

Taking back your turf: Understanding the role of law in medical decision making in opioid management (Part II—Putting legal/regulatory materials to work for you)

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In Part I of this series, I discussed the basic role of the law in the decision-making process for opioid management. I set out three basic rules: 1) read and learn applicable federal and state legal/regulatory materials on using controlled substances to treat pain, 2) stay current on accepted clinical standards of care, and 3) use a compliance program to minimize the potential for abuse and diversion of controlled substances. Here in Part II, I focus on the third rule and offer a few suggestions on developing and maintaining a compliance program. I also discuss using language from legal/regulatory materials in your practice forms in a manner that, once again, allows you to “take back your turf” and prescribe opioids without fear of legal/regulatory sanction (see Disclaimer). Take a minute to review the self-audit questions that follow and see where you stand on your knowledge and use of legal/regulatory matters in your daily practice. More “yes” answers indicate better knowledge of key compliance and documentation issues. More “no” and “I don’t know” answers indicate that more work should be done to minimize potential legal/regulatory compliance problems in your practice.

SELF-AUDIT QUESTIONS¹

1. Do you live in a state with an Intractable Pain Treatment Act and/or guidelines, position statements, or regulations on using controlled substances to treat pain?

If your answer is yes, have you read and educated your staff on these materials?

2. Have you compared your office forms with your state’s legal/regulatory materials on prescribing controlled substances to treat pain?

3. Do you use these forms consistently, are they drafted in relatively simple language, and are the terms and words you use internally consistent?

If your answer is yes, do you modify your forms as needed to stay current with the law and accepted medical practice?

If your answer is still yes, do you leave that modification to someone else in your practice, or do you take an active role in the process to ensure compliance?

4. Do you know the key elements of medical record documentation when it comes to prescribing controlled substances for the treatment of pain?

If your answer is yes, list them here as a reminder for the rest of this self-audit.

USING CONTROLLED SUBSTANCES TO TREAT PAIN: KEY PRESCRIBING GUIDELINES

It is not practical to discuss each state’s legal/regulatory materials and documentation requirements in this article. Moreover, some states do not have legal/regulatory materials on this subject matter, the absence of which may actually promote abuse and diversion of controlled substances and leave providers subject to the whim of federal and state authorities, not to mention hurt patients who have a legitimate medical need for this type of medication. Consequently, I use the Federation of State Medical Boards’ Model Policy for the Use of Controlled Substances for the Treatment of Pain (May 2004)² when discussing the key elements and documentation areas for guidelines on using controlled substances to treat pain.³

The Model Policy contains seven key compliance and documentation elements on the use of controlled substances for the treatment of pain.⁴ When comparing the Model Policy with your state’s materials on the use of controlled substances for the treatment of pain, look for differences in directive language, such as “shall” versus “should” or “must” versus “may.” Directive language

gives you a good idea where the state draws its boundaries relative to controlled-substance prescribing and key documentation requirements and what it expects of you to keep your license and controlled drug registration.

The seven elements from the Model Policy are as follows:

1. History and physical evaluation
2. Treatment plan
3. Informed consent and treatment agreement
4. Periodic review
5. Consultations (and referrals)
6. Medical records
7. Compliance with controlled substance laws and regulations

As with most state legal/regulatory materials, including guidelines and position statements, key elements like those set forth here come with basic instructions. Using a checklist format from my review of the Model Policy, here are the basic instructions for the seven Model Policy elements. You might consider using this to compare the Model Policy with a self-constructed checklist of your state's materials. By doing so, you will have a very complete list to use when you examine your current compliance and risk management status.

History and physical evaluation

Physicians:

- Must evaluate the patient's medical history and perform a physical examination and document these efforts.
- Should document the nature and intensity of the patient's pain.
- Should document the patient's current and past treatments for pain.⁵
- Should document underlying or coexisting diseases or conditions.
- Should document the effect of the pain on the patient's physical and psychosocial function.
- Should document the patient's history of substance abuse (including alcohol).

- Should document the presence of one or more recognized medical indications for the use of a controlled substance.

Based on my review of licensing board and law enforcement investigations on controlled-substance prescribing, I have a few of my own recommendations⁶ to add to this element of the Model Policy:

- Physicians should verify the patient's self-report of medication usage with prior providers and should attempt to do so before prescribing more than a couple of days' worth of that same medication to a new patient.
- Physicians should talk to the patient about his/her reluctance to try a different medication or combination of medications and document their efforts in the patient's medical record. Sometimes the reluctance stems from a fear of addiction or simply the process of "change" in general. Other times, the reluctance stems from an abuse and/or diversion problem. In either case, the physician's role is to determine how the patient's reluctance plays into his/her medical history and the development of the treatment plan.
- Physicians should review all documentation from prior prescribing healthcare providers and talk to that provider about the patient's case. Of course, this raises Health Insurance Portability and Accountability Act (HIPAA) issues, but your attorneys should be able to tell you that HIPAA permits communication between healthcare providers about the "treatment" of the patient, among other things such as "payment" and "healthcare options." This recommendation is especially important if a patient comes to you on high doses or combinations of controlled substances for pain management. This is just as important when a patient comes to you after having been discharged by the prior provider for whatever reason. Your job is to find out why the patient wants you to review his/her case, what the prior provider has documented about the patient's case, and what the answers to those questions mean in light of your obligations—ethical, legal/regulatory, and professional.
- Physicians may want to request an initial drug screen (blood or urine) from patients to verify patient self-reports and ensure proper patient assessment and selection in light of the obligation to follow accepted clinical care standards

and minimize the potential for abuse and diversion of controlled substances.

In saying all this, I by no means mean to suggest that you should not prescribe high doses or unusual combinations of controlled substances to your patients when there is a legitimate medical reason to do so within the usual course of professional practice. Instead, I want you to make sure you are evaluating and documenting the patient's case in the manner intended by your professional care standards, licensing board, and your Drug Enforcement Administration (DEA) registration obligations.

Treatment plan

Physicians:

- Should use a written treatment plan.⁷
- Should use the written treatment plan to state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function.
- Should use the written treatment plan to indicate if any further diagnostic evaluations or other treatments are planned.

After treatment begins, physicians:

- Should adjust drug therapy to the individual medical needs of each patient.
- Should realize that other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

One of the most problematic documentation issues I see in the audits I have done is the continued prescribing of the same controlled substances (sometimes even at higher levels) in the face of pain levels that are always the same, lack of improved functioning (on physical and psychosocial levels) according to treatment plan goals, and even in the face of aberrant drug-related behaviors. No doubt patients react differently to pain medications, but the measure of how each patient is doing must be guided by the treatment plan and the later element of "periodic review."

Informed consent and treatment agreements

Physicians:

- Should discuss the risks and benefits of the use

of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is without medical decision-making capacity.

- Should require the patient to receive prescriptions from one physician and one pharmacy whenever possible.

If the patient is at high risk for medication abuse or has a history of substance abuse, physicians:

- Should consider the use of a written agreement between physician and patient outlining patient responsibilities, including
 - urine/serum medication levels screening when requested;
 - number and frequency of all prescription refills; and
 - reasons for which drug therapy may be discontinued (e.g., violation of agreement).

This element of the Model Policy reads as if informed consent and treatment agreements are the same. In pain policy, they typically are; in the law, however, they are not.⁸ In fact, the Federation, and consequently many states and professional medical organizations, have blended informed consent elements with treatment agreement language, unintentionally resulting in the circulation of many "go-by" office forms that fall short of meeting legal/regulatory standards and fail to accurately document a physician's compliance in these areas. For these reasons, it is critical that you understand the legal/regulatory distinctions between informed consent and treatment agreements.

Informed consent relates to your ethical and, in most states, legal/regulatory obligation to discuss with the patient the risks, benefits, and treatment alternatives for use of controlled substances. Informed consent is not new. It is done when you perform procedures or surgery, and routinely as part of a general consent for treatment. While the Model Policy suggests that informed consent is a "should," you must remember that policy language is about "minimum standards," and this is not the same as a standard of care or obligation imposed on you by a state law or regulation/rule. Remember, too, that I view informed consent from a "more than minimum effort" perspective, because legal compliance and risk management incorporates a broader perspective—one that faces a different level of scrutiny when challenged, such as malpractice based on provider negligence. Thus, to ensure a solid compliance and risk management program, I

encourage you to adopt a must- or shall-do attitude and expand your use of the informed consent process when you recommend pain medications to your patients.⁹ In saying this, I am primarily speaking to those of you located in states that use policy language similar to that of the Model Policy. However, some of you are located in states where a law or a regulation/rule requires you to use informed consent when you prescribe controlled substances. Make sure you understand your state's position here. In addition, do not forget to search your state for a general patient "bill of rights," as these bills often designate informed consent as a key issue in all aspects of healthcare. A good example of a state with these materials is California, which has not only an Intractable Pain Treatment Act and Patient Bill of Rights, but also an organization, funded by state agencies, that publishes a Patient Rights handbook that includes a discussion on informed consent.¹⁰

A *treatment agreement* is meant to be a boundary document—a form setting forth office policies and limits relating to controlled substances. Treatment agreements typically remain the same over the term of care with all patients and change only when office policies change.

Treatment agreement terms include those listed in Figure 1. Of course, you can modify treatment agreements to your specific patient population so it reflects what you do when you treat the patient, what you expect in return from the patient, and what you do to minimize the potential for abuse and diversion of controlled substances.

As the Model Policy states, treatment agreements are something a physician "should" consider when handling patients with a high risk for medication abuse, or one with a history of substance abuse. Although the Model Policy and many states say "should," this does not mean you cannot use a treatment agreement with every patient. If you want to read more about the distinctions between informed consent and treatment agreements and view sample forms, you may do so on my Web site.¹¹

Periodic review

Physicians:

- Should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health.
- Should remember that the continuation or modification of controlled substances for pain management therapy depends on your evaluation of progress toward treatment objectives.
- Should remember that satisfactory response to

treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life.

- Should monitor the patient for objective evidence of improved or diminished function.
- Should consider information from family members or other caregivers in determining the patient's response to treatment, subject to HIPAA considerations.

If the patient's progress is unsatisfactory, physicians:

- Should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

In most states, licensing boards rightly give physicians discretion on the timing of periodic review based on the documented, individual circumstances of the patient's case. However, states like New Jersey¹² and Louisiana¹³ have regulations that set boundaries on the physician's discretion, obligating the physician to see his/her chronic controlled substances users every 12 weeks at a minimum. Currently, because of the DEA's Interim Policy Statement of November 2004, it appears that federal law may impact the timing for patient followups, particularly when they involve the issuance of a Schedule II controlled substance. Some states, like California, have issued some guidance on this issue.¹⁴ Check with your licensing board to see how it interprets the DEA's Interim Policy Statement regarding the issuance of multiple Schedule II prescriptions with "do not fill before" language on them in light of patient followup policies/regulations. You should also determine the appropriate followup period and criteria using current clinical care standards and document your reasons for the follow up period and criteria that you ultimately use.

Periodic review relates to patient monitoring and is a tough subject, because many patients are good and not a threat when it comes to handling controlled substances responsibly. You must remember, however, that when you use your DEA registration number, you do so under these conditions: 1) you will issue controlled-substance prescriptions for a legitimate medical purpose within the usual course of professional practice, and 2) you will minimize the potential for abuse and diversion of controlled substances. You must also consider the fact that the abuse and diversion of prescription controlled substances is a growing problem in the United States.

There are many ways to meet your periodic review obligations. Determine what your state says about the matter and decide how the language in your state's legal/regulatory materials can help you establish patient

(2005) Key Documentation Components Using Controlled Substances to Treat Pain

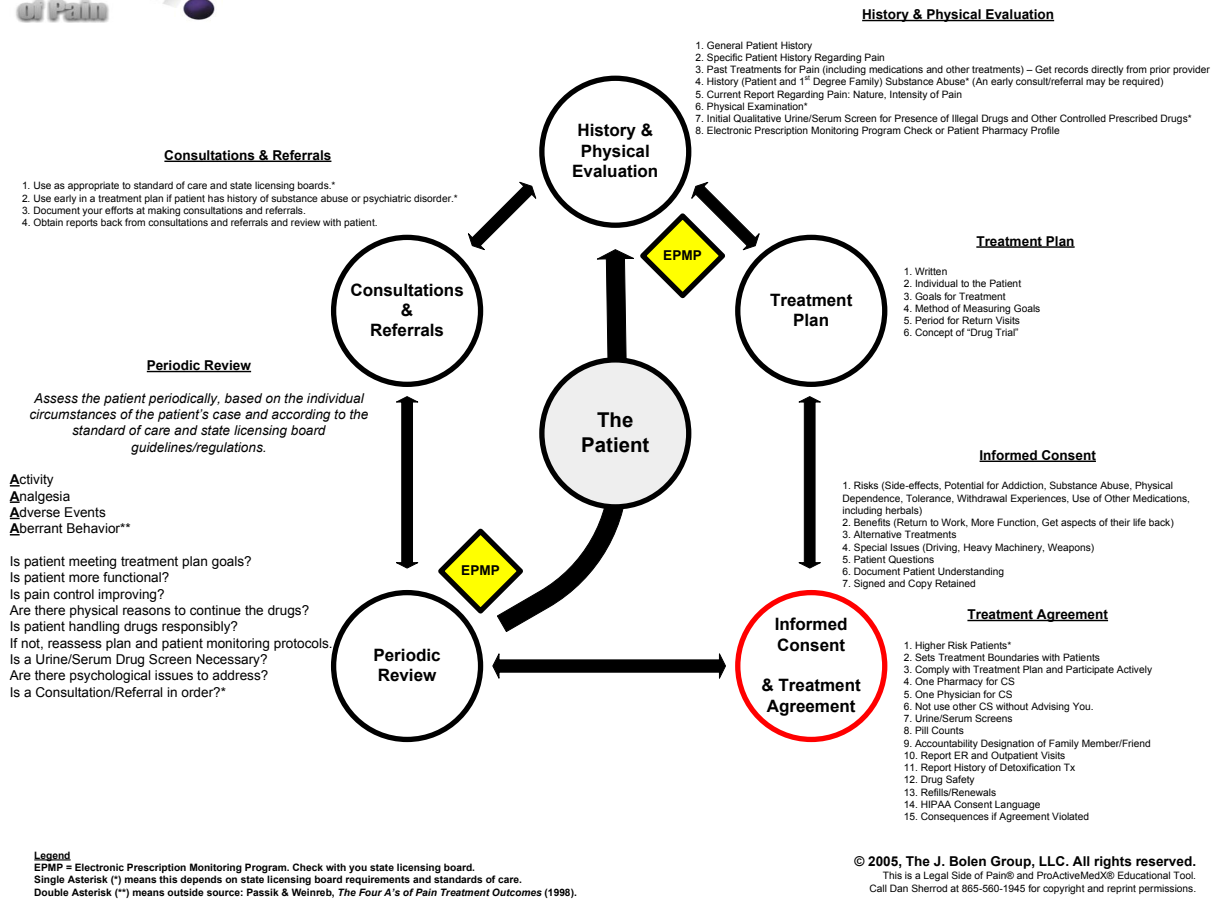


Figure 1.

monitoring forms and office policies.¹⁵ You might also consider using language from these materials to advocate for your patients when a healthcare plan wants you to do something inconsistent with clinical care standards and/or the state's legal/regulatory materials. Figure 1 makes some suggestions about periodic review concerns, as does the work of Passik and Weinreb, titled *The Four A's of Pain Treatment Outcomes* (1998).

Consultations and referrals

Physicians:

- Should be willing to refer the patient as necessary for additional evaluation and treatment to achieve treatment objectives.
- Should give special attention to those patients with pain who are at risk for medication misuse, abuse, or diversion.

Remember, "the management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients."¹⁶ For this reason, and as a matter of smart compliance, I recommend you take an active role in obtaining documentation of all consultations and referrals directly from the healthcare provider. When you receive these items, review them and determine whether the results support the continuation of your current treatment plan or a change relating to both treatment in general and controlled substances specifically. After you make your decision, document your rationale, together with the corresponding consultation/referral documentation, in the patient's medical record.

Typical medical records required

Physicians:

- Should keep accurate and complete records to include
 - the medical history and physical examination,
 - diagnostic, therapeutic and laboratory results,
 - evaluations and consultations,
 - treatment objectives,
 - discussion of risks and benefits,
 - informed consent,
 - treatments,
 - medications (including date, type, dosage and quantity prescribed),
 - instructions and agreements, and
 - periodic reviews.
- Should keep records current and maintain them in an accessible manner so they are readily available for review.

This policy statement is simple in words, but often difficult in deed. Check your state materials to make sure you are keeping the appropriate records. Audit yourself periodically and get help if necessary. Finally, if you are registered with the DEA to dispense controlled substances from your practice, you must comply with additional federal and state law record-keeping requirements.

Compliance with controlled-substance laws and regulations

Physicians:

- Must be licensed in the state where you practice medicine.
- Must comply with applicable federal and state regulations governing the prescribing, dispensing, and administering of controlled substances.
- Should read the *Physician's Manual* of the DEA and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

It should be noted that the *Physician's Manual* is not available at this time because the DEA is revising it. However, the DEA has an excellent *Pharmacist's Manual*, which can be obtained on their Web site, free of charge.¹⁷ I recommend that you or someone on your staff download a copy of this and read it. In doing so, you will have a better understanding of the DEA's role in monitoring the flow of controlled substances.

ADDITIONAL CONSIDERATIONS

The Model Policy contains several definitions relevant to your daily interactions with patients. As you read them, think about which of your office forms need these definitions and how you might incorporate them into patient educational materials. When you use the correct definitions of terms like addiction, physical dependence, and tolerance, even when your state does not, you will be giving your patients proper information and informed consent. You might also help a few understand that it is okay to use opioids and, assuming no history of chemical or substance abuse, dispel a few addiction myths. Here are the Federation's Model Policy terms and corresponding definitions:

Acute pain. The normal, predicted physiological response to a noxious chemical, thermal, or mechanical stimulus. It typically is associated with invasive procedures, trauma, and disease. It is also generally time limited.

Addiction. A primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestation. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic pain. A state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain. An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical dependence. A state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction. The iatrogenic syndrome resulting from the misinterpretation of relief-seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief-seeking behaviors

resolve on institution of effective analgesic therapy.

Substance abuse. The use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance. A physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

If your state's definitions are out of date, then encourage your licensing board to consider updating them. If your state uses definitions that appear to conflict with the Federation's definitions, then check with your licensing board and ask for clarification, probably best done through a professional medical organization. If all else fails, use your state's definition, but do not forget your ethical obligation to abide by accepted, current standards of care, which likely includes using appropriate and current definitions.

USING LEGAL/REGULATORY MATERIALS TO YOUR ADVANTAGE

Now that you have reviewed the Model Policy's key elements, go back and review your state materials with my comments in mind. When you do this, make notes on key legal/regulatory terms and make it a point to incorporate this language into your office forms. This sounds simple, but I have rarely audited a practice that did this before my teaching them why it is important and how to do it. When you use language from legal/regulatory materials in your practice forms and documentation practices, you signal that you know what the boundaries are and how to follow them. You can also do so without compromising patient care.

I do not believe the law is designed to prevent you from using controlled substances to treat pain. The law sets forth boundaries within which you must operate to preserve a medical license or DEA registration. As physicians, I want you to understand the legal/regulatory materials in your state and see how they actually protect those who prescribe within the state's legal/regulatory framework. Use key phrases from legal/regulatory materials in your office forms. Use these phrases when you write healthcare plans to explain your prescribing rationale. Use these phrases routinely and in connection with practices that meet or exceed accepted clinical care standards. When you do, you will have minimized the potential for abuse and diversion of controlled substances and the likelihood of any unfavorable legal/regulatory intrusion. None of this can stop the event of a board or DEA inquiry, but it can sure help determine the outcome—in your favor. Finally, it is important for you to know that thanks to the work of the Pain & Policy Studies Group at

the University of Wisconsin Comprehensive Cancer Center and the Federation of State Medical Boards, many states continue to work to improve existing pain policy and, where possible, other state legal/regulatory materials.

CONCLUSION

There is no way that I can cover all aspects of the issues mentioned previously in the space allotted for this article. I intend to continue this series with a Part III, in which I will focus on handling common patient challenges, responding to healthcare plans that ask you to do things inconsistent with accepted clinical care standards and legal/regulatory materials, and discharging patients. For now, however, after reading this article you are in a good position to make legal/regulatory materials work for you and your patients. Do your homework and revise your office forms and policies as necessary. Finally, in your documentation efforts, remember that patients are individuals, and your medical records should reflect that you have treated them as such.

DISCLAIMER

I do not intend for this paper to serve as specific legal advice. Instead, this paper contains a general outline of legal/regulatory responsibilities and assumes that the clinician will only prescribe controlled substances for a legitimate medical purpose within the usual course of professional practice. If you have a specific legal question, make sure you get legal advice from an expert in this area.

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NOTES

1. I do not intend for this section to cover every question relevant to compliance for controlled-substance prescribing.
2. You may obtain a copy of the Model Policy on the Federation's Web site: <http://www.fsmb.org>.
3. To determine where your state stands, visit <http://www.fsmb.org>.
4. It is important to remember that as a "policy," the Federation's Model Policy does not have the force of law in a state unless the state incorporates the document into a licensing board regulation or rule. Likewise, a "policy" does not itself set a standard of care. Instead, a "policy" typically sets forth minimum standards of medical practice as defined by a state licensing board, meaning that you should follow them or have a good and well-documented reason for not doing so.
5. This is commonly referred to as "verification." A good way to do this is to get records directly from prior providers instead of simply relying on the patient's self-report or delivery of his/her own medical records.
6. Remember, these are only my recommendations based on my experience. Your state's position on these issues is in control. If you have a specific legal question in this area, make sure

to ask your attorney or expert counsel.

7. In some states this is a “must,” and I believe personally that it is best to use a written treatment plan.

8. I am not attacking the Federation’s efforts here. I was privileged to participate in the drafting of the Model Policy, and I think that the Federation’s work product has had a very positive effect on furthering pain management policy in the United States. However, I also believe that it is important to emphasize the difference between pain policy and legal/regulatory standards, especially when it comes to educating physicians about compliance and risk-management issues. Not only do I look at documents like the Model Policy from the “how are we balancing pain care and legal/regulatory interests” perspective, but also from a “what can and does happen when legal and regulatory suits are filed in civil and criminal courts, or before licensing boards” perspective. I mean only for my comments here to help physicians think about the different approaches to these matters as they make decisions about their approaches to compliance and risk management.

9. I actually believe that informed consent is required any time you prescribe any medication to a patient. Take, for example, the anticoagulation drug, Coumadin. If you had to prescribe this to a patient, no doubt you would talk to the patient about the risks of not taking the drug at all, the risks of taking too much or too little, the risks of taking certain other medications in addition (e.g., aspirin), the effects of alcohol, etc. You would also discuss the benefits of using the drug, especially when the patient has a history of a Factor V Leiden mutation, as I do. And, finally, you would discuss the treatment alternatives to using Coumadin. I will discuss extended informed consent issues, including informed consent for off-label use of medications for pain management, in a future article.

10. As of August 22, 2005, the Web site for the Patient Rights handbook is <http://www.calpatientguide.org>. The American Medical Association Code of Ethics describes informed consent as a process, whereby the physician covers the elements

described above with the patient and then allows the patient to ask him/her directly questions about these matters. If, at any time, your treatment recommendations involve the use of different drugs or drugs in off-label ways, then a new informed consent process is in order.

11. <http://www.legalsideofpain.com>.

12. New Jersey Administrative Code Title 13, Chapter 35, Subchapter 7, section 7.6, available online at: <http://www.state.nj.us/lps/ca/bme/statreg/bmeregulations2.doc>.

13. Louisiana Administrative Code Title 46, Vol. 45, Chapter 69, Subchapter B, Section B-6921, available online at: http://www.lsbme.org/documents/laws_rules/rules/46V45069PrescriptionDispensationandAdministrationofMedicatio.pdf.

14. In April 2005, the California Medical Board issued a statement about the DEA’s Interim Policy Statement that suggested to some that the statement itself required physicians to see their patients every month, prior to issuing a new Schedule II prescription. In July 2005, the California Medical Board issued a “clarifying” statement about this matter, stating that the board did not mean to suggest that physicians must personally see their patients each month and referred CA physicians back to the CA guideline on using controlled substances to treat pain. To read these two items, go to the board’s Web site at <http://www.medbdca.gov> and look under Controlled Substances in the April and July Action Reports.

15. Of course, doing everything I mention in this paper does not guarantee that you will be problem free when it comes to issues surrounding the abuse and diversion of controlled substances. Nonetheless, you will be able to show that you understand the legal/regulatory boundaries and use them to guide your documentation process.

16. Federation of State Medical Boards’ Model Policy for the Use of Controlled Substances for the Treatment of Pain, May 2004.

17. To obtain the DEA’s Pharmacist’s Manual, go to <http://www.deadiversion.usdoj.gov> and click on “Publications” and then “Manuals.”