions within each topic!

SOURCE: Bolen, J., A personal Compendium of Cases, FSMB, Professional Society Material, and State Licensing Board Material (2000-2020).



Two Helpful FSMB Resources



FEDERATION OF STATE MEDICAL BOARDS

Guidelines for the Chronic Use of Opioid Analgesics

Adopted as policy by the Federation of State Medical Boards
April 2017

INTRODUCTION

In April 2015, the Federation of State Medical Boards (FSMB) Chair, J. Daniel Gifford, MD, FACP, appointed the Workgroup on FSMB's *Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain* to review the current science for treating chronic pain with opioid analgesics and to revise the Model Policy as appropriate.

To accomplish this charge, the workgroup conducted a thorough review and analysis of FSMB's existing policy document and other state and federal policies on the prescribing of opioids in the treatment of pain, including the March 2016 *CDC Guideline for Prescribing Opioids for Chronic Pain* (https://www.cdc.gov/drugoverdose/prescribing/guideline.html)

In updating its existing policy, the FSMB sought input from a diverse group of medical and policy stakeholders that ranged from experts in pain medicine and addiction to government officials and other thought leaders. Over the course of the last 12 months, the workgroup met on several occasions to examine and explore the key elements required to ensure FSMB's policy document remains relevant and is sufficiently comprehensive to serve as a prescribing guideline and resource for state medical and osteopathic boards and clinicians.

This policy document includes relevant recommendations identified by the workgroup, and is in keeping with recent releases of advisories issued by the CDC and FDA. This policy is intended as a resource providing overall guidance to state medical and osteopathic boards in assessing physicians' management of pain in their patients and whether opioid analgesics are used in a medically appropriate manner.

FSMB GUIDELINES FOR THE CHRONIC USE OF OPIOID ANALGESICS

Section 1 – PREAMBLE

The diagnosis and treatment of pain is integral to the practice of medicine[2,18-21]. In order to implement best practices for responsible opioid prescribing, clinicians must understand the relevant pharmacologic and clinical issues in the use of opioid analgesics and should obtain sufficient targeted continuing education and training on the safe prescribing of opioids and other analgesics as well as training in multimodal treatments.

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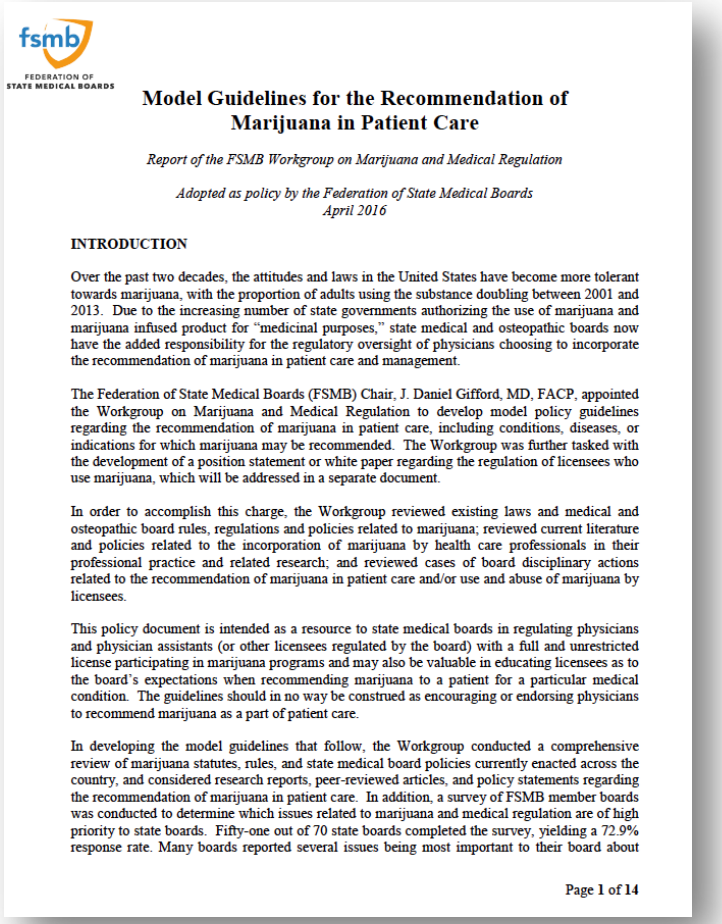

FEDERATION OF STATE MEDICAL BOARDS

Model Guidelines for the Recommendation of Marijuana in Patient Care

Report of the FSMB Workgroup on Marijuana and Medical Regulation

Adopted as policy by the Federation of State Medical Boards
April 2016

INTRODUCTION

Over the past two decades, the attitudes and laws in the United States have become more tolerant towards marijuana, with the proportion of adults using the substance doubling between 2001 and 2013. Due to the increasing number of state governments authorizing the use of marijuana and marijuana infused product for "medicinal purposes," state medical and osteopathic boards now have the added responsibility for the regulatory oversight of physicians choosing to incorporate the recommendation of marijuana in patient care and management.

The Federation of State Medical Boards (FSMB) Chair, J. Daniel Gifford, MD, FACP, appointed the Workgroup on Marijuana and Medical Regulation to develop model policy guidelines regarding the recommendation of marijuana in patient care, including conditions, diseases, or indications for which marijuana may be recommended. The Workgroup was further tasked with the development of a position statement or white paper regarding the regulation of licensees who use marijuana, which will be addressed in a separate document.

In order to accomplish this charge, the Workgroup reviewed existing laws and medical and osteopathic board rules, regulations and policies related to marijuana; reviewed current literature and policies related to the incorporation of marijuana by health care professionals in their professional practice and related research; and reviewed cases of board disciplinary actions related to the recommendation of marijuana in patient care and/or use and abuse of marijuana by licensees.

This policy document is intended as a resource to state medical boards in regulating physicians and physician assistants (or other licensees regulated by the board) with a full and unrestricted license participating in marijuana programs and may also be valuable in educating licensees as to the board's expectations when recommending marijuana to a patient for a particular medical condition. The guidelines should in no way be construed as encouraging or endorsing physicians to recommend marijuana as a part of patient care.

In developing the model guidelines that follow, the Workgroup conducted a comprehensive review of marijuana statutes, rules, and state medical board policies currently enacted across the country, and considered research reports, peer-reviewed articles, and policy statements regarding the recommendation of marijuana in patient care. In addition, a survey of FSMB member boards was conducted to determine which issues related to marijuana and medical regulation are of high priority to state boards. Fifty-one out of 70 state boards completed the survey, yielding a 72.9% response rate. Many boards reported several issues being most important to their board about

Page 1 of 14

FSMB Model Guidelines for the Chronic Use of Opioid Analgesics (2017), available online at https://www.fsmb.org/siteassets/advocacy/policies/opioid_guidelines_as_adopted_april-2017_final.pdf; and FSMB Model Guidelines for the Recommendation of Marijuana in Patient Care (2016), available online at https://www.fsmb.org/siteassets/advocacy/policies/model-guidelines-for-the-recommendation-of-marijuana-in-patient-care.pdf - BE SURE TO READ YOUR STATE BOARD MATERIAL ON THESE TOPICS AND KNOW YOUR STATE LAW REGARDING MARIJUANA. Just because there's a guideline, doesn't mean it protects your controlled substance prescribing.

DEA's Use of its Administrative Authority Over your Controlled Substance Registration

- DEA uses **Administrative Enforcement Actions** to suspend, revoke, or deny a DEA registration.
- DEA may issue a registrant an **Order to Show Cause** to set in motion DEA's initiation of administrative proceedings that may lead to revoking the registration.
- If the registrant's actions present a significant risk to public health and safety, **DEA may seek the voluntary surrender of the DEA registration OR issue an Immediate Suspension order** against the registrant.
    - **FOR THE ISO,** DEA must prove (1) the registrant's conduct presents an "imminent danger to the public health or safety" because the registrant failed to maintain effective controls against diversion or to otherwise comply with the obligations of the DEA registration AND (2) that there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance would occur unless there is an immediate suspension of the registration.
- **SOURCES:** 21 U.S.C. §§ 824(c)(2)(A) and 824(d)(1), and www.deadiversion.usdoj.gov under Resources. In April 2016, Congress enacted the Ensuring Patient Access and Effective Drug Enforcement Act of 2016, or the "Marino Bill," which created a new standard of proof necessary for DEA to issue an ISO. See 21 U.S.C. § 824(d)(2).

Understanding HOW the so-called “standard of care” for controlled substance prescribing is evaluated during administrative and legal proceedings

Text of Laws Regulations, Rules, Guidelines

- Federal
- State

Gathering of Evidence to “Look Inside” your Practice

- Your medical records
- Pharmacy records and database information
- Payor records may come into play
- Subpoenas for records
- Search warrants
- Sometimes undercover agents are used
- Sometimes wiretaps are used
- Packaged up and handed to medical experts in most cases

Interpretation of Your Prescribing Habits and Documentation

- Data summaries (volume, frequency, dose, patient load, financial application, ancillary services)
- Medical Expert Reports on
  - Prescribing for a Legitimate Medical Purpose
  - Prescribing within the usual course of professional practice

Part 2 – History and Physical Examination: What is Required to Meet the ‘Prescribing Standard of Care’?

A quick look at federal vs. state laws/regulations/guidelines on the topic.

REMEMBER THIS SLIDE

DEA Material

- ✓ ZERO reference to history and physical examination in DEA laws or regulations, but many references to history and physical examination in DEA Administrative Decisions and Orders
- ✓ 2006 Reference to history and physical examination in a DEA Final Policy Statement.
- ✓ A complete history and condition-appropriate physical examination are critical to establishing "legitimate medical purpose."
- ✓ These items, plus treatment plan and the other areas covered in MDL06 and MDL07, are also critical to establishing that the prescriber "acted in the usual course of professional practice and took reasonable steps to prevent abuse and diversion."

Licensing Board Material

- ✓ Most licensing boards require a complete history and condition-appropriate/focused physical examination *prior to prescribing controlled substances in chronic pain management*. Some states are more general in the timing of these steps vis the prescribing.

  This course is NOT addressing acute pain management.
- ✓ Some states have supportive guidelines/rules that explain the board's thinking and expectations; Other states, not so much.
- ✓ Licensing board rules and guidelines on the use of controlled substances to treat chronic pain are relevant to DEA Administrative cases and Licensing Board cases where opioid prescribing and the applicable standard is at issue.

Example: Alabama Board of Medicine Pain Management Services Rules - Evaluation of the Patient and Treatment Plan

SOURCE: Alabama BME, Pain Management Services Rule, Ala. Admin. Code, Chapter 540-X-19, available online at http://www.alabamaadministrativecode.state.al.us/docs/mexam/540-X-19.pdf.

available documentation. The goal is to reduce pain and/or improve patients' function.

(g) Physicians are referred to the Federation of State Medical Boards' Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain, July 2013, as amended from time to time, and the Drug Enforcement Administration Office of Diversion Control manual, Narcotic Treatment Programs Best Practice Guidelines, as amended from time to time.

(2) Requirements. The Board requires the following when a physician evaluates the use of controlled substances for pain control:

(a) Evaluation of the Patient. A medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record should also document the presence of one or more recognized medical indications for the use of a controlled substance.

(b) Treatment Plan. The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of the patient. Alternative non-opioid treatment modalities or a rehabilitation program may be necessary and should be considered.

Texas Administrative Code

TITLE 22	EXAMINING BOARDS
PART 9	TEXAS MEDICAL BOARD
CHAPTER 170	PRESCRIPTION OF CONTROLLED SUBSTANCES
SUBCHAPTER A	PAIN MANAGEMENT
RULE §170.3	Minimum Requirements for the Treatment of Chronic Pain

, physician's treatment of a patient's pain will be evaluated by considering whether it meets the generally accepted standard of care and whether the following minimum requirements have been met:

(1) Evaluation of the patient.

(A) A physician is responsible for obtaining a medical history and a physical examination that includes a problem-focused exam specific to the chief presenting complaint of the patient.

(B) The medical record shall document the medical history and physical examination. In the case of chronic pain, the medical record must document:

(i) the nature and intensity of the pain;

(ii) current and past treatments for pain;

(iii) underlying or coexisting diseases and conditions;

(iv) the effect of the pain on physical and psychological function;

(v) any history and potential for substance abuse or diversion; and

(vi) the presence of one or more recognized medical indications for the use of a dangerous or scheduled drug.

State Example – Texas – Evaluation of the Patient

Available online through the TMB at http://www.tmb.state.tx.us/page/board-rules.

(C) Prior to prescribing opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic pain, a physician must review prescription
Section 481.0764 of the Texas Health and Safety Code and §170.9 of this Chapter (relating to Prescription Monitoring Program Check). In addition, a pl
patient, if any. If a physician determines that a baseline toxicology drug screen is not necessary, the physician must document in the medical record his c

(2) Treatment plan for chronic pain. The physician is responsible for a written treatment plan that is documented in the medical records. The medical re

(A) how the medication relates to the chief presenting complaint of chronic pain;

(B) dosage and frequency of any drugs prescribed;

(C) further testing and diagnostic evaluations to be ordered, if medically indicated;

(D) other treatments that are planned or considered;

(E) periodic reviews planned; and

(F) objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function.

State Example – Texas – Treatment Plan

Available online through the TMB at http://www.tmb.state.tx.us/page/board-rules.

General Background – Pompy Decision and Order (2019)

The POMPY Case: Focus on the Michigan Opioid Prescribing Guidelines and FSMB Model Guidelines for Opioid Prescribing in Pain Management

- The intent of the Michigan Guidelines is to "communicate what the Boards ... consider to be within the boundaries of professional practice…medical management of pain should be based on current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities…Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes."

- **SOURCE: Drug Enforcement Administration,** Lesly Pompy, MD, Decision and Order, Fed. Reg., Vol. 84, No. 208, October 28, 2019, p. 57749, *57753.*

The POMPY Case and DEA's Administrative Decision and Order:
Focus on the Michigan Board's Perspective of a Valid Opioid Prescription

- Prescribing and dispensing is 'for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds."
    - "All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law."
- **SOURCE: Drug Enforcement Administration,** Lesly Pompy, MD, Decision and Order, Fed. Reg., Vol. 84, No. 208, October 28, 2019, p. 57749, *57753.*

The POMPY Case: Focus on the Michigan Board's Perspective of a Valid Opioid Prescription

- "The stated goal is to 'control the patient's pain for its duration, while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.'"

- [Boards] "will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation."

- **SOURCE: Drug Enforcement Administration,** Lesly Pompy, MD, Decision and Order, Fed. Reg., Vol. 84, No. 208, October 28, 2019, p. 57749, *57753.*

The POMPY Case: Focus on "How" Prescribing for Pain is Evaluated [in Michigan]

- Prescribing for pain is evaluated "on an individual basis."
- The [Michigan Boards] "will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, **if good cause is shown for such deviation…"**
- The physician's conduct 'will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs – including any improvement in functioning – and recognizing that some types of pain cannot be completely relieved."

- **SOURCE: Drug Enforcement Administration,** Lesly Pompy, MD, Decision and Order, Fed. Reg., Vol. 84, No. 208, October 28, 2019, p. 57749, *57753.*

Michigan's Guidelines on History, Physical Examination, and Treatment Plan, and Documentation of these items

In effect during the period of prescribing at issue in Pompy. Make sure you consult and are using your state's current board guidelines and/or rules.

POMPY CASE (2019)
Michigan Board Guidelines on History and Physical Exam

- **A complete medical history and physical examination MUST BE CONDUCTED AND DOCUMENTED IN THE MEDICAL RECORD.** The Board's expectation of documentation of this element are as follows:
- "The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or condition, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance."
- **SOURCE: Drug Enforcement Administration,** Lesly Pompy, MD, Decision and Order, Fed. Reg., Vol. 84, No. 208, October 28, 2019, p. 57749, *57754.*

POMPY CASE (2019)
Michigan Board Guidelines on Treatment Plan

- **The written treatment plan "should** state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned…**After treatment begins, the physician should** adjust drug therapy to the individual medical needs of each patient.

- **SOURCE: Drug Enforcement Administration,** Lesly Pompy, MD, Decision and Order, Fed. Reg., Vol. 84, No. 208, October 28, 2019, p. 57749, *57754.*

The POMPY Case:
Michigan Board's Focus on Documentation

- **The physician should keep accurate and complete records** to include medical history and physical examination; diagnostic, therapeutic, and laboratory results; evaluations and consultations; treatment objectives; discussion of risks and benefits; treatments; medications (including date, type, dosage, and quantity prescribed); instructions and agreements; and, periodic review…**Medical records "should remain current and be maintained in an accessible manner and readily available for review."**

- **SOURCE: Drug Enforcement Administration,** Lesly Pompy, MD, Decision and Order, Fed. Reg., Vol. 84, No. 208, October 28, 2019, p. 57749, *57754.*

Road Map of *Things to Avoid* when Prescribing Controlled Medication

(Source: Pompy Decision and Order, DEA 2019)

Inadequate attention to an initial assessment to determine if opioids are clinically indicated and to determine the risks associated with their use in a particular patient.	Inadequate monitoring drug the use of potentially abusable medications.	Inadequate education for the patient about the risks of opioid therapy and the patient's informed consent [process and for] opioid therapy.	Unjustified dose escalation without adequate attention to risks, such as concurrent alcohol use, or to alternative treatment.	Relying excessively on opioids, particularly high dose opioids for chronic pain management, and continuing opioid therapy that does not meet clear and objective outcomes.	No using available risk mitigation tools, such as the state's PDMP, in advance of prescribing opioids and during ongoing monitoring. 2

SOURCE: Drug Enforcement Administration, Lesly Pompy, MD, Decision and Order, Fed. Reg., Vol. 84, No. 208, October 28, 2019, p. 57749-57760.

HISTORY & PHYSICAL EXAM & OTHER FAILURES ILLUSTRATED IN THE POMPY CASE

How Pompy's Medical Records Appeared to the Government's Medical Expert

- Unnecessarily voluminous patient files due to "cut and pasted" segments repeated from note-to-note; poorly organized and frequently unintelligible.
- Descriptions of patient's pain problem that were not "adequate to permit informed decision-making.
- Used the word "guarded" for each patient's prognosis.
- Negative symptoms usually noted for the musculoskeletal system element of the review of systems, though each patient was apparently being seen for a chronic pain diagnosis.
- Failure to document consideration of alternative treatments to opioid prescribing [except for pain blocks].
- No treatment records from prior physicians.
- No documentation of any contact with other healthcare providers (except imaging study reports).

SOURCE: Drug Enforcement Administration, Lesly Pompy, MD, Decision and Order, Fed. Reg., Vol. 84, No. 208, October 28, 2019, p. 57749-57760.

HISTORY & PHYSICAL EXAM & OTHER FAILURES IN THE POMPY CASE

How Pompy's Medical Records Appeared to the Government's Medical Expert

- No patient narcotic agreements. Attend PainWeek on Demand MDL06!
- Multiple dates of service with no clinical information at all.
- No documented responses to evidence of abuse or diversion. MDL06
- Ongoing prescribing of high-dose opioids without documenting a conversation with the patient about whether they had exhausted their previous supply. MDL06
- Routine prescribing of high dose therapy.

SOURCE: Drug Enforcement Administration, Lesly Pompy, MD, Decision and Order, Fed. Reg., Vol. 84, No. 208, October 28, 2019, p. 57749-57760.

How a Licensing Board Says ”Inappropriate Prescribing” in a Consent Order

In the matter of Ebenezer K. Quainoo, MD, before the Maryland State Board of Physicians, Case No. 2217-0007A, Consent Order entered 9/3/2019 as a public document. Provided as a handout to accompany this lecture for educational purposes only. Note: There is much legal procedure and related items behind each board case. The educational focus for MDL05 is on the action and documentation failures listed by the Medical Experts and adopted by the board.

The Maryland State Board of Physicians may reprimand, probate, suspend, or revoke a license if the licensee:

- Fails to meet appropriate standards as determined by appropriate peer review for the delivery of quality medical and surgical care performed in an outpatient surgical facility, office, hospital, or any other location in [Maryland]; and

- Fails to keep adequate medical records as determined by appropriate peer review.

- **SOURCE:** In the matter of Ebenezer K. Quainoo, MD, Maryland State Board of Physicians, Consent Order in Case #2217-0007A, at p. 1, citing Maryland Medical Practice Act and other authorities.

Cited failures on history, physical exam, treatment plan, informed consent, and treatment agreement - 1

- Resource: Quainoo, Licensing Board Consent Order, Maryland, 2019; See handout.

History and Physical Exam	Risk Evaluation	Treatment Plan	Informed Consent and Treatment Agreement	Documentation
Failed to document or establish physical findings to support prescribing	Failed to perform an opioid risk assessment to assess the patient's risk for opioid misuse, abuse, diversion prior to prescribing opioids	Inappropriately prescribed opioids to a patient who was also receiving benzodiazepines from another practitioner.	Did not have the patient sign a treatment agreement until two years after MD initiated prescribing.	Progress notes are inadequate in that they appear to have multiple sections that are copied from previous notes, such as history of present illness, physical examination and assessments.
Imaging studies showed no sign of fracture or lumbar disc disease; negative imaging studies.	Failed to document or undertake an objective work-up for the event of drug withdrawal seizures and failed to document or undertake a follow-up on the patient's mental health history.	Inappropriately prescribed high-dose opioid therapy in combination with benzodiazepines	MD didn't provide sufficient informed consent education	Progress notes contain inconsistent notations about medications prescribed
Failed to establish a basis to prescribe opioid medication	Failed to document substance abuse in the lifestyle/risk factors, despite a hospital admissions note during the treatment period for the patient showed polysubstance abuse and current illicit drug use	Inappropriately prescribed two extended release opioid medications concurrently, without an appropriate [and documented] rationale.	MD didn't address aberrant drug test results and thus deviated from treatment agreement	Progress notes that contain other irregularities like a history of present illness for a completely different patient.

Cited failures on history, physical exam, treatment plan, informed consent, and treatment agreement - 2

- Resource: Quainoo, Licensing Board Consent Order, Maryland, 2019; See handout.

History and Physical Exam	Risk Evaluation	Treatment Plan	Informed Consent and Treatment Agreement	Documentation
Physical findings in each clinical note remain unchanged, and lumbar and knee x-rays did not demonstrate significant abnormalities.	Inappropriately placed a patient on high-dose opioid therapy on intake and without verifying her prior opioid usage or ordering UDT	Failed to discuss the patient's history of depression with her or collaborate with a mental health professional		Failed to document coordination of care efforts
Failed to verify patient's prior opioid usage or corroborate pathological findings on imaging studies prior to placing the patient on high-dose opioid therapy		Failed to adequately document HOW HE determined his medical plan for the patient		Poorly kept patient medication lists
Prescribed escalating doses of opioids without establishing appropriate objective findings or a clinical indication to support such prescribing		Prescribed high-dose opioid therapy over a three-year period without adequate justification, clear clinical indication, and without clear benefit or increased function; Did not correlated increase in prescribing with a worsening of symptoms or progression of disease		

Part 3 – Application of History, Physical Examination, and Treatment Plan in the COVID-19 Era

A brief look at DEA's expectations during the COVID-19 PHE and documentation suggestions for ensuring compliance with DEA's prescribing guidance when telemedicine and controlled substances are at issue.

DEA Website and Guidance

https://www.deadiversion.usdoj.gov

DEA's COVID-19 Web Page

https://www.deadiversion.usdoj.gov/coronavirus.html.

/www.deadiversion.usdoj.gov/coronavirus.html

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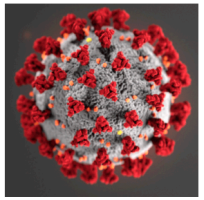
- Contact Us
- Customer Service Plan
- DEA Forms & Applications
- Mailing Addresses
- Meetings & Events
- Privacy Notice
- What's New

The mission of Drug Enforcement Administrations (DEA), Diversion Control Division is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.

During this National Emergency the Diversion Control Division is working with our Federal partners including ASPR, FEMA, HHS, FDA, ONDCP, SAMSHA, and members of the White House Task Force; DEA registrants; and representatives of the medical and health-care associations to assure that there is an adequate supply of controlled substances in the United States. The DEA will also work to assure that patients will have access to necessary drug products containing controlled substances.



Questions and Answers

Administering

DEA Guidance: **Q&A Concerning Administering Certain CS in the parking lot of a healthcare provider's DEA-registered location during the COVID-19 public health emergency**

Distributors

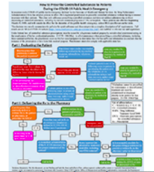
Information on Approved Alternate Satellite Locations

Suspicious Orders and Due Diligence

DEA Guidance: **Q&A Concerning Due Diligence and Knowing Your Customers.**

DEA Guidance: **Q&A Concerning Suspicious Orders.**

Prescriptions



DEA Policy: **COVID-19 Prescribing Guidance** (For assistance contact **Local DEA Field Office**) (Effective March 31, 2020)

DEA Policy: Registrant Guidance on Controlled Substance Prescription Refills (Effective March 21, 2020)

DEA Policy: **Exception to Separate Registration Requirements Across State Lines** (Effective March 25, 2020)

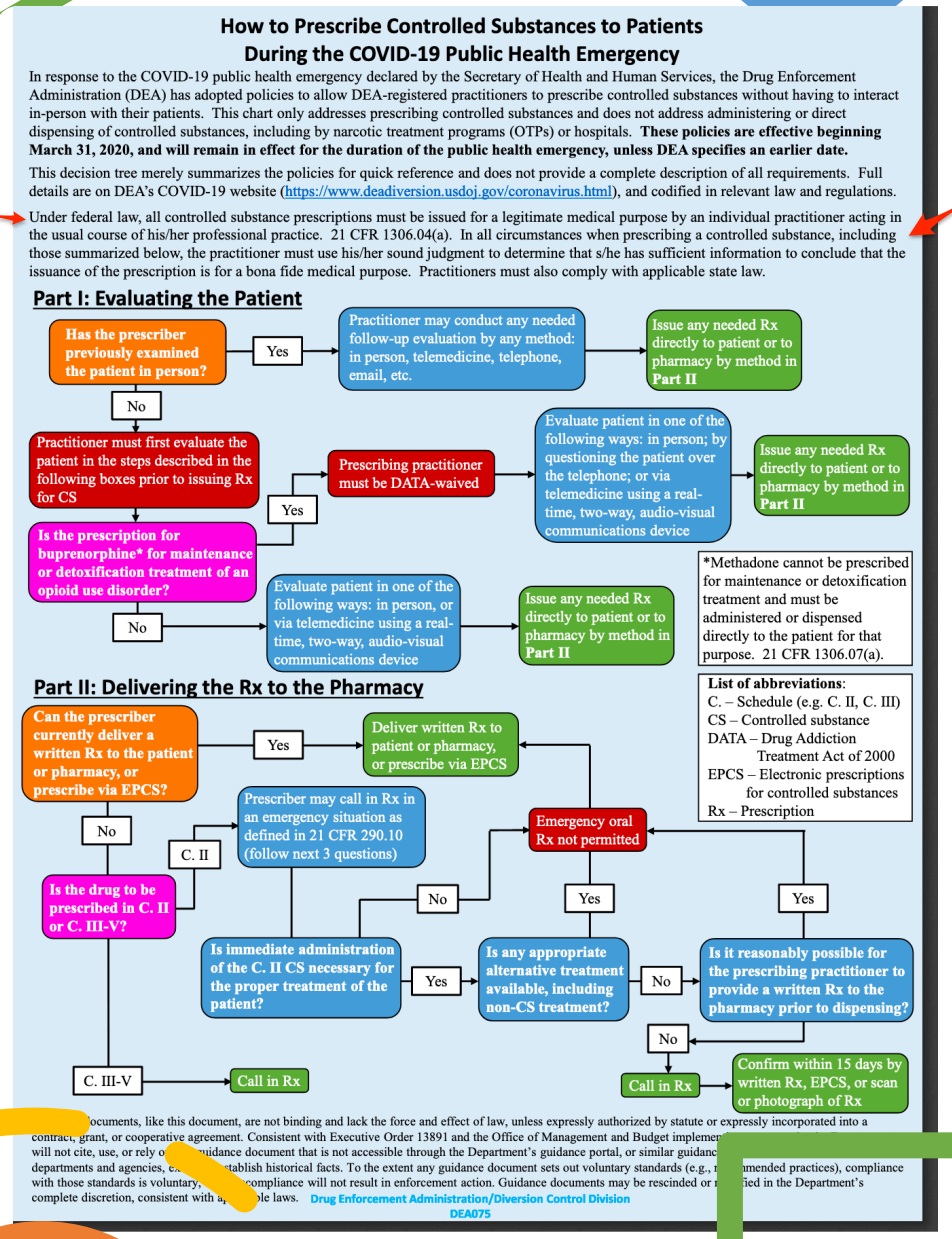
DEA Policy: **Exception to Regulations Emergency Oral CII Prescription** (Effective March 28, 2020)

DEA Guidance: Q&A Remote Identity Proofing EPCS at hospital/clinics

DEA's COVID-19 PRESCRIBING GUIDANCE

(Current as of August 11, 2020)

Available as a handout and at https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf



How to Prescribe Controlled Substances to Patients During the COVID-19 Public Health Emergency

In response to the COVID-19 public health emergency declared by the Secretary of Health and Human Services, the Drug Enforcement Administration (DEA) has adopted policies to allow DEA-registered practitioners to prescribe controlled substances without having to interact in-person with their patients. This chart only addresses prescribing controlled substances and does not address administering or direct dispensing of controlled substances, including by narcotic treatment programs (OTPs) or hospitals. **These policies are effective beginning March 31, 2020, and will remain in effect for the duration of the public health emergency, unless DEA specifies an earlier date.**

This decision tree merely summarizes the policies for quick reference and does not provide a complete description of all requirements. Full details are on DEA's COVID-19 website (https://www.deadiversion.usdoj.gov/coronavirus.html), and codified in relevant law and regulations.

Under federal law, all controlled substance prescriptions must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his/her professional practice. 21 CFR 1306.04(a). In all circumstances when prescribing a controlled substance, including those summarized below, the practitioner must use his/her sound judgment to determine that s/he has sufficient information to conclude that the issuance of the prescription is for a bona fide medical purpose. Practitioners must also comply with applicable state law.

Part I: Evaluating the Patient

- Has the prescriber previously examined the patient in person?
  - Yes → Practitioner may conduct any needed follow-up evaluation by any method: in person, telemedicine, telephone, email, etc. → Issue any needed Rx directly to patient or to pharmacy by method in **Part II**
  - No → Practitioner must first evaluate the patient in the steps described in the following boxes prior to issuing Rx for CS
- Is the prescription for buprenorphine* for maintenance or detoxification treatment of an opioid use disorder?
  - Yes → Prescribing practitioner must be DATA-waived
    - Yes → Evaluate patient in one of the following ways: in person; by questioning the patient over the telephone; or via telemedicine using a real-time, two-way, audio-visual communications device → Issue any needed Rx directly to patient or to pharmacy by method in **Part II**
    - No → Evaluate patient in one of the following ways: in person, or via telemedicine using a real-time, two-way, audio-visual communications device → Issue any needed Rx directly to patient or to pharmacy by method in **Part II**

*Methadone cannot be prescribed for maintenance or detoxification treatment and must be administered or dispensed directly to the patient for that purpose. 21 CFR 1306.07(a).

Part II: Delivering the Rx to the Pharmacy

- Can the prescriber currently deliver a written Rx to the patient or pharmacy, or prescribe via EPCS?
  - Yes → Deliver written Rx to patient or pharmacy, or prescribe via EPCS
  - No → Is the drug to be prescribed in C. II or C. III-V?
    - C. II → Prescriber may call in Rx in an emergency situation as defined in 21 CFR 290.10 (follow next 3 questions)
      - Is immediate administration of the C. II CS necessary for the proper treatment of the patient?
        - Yes → Is any appropriate alternative treatment available, including non-CS treatment?
          - No → Is it reasonably possible for the prescribing practitioner to provide a written Rx to the pharmacy prior to dispensing?
            - No → Call in Rx → Confirm within 15 days by written Rx, EPCS, or scan or photograph of Rx
            - Yes → Emergency oral Rx not permitted
          - Yes → Emergency oral Rx not permitted
        - No → Emergency oral Rx not permitted
    - C. III-V → Call in Rx

List of abbreviations:
C. – Schedule (e.g. C. II, C. III)
CS – Controlled substance
DATA – Drug Addiction Treatment Act of 2000
EPCS – Electronic prescriptions for controlled substances
Rx – Prescription

ocuments, like this document, are not binding and lack the force and effect of law, unless expressly authorized by statute or expressly incorporated into a contract, grant, or cooperative agreement. Consistent with Executive Order 13891 and the Office of Management and Budget implemen will not cite, use, or rely o uidance document that is not accessible through the Department's guidance portal, or similar guidanc departments and agencies, e tablish historical facts. To the extent any guidance document sets out voluntary standards (e.g., r mended practices), compliance with those standards is voluntary, compliance will not result in enforcement action. Guidance documents may be rescinded or r fied in the Department's complete discretion, consistent with a le laws. Drug Enforcement Administration/Diversion Control Division DEA075

Part 4 – Using What We've Learned to Move Forward

Updating Documentation of History and Physical Exam and Ideas on Individualizing During the COVID Era

Plan for Demonstrating that you are prescribing for a “Legitimate Medical Purpose”

- The use of opioids for pain management is for a legitimate medical purpose when the use is based on sound clinical judgement and current best clinical practices and is appropriately documented and demonstrably benefits the patient.
- Stay current with clinical literature and position statements facilitating the landscape called “standard of care.”
- Undertake a careful written analysis of the risks and benefits of opioid therapy for each individual patient. What may be obvious to you may not be discovered by a reviewing medical expert!
- Make a point of leaving a ”cheese trail” highlighting and/or summarizing your rationale and your actions in compliance with licensing board guidelines/rules.

Plan for Demonstrating that you are “Acting within the usual course of professional practice”

- The use of opioid therapy for pain management is within the usual course of professional practice when a legitimate physician-patient relationship exists, the [opioid] use is appropriate for the identified diagnosis, and there is careful follow up monitoring of the patient’s response to treatment and the patient’s safe use of the medication, the opioid therapy is adjusted when needed, and appropriate referrals are documented.

- Physicians are expected to incorporate safeguards into their practices to minimize the risk of misuse and diversion of controlled substances.

Recommended Steps for Attendees: Reflect and Evaluate

Obtain copies of current board guidelines and/or rules.

Read the Pompy and Kahn-Jaffrey cases (MDL05 and MDL06); Read Quainoo Maryland Board Consent Order.

Create your own checklist of board requirements for each element, i.e., History, Physical Exam, Treatment Plan; Consult the DEA's COVID-19 Prescribing Guidance to Ensure Proper Handling of Patients whom you have not previously evaluated.

Identify two or three charts and review them using what you've learned

Create a template that will help you remember to enter individualized decision-making summaries into each patient chart; Templates help you because they require you to add individual patient facts and document rationale for your actions.

Summary of Critical Points for MDL05

- ✓ Make sure your history and physical examination of each patient is "individualized" and go beyond the boiler-plate entries generated by the EMR. Try to include factual statements that make it obvious you took appropriate steps to gather a complete history (general and pain specific) and that you performed a condition-appropriate physical examination. Initial and date all documents you review and make reference to them in your treatment plan and as relevant during periodic review.

- ✓ Make sure you are conducting a situation appropriate "telemedicine or telehealth" visit using the DEA's guidance document (handout). DEA distinguishes between NEW (not previously evaluated) and ESTABLISHED (where you have performed an evaluation and with whom you have established a practitioner-patient relationship).

Summary of Critical Points for MDL05

- ✓ Familiarize yourself with and follow licensing board expectations regarding individualization of patient care when prescribing chronic opioid therapy.
- ✓ Use caution when relying on the boilerplate statements like “performed a physical examination,” especially watch cutting and pasting vital signs and certain terms that should vary each visit versus read 100% the same. Strive to clearly document your efforts to perform the physical examination and make sure it’s not just an observation. A few sentences summarizing your individual thoughts about the patient, their diagnosis, and your treatment plan, will go a long way.
- ✓ Make sure your treatment plan establishes clear goals and time frames within which to measure treatment failure or success; be sure treatment alternatives are not only explained to the patient but documented and explained as to why they will or will not work for the patient.
- ✓ Explain your plan for keeping the patient safe and moving along the path toward improved function (physical and psychosocial) and contain reasonable efforts to mitigate against patient harm and abuse/diversion.
- ✓ A well, thought-out treatment plan at the beginning is critical. Establish boundaries that can be reviewed, tested, changed, and updated based on incoming facts and current clinical care.

Summary of Critical Points for MDL05

- ✓Success starts with a reflection on and acceptance of your responsibilities as a healthcare professional and prescriber of controlled substances.

- ✓The “acceptance” role must be genuine for it to help if you find yourself in a DEA Administrative or Licensing Board Case.

- See Pompy (2019) and Kahn-Jaffrey (2020).

Other initial considerations

- Get records *directly* from prior providers where possible.
- Use a written treatment plan that includes a summary of your risk evaluation and medical decision-making regarding patient's risk level and an opioid trial (if applicable)(See MDL06 on Risk Evaluation).
- Order other diagnostic tests; Evaluate and tie into a provider summary explaining the diagnosis/working diagnosis and next steps with goals and time frame.
- Reassess frequently in accordance with objective patient data. needs

Ask yourself and create a paper trail answering these questions and their obvious sub-parts

- What is conventional medical practice when treating the patient's specific pain state and overall medical situation?
- Are there other treatments that are effective and feasible, and have a risk-to-benefit ratio as good as or better than opioids?
- Is the patient particularly vulnerable to opioid side-effects?
- Is the patient likely to take opioids responsibly or within boundaries of a treatment agreement?

Document your thought process and capture conversations with the patient in a manner that goes beyond boilerplate!

- "[Pompy's] medical expert testified that he "would expect more medical decision-making and talk about treatment and why certain treatments are implemented…It's just good practice to explain what you've discussed with the patient and their response."

- **SOURCE: Drug Enforcement Administration,** Lesly Pompy, MD, Decision and Order, Fed. Reg., Vol. 84, No. 208, October 28, 2019, p. 57749, *57760.*

Thank you for attending PainWeek and MDL05!

- Jennifer Bolen, JD
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- I appreciate you!

Question 1 – MDL05

- History and Physical Examination, together with a Treatment Plan, relate most to which element of the federal requirement for a valid controlled substance prescription?
- A. Evaluation of the patient
- B. Risk Assessment
- C. The Legitimate Medical Purpose for the Use of a Controlled Substance
- D. Informed Consent
- The correct answer is C. By performing a history and physical examination, the prescriber is able to identify whether there is one or more generally recognized indications for the patient's use of a controlled substance. This, together with a formal diagnosis and treatment plan, is how a prescriber shows legitimate medical purpose aspect of a valid controlled substance prescription.

Question 2 – MDL05

- **FACT PATTERN: Jane Smith is a new patient**. You obtain records from Jane's family physician and these records show that Jane has been diagnosed with chronic pain deriving from an old bicycle accident. Jane has been using hydrocodone, 10/325, three times per day, and occasionally uses cyclobenzaprine to treat back and leg spasms. Recently, Jane has experienced burning pain down her right side and into her right leg. She's been using all her daily allotment of hydrocodone as well as her muscle relaxant. Jane is anxious and slightly depressed because she doesn't like using these medications, especially because she caters meals around town and often finds herself taking potential clients out to dinner where wine is served. Jane is a non-smoker, social drinker, and has no history of illicit drug use. Her mom was an alcoholic, which is why Jane doesn't drink much. Jane reports having about seven days of her opioids left and a four-day supply of her other medication.
- **QUESTION:** What else should you do during your evaluation of Jane to ready yourself to write a treatment plan that includes a continuation of opioid therapy (>90 days), a switch of medication from hydrocodone to oxycodone and a new muscle relaxant or Gabapentin for the burning pain Jane has described? [Pick the most complete answer that allows you to demonstrate that you are acting in the usual course of professional practice as identified by your licensing board guidelines/rules].

Question 2 – MDL05

- A. Evaluate existing diagnostic reports and perform a condition-appropriate physical examination of Jane to establish a working diagnosis; order updated imaging studies to evaluate Jane's complaint of burning nerve pain down her hip and into her right leg; Examine the PDMP database, talk to Jane about her family and personal history of alcohol use, drug use (prescribed or not and illicit drugs), and behavioral health issues, and order a drug test; Ask Jane to tell you how many tablets of hydrocodone you have left and ask her to come back in a week for discussion of her UDT results and a trial of oxycodone; Begin the informed consent process and review the treatment agreement with her.
- B. Perform a drug test and a PDMP check and issue Jane a 14-day supply of hydrocodone and have her come back in two weeks for a checkup.
- C. Order an MRI and write Jane a 3-day supply of oxycodone and a 30-day supply of Gabapentin to help her gain some relief; Check the PDMP before releasing the prescriptions and get Jane's signature on your informed consent and treatment agreement document.
- D. Send Jane for a psychiatric evaluation to identify her true risk level and wait on all prescribing until you get the results of this report, the results of the drug test, and the results of her new imaging studies before you consider prescribing anything to Jane.

- The correct answer is A, because it most closely resembles the "usual course of professional practice" steps a prescriber is expected to take when considering a patient for chronic opioid therapy. While it doesn't contain every step required by most licensing boards, it captures the spirit of the practitioner's obligation to following the prescribing standards for chronic opioid therapy and is therefore the most complete answer in the context of this educational effort.

Question 3 – MDL05

- TRUE OR FALSE: Most state licensing boards with published regulations and/or guidelines for chronic opioid therapy require a written treatment plan and recommend that the treatment plan include specific goals for the patient's care plan and how the practitioner and patient will measure improvement in function and evaluate the risks and benefits of the prescribed medication during a trial period. The plan should also include identified visit intervals, use of UDT, medication counts, complimentary drug and non-drug therapies as appropriate to the patient, and any planned/updated diagnostic tests.
- A. True
- B. False

- The correct answer is A, True. Most state licensing boards have adopted rules and/or guidelines that require a written treatment plan and either requirements or suggestions that the plan include, among other things, the items listed in the statement above.