BEST PRACTICES FOR PRESCRIBING CONTROLLED MEDICATIONS FOR PAIN: THE LEGAL PERSPECTIVE

Jennifer Bolen, JD
Former Federal Prosecutor
Founder, the Legal Side of Pain®
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The presentation was created by Jennifer Bolen, JD.
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Objectives

• Describe the current landscape for the use of chronic opioid therapy

• Identify common substandard clinical practices that often lead to liability for the prescriber

• Identify critical improvements and best practices that lead to improved prescribing and risk management
State of Pain 2013

Unprecedented Change

- Increased Investigations
- Harsh Pressure
- Harsh Penalties
- Increased Overdose Events
- Fight for Balance
The Landscape – Government Perceptions, Presumptions and Suspicions

Clinics that only prescribe CS without other forms of treatment (real, not just recommended) are providing substandard care.

Cash-only clinics are designed to deal drugs and

Clinics that prescribe OPI and BZO chronically without having the patient properly evaluated

Clinics that consistently prescribe high-dose opioid therapy (greater than 200mg MEDD)

“Hamster-mill” operations

Combination of health care fraud and improper prescribing
There is a movement (PROP) to limit access to opioids backed by numerous members of the clinical community; *The movement has momentum.*

Medical experts (Administrative and Criminal Cases) are wildly divergent in their testimony regarding standard of care; *Proactive understanding is a must.*

Inappropriate prescribing investigations are focused on many different types of prescribers, including board-certified clinicians, and often include criminal charges, especially when overdose is involved.

The pain community failed you when they taught you about “informed consent”; It’s a process not just a piece of paper.

Standards of care are increasingly focused on dose, chronicity, and overall patient selection (suitability) and risk management, including the role of drug testing in the clinical setting.
Identified Risk Areas - Clinical

- Dose (> 100mg MEDD)
- Unexplained jumps in dosing
- Chronicity (>90 consecutive days on COT without proper review and documentation)
- Combination LAO+SAO, SAO + SAO, LAO + LAO
- Combination Opioids and Benzodiazepines
- Co-morbid psychiatric problems
- Sleep Apnea
- History of Cocaine Abuse
- Current Cocaine Abuse
- Alcohol
Identified Risk Areas – Case Management

• Lack of physical evaluation

• Lack of treatment plan

• Lack of informed consent and patient education

• Inconsistent Drug Testing

• Weaknesses in Drug Testing Response

• Inconsistencies in PDMP usage

• Scope of Practice

• Inconsistent use of specialty referral (internal) and failure to coordinate care

• Lack of an appropriate opioid suitability review

• Failure to document clinical rationale
1. The government is investigating more than just pill mills.

2. You can lose your DEA registration for one instance of prescribing without a legitimate medical purpose and outside the usual course of professional practice.

3. The government (and many clinicians) believe that people who take opioids become addicted within 90 days.

4. There is huge pressure on law enforcement to hold prescribers accountable, especially in instance of overdose deaths. **CAUSATION ISSUES**

5. You will be held accountable in court for failing to take steps, such as appropriate drug testing, responding to inappropriate test results, including marihuana, and more.
How Do Licensing Board Investigations Begin?

- Pain Clinic Inspection (Routine)
- Follow-Up
- Report Rendered w/deficiencies
- Licensing Board

Complaint filed by the public (often pharmacists or family members)

- Adverse Incident Occurs
- Adverse Incident Report filed

- Law Enforcement investigation
- Criminal conduct suspected
- Criminal Process Instituted
Critical Issues

- Patient non-fatal and fatal overdose events
  - How do you handle your adverse events?
  - What do you do to stay current?
  - How would you rank yourself in terms of patient education?
  - How can you improve?
CASE FACTORS
Substandard practices revealed through published legal cases (administrative and criminal)
Inside or Outside? Where do your prescribing practices fall?

- Best Practices (Evidence Based Medical Standards)
- Generally Accepted Practices
- Guidelines and Position Statements
LOOK BACK SYNDROME: Legal Perspective

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IYER (DEA Administrative Case 2009)

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 03–8]

Jayam Krishna-Iyer, M.D.; Suspension of Registration; Granting of Renewal Application Subject to Condition

On September 1, 2006, I, the Deputy Administrator of the Drug Enforcement Administration, ordered that the DEA Certificate of Registration issued to Jayam Krishna-Iyer, M.D. (Respondent), of Clearwater, Florida, be revoked.
3 Having carefully re-reviewed the charts, it should be noted that some of the files suggest that this is an assumption which is highly favorable to Respondent. Under agency precedent, DEA’s authority to suspend or revoke a registration is not limited to those instances in which a practitioner intentionally diverts. See Paul J. Caragine, Jr., 63 FR 51592 (1998). A practitioner who ignores the warning signs that her patients are either personally abusing or diverting controlled substances commits “acts inconsistent with the public interest,” 21 U.S.C. 824(a)(4), even if she is merely gullible or naïve. 63 FR at 51600. The twelve patient charts cited by Respondent as evidence of her “positive experience” included numerous instances in which Respondent appears to have ignored warning signs that the patient was either abusing or diverting controlled substances.
IYER POINTS

• Responsibility to issue prescriptions for a legitimate medical purpose while acting in the usual course of professional practice.

• Responsibility to monitor patients (as a part of routine clinical practice) for warning signs that they are personally abusing or diverting their medications.
  • Warning signs include, among other things, the use of illicit substances.

• Failure to fulfill these responsibilities constitutes acts inconsistent with the public health and safety.
INTRODUCTION TO STATE LEGAL AND PAIN POLICY MATERIALS

General background
Examples of State Legal Materials

- Prescribing Guidelines by Boards
- Policy Statements by Licensing Boards
- Controlled Substances Act Rules
- Licensing Board Rules
- Unprofessional Conduct Codes
- Controlled Substances Act
- Intractable Pain Treatment Act**
- Medical Practice Act
Preventing Opioid Diversion and Abuse: The Board also recognizes that individuals' use of opioid analgesics for other than legitimate medical purposes poses a threat to the health and safety of the individual as well as to the public health [3]. The Board further recognizes that inappropriate prescribing of controlled substances by physicians may contribute to drug misuse and diversion by individuals who seek opioids for other than legitimate medical purposes [5,19,44]. Accordingly, the Board expects physicians to incorporate safeguards into their practices to minimize the risk of misuse and diversion of opioid analgesics and other controlled substances [19-23,38,45-46].

Allegations of inappropriate pain management will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for deviating from this Model Policy when contemporaneous medical records show reasonable cause for such a deviation.

The Board will judge the validity of the physician’s treatment of a patient on the basis of available documentation, rather than solely on the quantity and duration of medication administered. The goal is the management of the patient’s pain while effectively addressing other aspects of the patient’s functioning, including physical, psychological, social and work-related factors [4,29].

The Board will consider the unsafe or otherwise inappropriate treatment of pain to be a departure from accepted standards of practice, taking into account whether the treatment is appropriate to the diagnosis and the patient's level of risk.
Patient Evaluation and Risk Stratification: The medical record should document the presence of one or more recognized medical indications for prescribing an opioid analgesic [7] and reflect an appropriately detailed patient evaluation [38]. Such an evaluation should be completed before a decision is made as to whether to prescribe an opioid analgesic.

The nature and extent of the evaluation depends on the type of pain and the context in which it occurs. For example, meaningful assessment of chronic pain, including pain related to cancer or non-cancer origins, usually demands a more detailed evaluation than an assessment of acute pain. Assessment of the patient’s pain typically would include the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical and psychological functioning [31]. Validated brief assessment tools that
measure pain and function, such as the three-question "Pain, Enjoyment and General Activity" (PEG) scale [47], may be helpful.

For every patient, the initial work-up should include a systems review and relevant physical examination, as well as laboratory investigations as indicated [33,36,48-53]. Such investigations help the physician address not only the nature and intensity of the pain, but also its secondary manifestations, such as its effects on the patient's sleep, mood, work, relationships, valued recreational activities, and alcohol and drug use.

Social and vocational assessment is useful in identifying supports and obstacles to treatment and rehabilitation; for example: Does the patient have good social supports, housing, and meaningful work? Is the home environment stressful or nurturing? [14].

Assessment of the patient's history of alcohol or drug abuse and relative risk for medication misuse or abuse also should be part of the initial evaluation [11,14,21-23,45], and ideally should be completed prior to a decision as to whether to prescribe opioid analgesics [56-58]. This can be done through a careful clinical interview, which also should inquire into any history of physical, emotional or sexual abuse, because those are risk factors for substance misuse [31]. Use of a validated screening tool (such as the Screener and Opioid Assessment for Patients with Pain [SOAPP-R; 48] or the Opioid Risk Tool [ORT; 49]) can save time in collecting and evaluating the information and determining the patient's level of risk.
Informed Consent and Treatment Agreement: The physician should discuss the risks and benefits of the treatment plan (including any proposed use of opioid analgesics) with the patient, with persons designated by the patient, or with the patient’s surrogate or guardian if the patient is without medical decision-making capacity [32,35]. If opioids are prescribed, the patient (and possibly family members) should be counseled on safe ways to store and dispose of medications [3,37].

Use of a written informed consent and treatment agreement (sometimes referred to as a "treatment contract") is recommended [21-23,35,38].

Informed consent documents typically address:

- The potential risks and anticipated benefits of chronic opioid therapy;
- Potential side effects (both short- and long-term) of the medication, such as constipation and cognitive impairment;
- The likelihood that tolerance to and physical dependence on the medication will develop;
- The risk of drug interactions and over-sedation;
- The risk of impaired motor skills (affecting driving and other tasks);
- The risk of opioid misuse, dependence, and overdose;
- The physician's prescribing policies and expectations, including the number and frequency of prescription refills, as well as the physician's policy on early refills and replacement of lost or stolen medications.
- Specific reasons for which drug therapy may be changed or discontinued (including violation of the policies and agreements spelled out in the treatment agreement).
**Ongoing Monitoring and Adapting the Treatment Plan:** The physician should regularly review the patient's progress, including any new information about the etiology of the pain or the patient's overall health and level of function [35, 49-50]. The patient should be seen more frequently while the treatment plan is being initiated and the opioid dose adjusted [44-51]. As the patient is stabilized in the treatment regimen, follow-up visits may be scheduled less frequently. (However, if the patient is seen less than monthly and an opioid is prescribed, arrangements must be made for the patient to obtain a refill or new prescription when needed.)

At each visit, the results of chronic opioid therapy should be monitored by assessing what have been called the “4 As” of chronic pain management; these involve a determination of whether the patient is experiencing a reduction in pain (Analgesia), has demonstrated an improvement in level of function (Activity), whether there are significant Adverse effects, and whether there is evidence of Aberrant substance-related behaviors [38, 52].
Periodic drug testing may be useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs [53-54]. Drug testing is an important monitoring tool because self-reports of medication use by pain patients can be unreliable and behavioral observations may detect some problems but not others [55-59].

Urine may be the ideal biologic specimen for testing because of its ease of collection and storage and the cost-effectiveness of such testing [53]. When such testing is conducted as part of pain treatment, forensic standards are not in place, so collection is not observed and chain-of-custody protocols are not followed. Initial testing may be done using class-specific immunoassay drug panels (point-of-care or laboratory-based), which typically do not identify particular drugs within a class unless the immunoassay is specific for that drug. If necessary, this can be followed up with a
more specific technique, such as gas chromatography/mass spectrometry (GC/MS) or other chromatographic tests to confirm the presence or absence of a specific drug or its metabolites [53].

Physicians need to be aware of the limitations of available tests (such as their limited sensitivity for many opioids) and take care to order tests appropriately [54]. For example, when a drug test is ordered, it is important to specify that it include the opioid being prescribed [53]. Because of the complexities involved in interpreting drug test results, it is advisable to confirm significant or unexpected results with the laboratory toxicologist or a clinical pathologist [59-60].

Test results that suggest opioid misuse should be discussed with the patient. It is helpful to approach such a discussion in a positive, supportive fashion, so as to strengthen the physician-patient relationship and encourage healthy behaviors (as well as behavioral change where that is needed). Both the test results and subsequent discussion with the patient should be documented in the medical record [53].
Bolen’s Five Laws of Survival
Law #1

Stay current with federal and state law changes.
Law #2

Review your documentation and make sure it is more than just checklists and EMR template language;

Your decision-making/clinical rationale is critical to proper documentation!
Law #3

Informed consent is a process *not* just a piece of paper a/k/a Treatment Agreement.
### Informed Consent v. Treatment Agreement (Paper and Process)

<table>
<thead>
<tr>
<th>Informed Consent</th>
<th>Treatment Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Risks</td>
<td>• One physician for Rx of CS</td>
</tr>
<tr>
<td>• Benefits</td>
<td>• One pharmacy for Fill of CS Rx</td>
</tr>
<tr>
<td>• Treatment Alternatives</td>
<td>• Drug Testing</td>
</tr>
<tr>
<td>• Special Issues</td>
<td>• Prescription Monitoring Reports</td>
</tr>
<tr>
<td>• Patient Education BEYOND the label and just letting the pharmacist do it!</td>
<td>• Medication Counts?</td>
</tr>
<tr>
<td></td>
<td>• Family Conferences?</td>
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<tr>
<td></td>
<td>• Visit Frequency?</td>
</tr>
<tr>
<td></td>
<td>• Other boundaries associated with patient monitoring and practice protocols.</td>
</tr>
</tbody>
</table>
Law #4

If you are not drug testing new and established patients, get on the bus or stop prescribing chronic opioid therapy.
Law #5

A. Proper patient selection is a must.
B. Scope of Practice Issues Critical.
C. Risk Assessment and Monitoring must be real and be based on current clinical literature and consultations and referrals must be used to address addiction, behavioral issues, and other special healthcare needs.
Peer-Proofing your practice
Critical Guideposts
Language Lessons

Should

Shall

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Example

**SHALL MEANS . . .**

those items a practitioner is required to perform

**SHOULD MEANS . . .**

those actions that a prudent practitioner will either do and document or be able to provide a thoughtful explanation as to why the practitioner did not do so

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Harm Reduction Strategies*

- Patient and Staff Education
- Address CNS issues and related medical conditions (sleep apnea, multiple CNS depressants in medication therapy, sleep hygiene)
- Weight Loss, Smoking Cessation
- Alcohol education and compliance measures
- Safe Use, Storage, and Disposal Education
- Coordination of Care issues

- Adapted from Ballantyne slides 2012
Another Reason to Proactively Engage in Active Patient Management

4 Drug addicts can be vulnerable victims. See, e.g., United States v. Dullum, 560 F.3d 133, 135 (3d Cir. 2009); United States v. Amedeo, 370 F.3d 1305, 1317 (11th Cir. 2004); United States v. Evans, 272 F.3d 1069, 1095 (8th Cir. 2001); United States v. Pavao, 948 F.2d 74, 78 (1st Cir. 1991).
A Guide to Safe Use of Pain Medicine

If you’ve ever been treated for severe pain from surgery, an injury, or an illness, you know just how vital pain relief medications can be.

Pain relief treatments come in many forms and potencies, are available by prescription or over-the-counter (OTC), and treat all sorts of physical pain—including that brought on by chronic conditions, sudden trauma, and cancer.

Pain relief medicines (also known as “analgesics” and “painkillers”) are regulated by the Food and Drug Administration (FDA). Some analgesics, including opioid analgesics, act on the body’s peripheral and central nervous systems to block or decrease sensitivity to pain. Others act by inhibiting the formation of certain chemicals in the body.

Among the factors health care professionals consider in recommending or prescribing them are the cause and severity of the pain.

Types of Pain Relievers

OTC Medications
These relieve the minor aches and pains associated with conditions such as headache, fever, colds, flu, arthritis, toothaches, and menstrual cramps.
How to Dispose of Unused Medicines

Is your medicine cabinet filled with expired drugs or medications you no longer use? How should you dispose of them?

Most drugs can be thrown in the household trash, but consumers should take certain precautions before tossing them out, according to the Food and Drug Administration (FDA). A few drugs should be flushed down the toilet. And a growing number of community-based “take-back” programs offer another safe disposal alternative.

Guidelines for Drug Disposal

FDA worked with the White House Office of National Drug Control Policy (ONDCP) to develop the first consumer guidance for proper disposal of prescription drugs. Issued by ONDCP in February 2007 and updated in October 2009, the federal guidelines are summarized here:

- Follow any specific disposal instructions on the drug label or patient information that accompanies the medication. Do not flush prescription drugs down the toilet unless this information specifically instructs you to do so.
- Take advantage of community drug take-back programs that allow the public to bring unused drugs to a central location for proper disposal. Call your city or county government’s household trash and recycling service (see blue pages in phone book) to see if a take-back program is available in your community. The Drug Enforcement Administration, working with state and local law enforcement agencies, is sponsoring National Prescription Drug Take Back Days (www.deadwarsenends.gov) throughout the United States.
- If no instructions are given on the drug label and no

Take drugs out of their original containers and mix them with an undesirable substance, such as used coffee grounds …

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NEW FDA PATIENT COUNSELING TOOL

Creating a cheese trail

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Drug Testing Policy: Overview

• **YOU NEED ONE** – The policy should consider directives from clinical, coverage, and regulatory materials.

• **EVERYONE SHOULD FOLLOW IT** - The policy will be written and all stakeholders will be required to undergo education on same.

• **IT ALLOWS FOR INDIVIDUALIZATION** - According to evaluated and documented patient risk levels (L, M, H, VH)

• **BALANCED** – Need for testing with fiscal responsibility.
Dr. Kennedy found the Respondent’s controlled substance patient monitoring to be deficient in numerous respects. From the reviewed patient charts, Dr. Kennedy gleaned that an initial, in-office urine drug screen was frequently executed during the patients’ initial visit to the office but repeated only occasionally. Govt. Ex. 55 at 14. It was Dr. Kennedy’s observation that even a drug screen anomaly did not alter the seemingly inexorable continuation of controlled substance prescribing from the Respondent. Id. Dr. Kennedy also noted that the Respondent did not utilize out-of-office toxicology tests, or obtain out-of-State prescription monitoring program or outside pharmacy drug profiles. Furthermore,
EXAMPLE – REASONS FOR TESTING

- **Targeted Testing**
  (Based on Developing Facts)

- **Randomized Screen with Limited Confirmations**
  (Based on Risk Level)

- **Baseline**
  (all patient-candidates subject to 2 prior appropriate tests policy)*

*See written policy*
Common Questions

• Is a Point of Care drug screen sufficient?
• Do I have to test for marihuana?
• Do I have to confirm POC screen results?
• Do I have to use urine testing?
The consequences of not getting this right
Follow-up & Questions?

Jennifer Bolen, JD
jbolen@legalsideofpain.com
865-755-2369