BEST PRACTICES:
DOCUMENTATION OF CLINICAL RATIONALE
FOR CHRONIC OPIOID THERAPY –
THE LEGAL PERSPECTIVE PART I

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Founder, the Legal Side of Pain®
Presented August 2013

The presentation was created by
Jennifer Bolen, JD.
The following slides are provided for your
information and are not intended to
provide legal advice.
Please consult with qualified legal
counsel for specific legal advice.

Objectives
• 1. To facilitate practice improvements by educating practitioners about
state licensing board expectations about medical record documentation
relating to the use of chronic opioid therapy;

• 2. To facilitate practice improvements and understanding of the
informed consent and patient education process surrounding the
chronic opioid therapy treatment plan, using a comparison of poor,
average, and good documentation of the same; and

• 3. To facilitate improved quality of care by providing practitioners with
new tools to document patient education on safe use, storage, and
disposal of prescription medication, and to properly handle termination
of care through discharge and referral, so the patient is not abandoned.
State of Pain 2013

Unprecedented Change

- Increased Investigations
- Increased Overdose Events
- Harsh Pressure
- Harsh Penalties
- Fight for Balance

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

Inside or Outside? Where do your prescribing practices fall?

- Best Practices (Evidence Based Medical Standards)
- Generally Accepted Practices
- Guidelines and Position Statements
### FSMB 2013 Model Policy (FINAL)
A look at critical risk issues

<table>
<thead>
<tr>
<th>Problem</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadequate attention to initial</td>
<td>A solid risk vs. benefit analysis with proper history, physical examination, review of prior</td>
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<tr>
<td>assessment to determine if opioids</td>
<td>records, including an evaluation of prior treatments tried and patient response. Also</td>
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<tr>
<td>are clinically indicated and to</td>
<td>includes proper risk evaluation.</td>
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<tr>
<td>determine risks associated with their</td>
<td></td>
</tr>
<tr>
<td>use in a particular individual with</td>
<td></td>
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<tr>
<td>pain</td>
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<thead>
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<tbody>
<tr>
<td>Inadequate monitoring during the use</td>
<td>Use reliable and validated tools available to you. Drug testing, medication</td>
</tr>
<tr>
<td>of medication with potential abuse</td>
<td>counts, PMP database information, adjusted visit frequencies, ongoing risk and</td>
</tr>
<tr>
<td>profiles</td>
<td>behavioral evaluation interview questions, and the Four A's of patient follow-up</td>
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<td></td>
<td>care: Activity, Analysis, Adverse Events, and Aberrant Behavior.</td>
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</table>

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<th>Problem</th>
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<tr>
<td>Inadequate attention to patient</td>
<td>The traditional narcotic contract, more properly referred to as a treatment</td>
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<tr>
<td>education and informed consent</td>
<td>agreement, is not the real focus of the process of informed consent. You must</td>
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<tr>
<td></td>
<td>educate the patient on the risks, benefits, special issues and treatment</td>
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<tr>
<td></td>
<td>alternatives to the opioid therapy. You should also educate the patient on the</td>
</tr>
<tr>
<td></td>
<td>safe use, storage and disposal of controlled medication. This information should</td>
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<tr>
<td></td>
<td>be updated when making major changes to the treatment plan or as otherwise</td>
</tr>
<tr>
<td></td>
<td>necessary to keep the patient informed.</td>
</tr>
<tr>
<td>Unjustified dose escalation without adequate attention to risks, special issues and alternative treatments</td>
<td>Documenting clinical rationale for any upward dose adjustments is critical. Before making an upward adjustment (or adding in another controlled medication), the practitioner should update a summary of the patient’s status and ensure a proper discussion regarding risks, special issues and alternative treatments.</td>
</tr>
<tr>
<td>---</td>
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</tr>
<tr>
<td>Excessive reliance on opioids, particularly high dose opioids for chronic pain management, increases risk for multiple health-related issues.</td>
<td>Practitioners should be familiar with the developing body of literature tying dose to increased risk of all kinds.</td>
</tr>
</tbody>
</table>

**Net making use of available tools for risk mitigations**

**Caution:** Many of the tools have poor data behind them. Use only those tools with statistically relevant application and solid evidence of assisting you in the risk evaluation and monitoring process. Uninformed risk stratification can ruin it for all providers and the patient!

**LANGUAGE FROM NEW FSMB MODEL POLICY**

**IMPORTANT:** According to the 2013 FSMB Model Policy (cited above) and pursuant to evolving new clinical and regulatory guidelines, providers are likely to be held to a more aggressive legal standard referred to by the FSMB as the “safe and BEST CLINICAL PRACTICE STANDARD.” This language appears to vary from the legal standard for a valid controlled substance prescription, which involves a legitimate medical purpose and an individual prescribing acting in the “usual course of professional practice.” Thus, law enforcement authorities may now seek medical expert testimony along the lines that “usual course of professional practice” is now a best clinical practice standard, leaving little room for error. Practitioners should discuss the legal standard issue with qualified legal counsel.

Under new guidelines, licensing boards are likely to “consider the unsafe or otherwise inappropriate treatment of pain to be a departure from best clinical practice, taking into account whether the treatment is appropriate to the diagnosis and the patient’s level of risk.”
Rule #1

Prepare a checklist using your state licensing board’s pain prescribing rules and policies.
Language Lessons

Should  Shall

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

Rule #2
Use the checklist to evaluate your current documentation practices:

A. Forms
B. Correspondence
C. Update Chart Summaries
Rule #3

Learn to document *why* you did or not do something mandated or recommended by your licensing board.
Rule #4

Perform a true risk evaluation and document your findings and decision making based thereon. Your treatment plan should reflect this evaluation.
Risk Evaluation

- Medication specific
  - 100mg MEDD or greater (increases risk; not an end-point)
  - Controlled Medication from multiple providers?
  - Recent history of pain-related ER visits?

- Behavior-related
  - Dismissed from Other Practice?
  - History of Overtaking Medications?
  - History of Street Drug Use?
  - Pushing for Specific Medication?
  - Bi-Polar or ADD/ADHD?
  - Past Medication Thefts
  - Involved in Legal Cases?
  - Honesty Issues (Lie about anything)?

- Other
  - Any intellectual challenges (cognitive)?
  - Other Family Members on Meds?

Document Risk Analysis

Risk Stratification

- Behavioral & Substance Abuse History
- Current Medication Usage & PMP
- Personal
- Family
- UDT
Rule #5

Create and document a true informed consent process (not just a piece of paper).
Informed Consent v. Treatment Agreement (Paper and Process)

Informed Consent
- Risks
- Benefits
- Treatment Alternatives
- Special Issues
- Patient Education
  BEYOND the label and just letting the pharmacist do it!

Treatment Agreement
- One physician for Rx of CS
- One pharmacy for Fill of CS Rx
- Drug Testing
- Prescription Monitoring Reports
- Medication Counts?
- Family Conferences?
- Visit Frequency?
- Other boundaries associated with patient monitoring and practice protocols.

21. Informed consent documents typically address:
   - A. The potential risks and anticipated benefits of chronic opioid therapy.
   - B. Potential side effects (both short- and long-term) of the medication, such as constipation and cognitive impairment.
   - C. The likelihood that tolerance and physical dependence on the medication will develop.
   - D. The risk of drug interactions and overdose.
   - E. The risk of impaired motor skills (affecting driving and other tasks).
   - F. The risk of opioid misuse, dependence, addiction, and overdose.
   - G. The limited evidence as to the benefit of long-term opioid therapy.
   - H. 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.

22. Treatment agreements outline the joint responsibilities of physician and patient [35-37] and are indicated for opioid or other abusable medications. They typically discuss:
   - A. The goals of treatment, in terms of pain management, restoration of function, and safety.
   - B. The patient's responsibility for safe medication use (e.g., by not using more medication than prescribed or using the opioid in combination with alcohol or other substances; storing medications in a secure location and safe disposal of any unused medication).
   - C. The patient's responsibility to obtain his or her prescribed opioids from only one physician or practice.
   - D. The patient's agreement to periodic drug testing (e.g., of blood, urine, hair, or saliva).
   - E. The physician's responsibility to be available or to have a covering physician available to care for unforeseen problems and to prescribe scheduled refills.
Rule #6
Create and use a “cheat sheet” to assist you in patient follow-up care, especially when weighing the risks and benefits of ongoing opioid therapy.

<table>
<thead>
<tr>
<th>QID dosage of OUD</th>
<th>LOW</th>
<th>MODERATE</th>
<th>HIGH</th>
</tr>
</thead>
<tbody>
<tr>
<td>More than QID dosage:</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Car昔痛</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Reduction in dosages</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>EOT (Clinical and Therapeutic Risk): Baseline remained</td>
<td>Twice a year</td>
<td>More than 3 times a year</td>
<td>Each visit</td>
</tr>
<tr>
<td>Random urine test on current OUD</td>
<td>As needed</td>
<td>As needed</td>
<td>As needed</td>
</tr>
<tr>
<td>FPI</td>
<td>Twice a year</td>
<td>More than 3 times a year</td>
<td>Each visit</td>
</tr>
<tr>
<td>Medication count</td>
<td>Every other visit</td>
<td>Every visit</td>
<td>Every visit</td>
</tr>
<tr>
<td>Visit frequency</td>
<td>Monthly to bi-monthly</td>
<td>Monthly</td>
<td>Monthly or more often as needed</td>
</tr>
</tbody>
</table>

Specific Review Protocol at 30 Day Intervals: 100 mg (10 mg/30 mg/50 mg/100mg)
Rule #7

If you decide to give a patient a second (or third) chance to continue opioid therapy in the face of Aberrant, Drug-Related Behavior, prepare an updated chart summary (containing a well-founded explanation for your decision) and consider the need for peer review (internal or external).
Rule #8

Ask yourself:

What would my office staff and peers say about my documentation?

Medical Records

5. Every physician who treats patients for chronic pain must maintain accurate and complete medical records. Information that should appear in the medical record includes the following (32-23,38.43-44):

   a. Copies of the signed informed consent and treatment agreement.
   b. The patient’s medical history.
   c. Results of the physical examination and all laboratory tests.
   d. Results of the risk assessment, including results of any screening instruments used.

   e. A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity).
   f. Instructions to the patient, including discussions of risks and benefits with the patient and any significant others.
   g. Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement.
   h. Notes on evaluations by and consultations with specialists.
   i. 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 (32-23,38.43-44). These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers.
   j. Authorization for release of information to other treatment providers.
Next Time...

- Documenting Follow-up Review
- Handling Special Issues
  - Anonymous Calls
  - Drug Test Failures
  - PMP Problems
- Termination of Care

Follow-up & Questions?

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