

Getting Informed Consent and Agreement for Treatment right: A legal perspective on key obligations for practitioners who use controlled substances to treat chronic pain

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Medical practitioners who use controlled substances to treat pain must learn and demonstrate compliance with the ethical and medical obligations of Informed Consent and Agreement for Treatment. This article distinguishes the concept of Informed Consent from that of Agreement for Treatment (sometimes called a Narcotic or Opioid Contract¹) and offers basic suggestions for demonstrating compliance with federal and state legal/regulatory materials related to these concepts. In this regard, this paper offers suggestions on how to:

1. determine your state's position on the matter;
2. distinguish Informed Consent elements from terms comprising an Agreement for Treatment and properly construct office forms based on the key distinctions between these concepts; and
3. perform a self-audit of your existing Informed Consent and Agreement for Treatment document (in whatever form) to determine whether changes are necessary to improve compliance with state legal/regulatory materials on the use of controlled substances to treat pain.

No amount of medical record documentation, let alone an Informed Consent document or an Agreement for Treatment, will prevent a lawsuit or licensing board investigation, but all documentation plays a role in how a jury or board reviewer perceives you and your practice. When you use well-drafted office forms and understand your legal/regulatory obligations related to prescribing controlled substances to treat pain, you will be in a better position to stay focused on quality medical care and preserve your patients' access to controlled substances. Remember, quality medical care starts with a commitment to professional interaction with your patients and is supported by the proper paperwork. Time invested in reviewing this article and following the suggestions set forth herein will help you better understand the concepts of Informed Consent

and Agreement for Treatment and improve your compliance with state legal/regulatory materials on the use of controlled substances to treat pain.

WHAT IS YOUR STATE'S LEGAL/REGULATORY POSITION ON THE AGREEMENT FOR TREATMENT?

You need to know whether your state has a guideline or regulation on using controlled substances for the treatment of pain (or a similarly worded item). In fact, your state may have more than one of these, so be prepared to read all items related to the use of controlled substances in the treatment of chronic pain. Use a comprehensive legal/regulatory Web site² or your state board's Web site and search for items posted under headings like "laws and regulations," "guidelines," or "policies/position statements."

WHAT IS A GUIDELINE/POSITION STATEMENT?

It is easier to state what a guideline or a position statement is not. First, these items are not clinical standards of care or laws themselves; they generally do not have the force of law, meaning that your failure to follow them exactly is not likely to bring board reprisal so long as you have documented good-faith reason for your departure from them. Through guidelines or position statements, licensing boards usually attempt to define or explain the meaning of a state law or regulation/rule that governs medical practice in the state. Licensing boards usually do not intend for guidelines or position statements to be comprehensive or to exhaustively set out every standard that might apply in every circumstance. Moreover, the absence of a guideline or position statement, or the silence of such material on certain matters, should not be construed as the lack of an enforceable licensing board standard.

WHAT ARE REGULATIONS/RULES?

Most licensing boards have legal authority to make regulations or rules, and these items have the force of

law, meaning that your failure to follow them may result in your loss of license privileges and the imposition of monetary sanctions. Regulations and rules generally explain state laws and set conduct expectations, stating what the licensing board expects you to do or not do concerning specific aspects of medical practice. States often define the failure to follow a regulation or rule as “unprofessional conduct.”

UNDERSTANDING YOUR STATE’S POSITION

Once you locate your state materials and determine what category these items fall into (guideline, regulation, or both), read them and look specifically for a section called “Informed Consent and Agreement for Treatment.” Because many state prescribing guidelines or regulations are based wholly or in part on the Federation of State Medical Boards’ *Model Policy for the Use of Controlled Substances for the Treatment of Pain*,³ or an older version of this document known as the *Model Guideline for the Use of Controlled Substances for the Treatment of Pain*,⁴ I have quoted the language from the “Informed Consent and Agreement for Treatment” section of the Federation’s 2004 policy below. However, I have divided this language into three sections to help you follow my legal/regulatory perspective on it.

Informed Consent and Agreement for Treatment

Section One. The physician 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.

Section Two. The patient should receive prescriptions from only one physician and one pharmacy whenever possible.

Section Three. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including:

- urine/serum medication-level screening when requested;
- awareness of the number and frequency of all prescription refills; and
- understanding of reasons for which drug therapy may be discontinued (e.g., violation of agreement).

To learn how to distinguish Informed Consent from Agreement for Treatment in your practice, use the *Model Policy’s* language above and my discussion below, and

note the subtle distinctions between the sentences in each section of the *Model Policy’s* component on Informed Consent and Agreement for Treatment.

Section One underscores the ethical and medical obligation of Informed Consent and contains a legal/regulatory directive suggesting the physician *should* discuss the risks and benefits of using controlled substances with the patient.⁵ Arnold et al.⁶ discuss the ethical obligation of informed consent related to controlled substances. Pain practitioners should familiarize themselves with the Informed Consent process described by Arnold et al.⁶ and others,^{7,8} including myself, who have written on the subject.

Section One also implicates the legal/regulatory directive to prescribe controlled substances *for a legitimate medical purpose within the usual course of professional practice*,⁹⁻¹¹ and to minimize the potential for abuse and diversion of these substances.¹⁰ Although these directives originate in federal law, most states adopt these standards and incorporate them into state controlled-substances acts and state medical-practice acts.

Look at Section One again; you will find the *Model Policy* and many state legal/regulatory materials suggest that the physician need only discuss “risks and benefits” of using controlled substances, seemingly suggesting that the Informed Consent ethical obligation stops there; it does not. The Arizona Board of Medical Examiners is one of the only states in the country to set out the ethical obligation of Informed Consent correctly, as reflected in its new *Guidelines for the Treatment of Chronic Pain*, issued Spring 2006 (discussed below).¹²

As I have previously stated,^{8,13-15} and as Arnold et al.⁶ correctly point out, there are two additional elements of a legal Informed Consent: 1) available treatment alternatives, if any; and 2) special issues concerning the use of controlled substances, like driving, pregnancy, lowered testosterone levels, etc.¹⁶ The new Arizona guideline contains the element of available treatment alternatives, and one can argue that the element called “special issues” may be considered part of “risks” and/or “benefits.” All of this is important because guidelines and regulations, and “go-by” Informed Consent and Agreement for Treatment documents that omit critical elements and language, put pain practitioners at a disadvantage, at the very least from a legal/regulatory perspective. This means there is potential for increased legal exposure. It also means there is greater potential for licensing board sanctions, but a licensing board might be hard pressed to argue that you messed up these concepts if the board has not stated them correctly to begin with. Thus, you should take care to distinguish between the concepts of Informed Consent and Agreement for Treatment and document them separately, or at the very least in separate sections of the same document, so you do not mingle concepts and terms and make it more confusing for your patients and those who might end up reviewing your documentation. Also, take

care to ensure your Informed Consent and Agreement for Treatment contain the proper elements and proper terminology, so your intent is clear—legal/regulatory compliance and quality medical care.^{17,18}

Sections Two and Three do not implicate any ethical obligations per se, but these sections do relate to minimum licensing board expectations concerning the physician's duty to evaluate patients, establish a treatment plan, review the treatment plan, and make changes during patient follow-up based on whether the patient is meeting treatment plan goals and acting responsibly in terms of medication handling and usage. Further, these sections relate to a practitioner's obligation to minimize the potential for abuse and diversion of controlled substances.^{10,11,19} In the introductory paragraphs to most state guidelines or regulations on the use of controlled substances for the treatment of pain, you will find this statement, or something like it:

The Board is obligated under the laws of the State of _____ to protect the public health and safety. The Board recognizes that the use of [controlled substances/opioid analgesics] for other than legitimate medical purposes poses a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, *the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.*²⁰

Looking individually at the points in Section Two, one sees that it contains a suggestion to limit control of the patient's access to, or oversight authority for the patient's use of controlled substances for the treatment of pain to, one provider and one pharmacy. This certainly makes sense in theory, but in reality it is extremely difficult to enforce and monitor, especially if you live in a state that lacks a prescription drug monitoring database. I think this is a good practice or boundary for an Agreement for Treatment, and I think you should have this statement in yours. Remember, however, that it is up to the patient to select the pharmacy, and you should not tell him or her which pharmacy to pick. Likewise, if you are a specialist and the patient will be seeing you and continuing to see his/her primary care physician, you may consider using an Agreement for Treatment that involves you, the primary care physician, and the patient, and a clear statement as to which medical professional will be prescribing controlled substances to the patient. Fishman et al.²¹ have discussed the concept of "trilateral agreements," and you should read their paper if you have not already done so.

Section Three seems to suggest that licensing boards want practitioners to address varying risk potentials in patient populations. This is significant, as such language arguably implies the practitioner has at least a medical obligation to do some form of risk analysis on his/her patients if he/she intends to prescribe them controlled substances to treat pain. If your state has this language in a regulation or rule instead of a guideline or position statement, then I would urge you to see this section as a mandate to perform some form of risk analysis; you probably do this anyway, but you may need to find a more formal way of demonstrating your efforts. By this, I mean you might want to use a tool like the 1) Drug Abuse Screening Test (DAST-20),²² 2) Screener and Opioid Assessment for Patients in Pain (SOAPP®),²³ or 3) Opioid Risk Tool.²⁴ Once you assess the patient's risk level, then you can construct your treatment plan, risk monitoring, periodic review sessions, and necessary consultations/referrals accordingly.

Section Three clearly contains a suggestion that if the practitioner determines the patient is at high risk for medication abuse or has a history of substance abuse, then he/she should consider the use of a written agreement between the physician and patient outlining patient responsibilities, including:

- urine/serum medication-level screening when requested;
- being aware of the number and frequency of all prescription refills; and
- understanding the reasons for which drug therapy may be discontinued (e.g., violation of agreement).

This language is significant because states using this language appear to suggest that, at a minimum, the licensing board's interest is in the use of a written Agreement for Treatment for *high-risk* patients. Some states attach a sample agreement to the guideline or regulation, like Colorado.²⁵ If your state does not "mandate" the use of any particular form for the Agreement for Treatment, you might consider the value of a frank discussion with the patient about your office policies, treatment expectations, and the patient's responsibilities, concerning the use of controlled substances. Look the patient in the eye, engage him or her in a real conversation and set clear boundaries and explain consequences. Following this meeting with the patient, send him or her a letter memorializing the conversation and, if you want, obtain the patient's signature on the letter at his or her next visit. Much of this is a matter of style and your patient population plays an important factor in how you approach the use of an Agreement for Treatment. Nonetheless, do not forget how important it is to interact

with the patient—pieces of paper cannot do this like you can. Be careful to note whether your state “suggests” or “mandates” the use of a written Agreement for Treatment and whether it draws distinctions between patient risk levels. Finally, to my knowledge, the law does not prohibit a practitioner from using a written Agreement for Treatment with all patients, if that is what he/she desires to do.

INFORMED CONSENT IS NOT THE SAME AS AGREEMENT FOR TREATMENT

Informed Consent is not the same as Agreement for Treatment, and it is important for you to modify your existing paperwork if it inaccurately refers to Informed Consent as something the patient must agree to in order to obtain treatment from your office and/or omits key elements. The State of Arizona recently recognized the distinctions between Informed Consent and Agreement for Treatment in its new 2006 *Guideline for the Treatment of Chronic Pain*.¹² In doing so, Arizona separated the concepts of Informed Consent and Agreement for Treatment within the guideline and differentiated the directive language associated with each concept as demonstrated below, making Informed Consent mandatory and Agreement for Treatment discretionary based on the circumstances of the patient’s case.

Informed Consent—The physician **must** 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. ***This discussion should include the risks of addiction/abuse, not alleviating all pain, and treatment alternatives including the effects of no treatment.***

Agreement for Treatment—There are circumstances in which the use of a documented verbal or written agreement between physician and patient outlining patient responsibilities ***may be necessary*** for safe and responsible opioid prescribing. ***Such an agreement should include:***

- urine/serum medication levels and baseline screening when requested;
- number and frequency of all prescription refills;
- reasons for which drug therapy may be discontinued (e.g., violation of agreement);
- requirement that the patient receive all controlled substance prescriptions from one physician and one pharmacy whenever possible.¹²

RELATED CONCEPT OF “MEDICAL RECORDS”

No discussion about the Agreement for Treatment is complete without reference to the physician’s obligation to keep accurate and complete medical records. Most licensing boards have a guideline or regulation addressing medical records—what they are, what is to be included, how they are to be kept and for how long, who owns them, and what fees may be charged for copying them. The Medical Records component of the *Model Policy* reads as follows:

Medical Records—The physician **should** keep accurate and complete records to include:

1. the medical history and physical examination;
2. diagnostic, therapeutic and laboratory results;
3. evaluations and consultations;
4. treatment objectives;
5. **discussion of risks and benefits;**
6. **Informed Consent;**
7. treatments;
8. medications (including date, type, dosage, and quantity prescribed);
9. **instructions and agreements;** and
10. periodic reviews.

Records should remain current, be maintained in an accessible manner, and be readily available for review.³

You need to know what your state says about the type of medical records you “should” or “must” keep related to your prescribing of controlled substances to treat pain. You also need to know to what extent your licensing board expects you to document the listed items. It is likely your board will apply a standard that would allow a similarly situated physician to “step into your shoes” and follow your treatment logic and plan based on your documentation (or a similarly stated standard).

PERFORMING A SELF-AUDIT OF YOUR AGREEMENT FOR TREATMENT

Now that you know a bit about the distinctions between Informed Consent and Agreement for Treatment, take the

next step and review your current form(s). Use the checklist (Appendix 1) at the end of this article to guide your review, and consider the following additional items:

What should you call your form?

Use language similar to the language used by your state's guideline or regulation. For example, if your state has a guideline called the *Guideline for the Use of Controlled Substances for the Treatment of Pain* and refers to an individual step as "Informed Consent and Agreement for Treatment," then consider calling your form "Informed Consent and Agreement for Treatment for the Use of Controlled Substances for the Treatment of Pain," and refer to "controlled substances" throughout instead of any specific drug. Inconsistencies between state terminology and your form and/or the use of multiple terms to refer to controlled substances (i.e., pain medications, opioids, narcotics, narcotic medications) can cause confusion and look sloppy when viewed on the "big screen." I will post a marked-up form on my Web site (www.legalsideofpain.com) for your reference with the on-line version of this article.

What drugs should the Agreement for Treatment cover?

Once again, I recommend you use language similar to the language used by your state's guideline or regulation. This answer applies both to Informed Consent and Agreement for Treatment forms. For example, if your state guideline is called the *Guideline for the Use of Controlled Substances for the Treatment of Pain*, use the phrase *controlled substances* both in the introduction and throughout the body of your form. Remember, as pain practitioners you prescribe more than opiates, and your ethical obligation on Informed Consent is not limited to opiates; it applies to all medications and treatments you recommend.^{7,26} Similarly, you likely intend for any boundary-type document, like an Agreement for Treatment, to cover the patient's conduct relative to the entire treatment plan, including all drugs prescribed, not just the opiates. If you limit your forms to specific medications, you may be limiting your ability to take action with your patient or, as I usually phrase it, you may be "handcuffing" yourself in the sense of limiting your discretion, and this is not smart business or compliance. In your review of your state materials, you may notice that very few states follow this rule, and most state guidelines or regulations jump back and forth between "controlled substances" and "opioids" or other terms, thereby making it hard for you to understand just where your state will draw lines or apply them.

What kind of "introductory" language should you use in an Informed Consent versus an Agreement for Treatment?

This is a very important question, and I am going to

demonstrate its answer by quoting language from a form I recently reviewed during a compliance audit. If your form contains the following introductory language and you intend that form to represent Informed Consent, you will need to change it for the reasons described below:

I agree to the following conditions and I am aware that my failure to abide by any of these conditions will be considered a breach of the contract and, at the sole discretion of my physician, may result in the termination of our physician-patient relationship.

This introductory language is not appropriate for an Informed Consent form. Moreover, if you were going to use it for an Agreement for Treatment, you would need to make a few changes. The language is not appropriate for an Informed Consent because, as discussed above, Informed Consent is not about "conditions" or the "patient's failure to abide by conditions." Also, Informed Consent is not a contract; it is the practitioner's ethical obligation to discuss the risks and benefits of using the controlled substances recommended, along with an explanation of available treatment alternatives and special issues associated with the use of the recommended controlled substances.

The sample language above, minus the word "contract" and the reference to a "breach of contract," is better suited as a "consequences statement" in an Agreement for Treatment. For an example of an introductory statement to an Informed Consent form, see the example on my Web site associated with the on-line version of this article.

What "boundary terms" should an Agreement for Treatment contain?

Incorporate the suggestions from your state's guideline or regulation and then, if you want, add a few of your own to clearly establish your practice boundaries. Many have published on the general categories of boundary terms (Arnold et al.,⁶ Fishman et al.,²⁷ and Heit²⁸), and it is not necessary to repeat their statements here.

PATIENT PROTECTION AND PHYSICIAN COMPLIANCE

Physicians must find a professional way to protect their patients' legitimate access to controlled substances and demonstrate compliance with legal/regulatory materials. Development of practice policies that insist on patient responsibility will help accomplish these goals. Controlling human behavior is difficult at best. In accomplishing the tasks suggested in this paper, remember that it is not about having lots of paper to show your compliance. Instead, it is about having the right paper—the kind that demonstrates your knowledge of and compliance

with your ethical, medical, and legal obligations and your knowledge of and adherence to accepted current clinical standards of care, and that paper can take many forms and may be even more effective when, as in the case of an Agreement for Treatment, it is a letter sent to the patient after and confirming a frank discussion about behavioral expectations and patient responsibilities during treatment involving the use of controlled substances. Overall, we know that the Agreement for Treatment is only as effective (and thus efficient) as those who stand behind it. Physicians must train themselves and their staff to stand behind the spirit and letter of a well-drafted Agreement for Treatment. The document should incorporate key provisions from your state legal/regulatory materials and should also be drafted professionally and in a manner that is helpful to your patient population.

If you want to get a good opinion of your Informed Consent and Agreement for Treatment, put your form(s) into PDF format and then into a PowerPoint presentation, and then project their image onto an office wall. When you see your form(s) "up in lights" you will notice the little things that can make a big difference, and you will understand why it is important to make changes now—proactively—before some attorney gets a chance to use these items against you on a courtroom screen before a board panel or jury. Empirical evidence may make you feel better about how science looks at the process of Informed Consent or the use of an Agreement for Treatment. Informed Consent is required, and you will want to get this concept right in your practice so you do not contribute to the likelihood of a successful malpractice case (like a wrongful-death action) against you. On the other hand, your state legal/regulatory materials will decide whether you *must* or *should* use an Agreement for Treatment.

CONCLUSION

The legal perspective in this paper is a relatively small part of the matter when it comes to the physician-patient relationship and the prescribing of controlled substances to treat pain. It is vital that medical professionals not lose sight of the fact that a "relationship" requires interaction and that the processes of Informed Consent and Agreement for Treatment cannot and should not be replaced by pieces of paper. While the law may require the documentation of processes, medicine requires, and safe prescribing mandates, good solid communication with patients about the issues surrounding the use of controlled substances to treat pain and the responsibilities of both parties—the physician and the patient.

Physicians will continue to study the concepts of Informed Consent and Agreement for Treatment and the effectiveness of these items in medical practice. Remember, however, that your medical license and DEA registration

number depend, in part, on a slightly different perspective of your responsibilities, especially when it comes to prescribing controlled substances. Consequently, there is and will continue to be a focus on physicians' responsibility to minimize the potential for abuse and diversion of controlled substances, and many legal/regulatory entities—federal and state—consider the process of Informed Consent and the use of and adherence to an Agreement for Treatment or similar boundary-setting arrangement as a solid demonstration of a physician's compliance with his/her legal obligations in this area.

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NOTES AND REFERENCES

1. The terms "Narcotic Contract" and "Opioid Contract" are not really appropriate in a legal/regulatory context, even though these terms may sound more official. Most state legal/regulatory materials on prescribing controlled substances for the treatment of pain refer to a written agreement between the physician and patient as an "Agreement for Treatment." Once you learn what your state says about the use of such a document, you should call it what your state calls it and use language similar to your state's language. However, if you live in a state that refers to the agreement as a contract, consult with your legal counsel or a legal expert on the matter to decide whether you increase your legal exposure by using the term "contract." The rationale for using your state's terminology (unless it says "contract") is obvious—you signal your knowledge of your state's materials and, hopefully, you demonstrate your compliance with the same by the manner in which you document and use your Agreement for Treatment. Once again, the exception to the term "contract" relates to the potential increase in legal exposure or obligations.
2. The University of Wisconsin's Pain & Policies Studies Group Web site contains an index of state materials and may be accessed at www.medsch.wisc.edu/painpolicy/index.htm. The Legal Side of Pain Web site contains a comprehensive set of quick reference materials for all states related to the use of controlled substances to treat pain and related ethical and professional obligations and may be accessed at www.legalsideof-pain.com.
3. Federation of State Medical Boards: *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (May 2004). Federation of State Medical Boards Web site. Available at www.fsmb.org/pdf/2004_grpol_controlled_substances.pdf. Accessed June 23, 2006.
4. Federation of State Medical Boards: White Paper on *Model Guideline for the Use of Controlled Substances for the Treatment of Pain* (1998). Federation of State Medical Boards Web site. Available at www.fsmb.org/pdf/1998_grpol_Pain_Management_Guidelines.pdf. Accessed June 23, 2006.
5. Remember, in some states, like Arizona, the directive language is "must," and case law often sees informed consent as a "must" as well.
6. Arnold RM, Han KJ, Seltzer D: Opioid contracts in chronic nonmalignant pain management: Objectives and uncertainties. *Am J Med.* 2006; 119: 292-296.
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- Consent facilitates use of controlled substances. *Pain Medicine News*. 2005; 3(4): 10. Available at www.painmedicineneews.com.
9. Title 21, Code of Federal Regulations, Section 1306.04.
10. US Drug Enforcement Administration: Interim policy statement on dispensing controlled substances for the treatment of pain. *Fed Regist*. 2004; 69(220): 67170-67172. US Government Printing Office Access Web site. Available at www.gpoaccess.gov/fr/index.html. Accessed January 10, 2006.
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12. Arizona Board of Medical Examiners: Guidelines for the treatment of chronic pain. Arizona Board of Medical Examiners Web site. Available at azmdboard.org/pain_management/Guidelines.pdf. Accessed June 10, 2006.
13. Bolen J: Pain & the law: Back to basics, Part II—a treatment agreement establishes boundaries with patients. *Pain Medicine News*. 2005; 3(4): 20, 35. Available at www.painmedicineneews.com.
14. Boswell MA, Cole BE: *Weiner's Pain Management: A Practical Guide for Clinicians, Seventh Edition*. Boca Raton: Taylor & Francis Group, 2005.
15. Bolen J: Pain & the law: Ten common documentation errors and ways to fix them. *Pain Medicine News*. 2004; 2(4): 13, 21-22. Available at www.painmedicineneews.com.
16. Most states' legal/regulatory materials likewise overlook the last two elements of a legal Informed Consent. One exception is Arizona's relatively new *Guidelines for the Treatment of Chronic Pain*, adopted in early 2006. If you want your Informed Consent to help you minimize liability and risk potentials, then use all four elements and review this issue with qualified legal counsel.
17. See example Informed Consent and Agreement for Treatment located on www.legalsideofpain.com. The American Academy of Pain Medicine also splits the concepts of Informed Consent and Agreement for Treatment into separate forms, and readers can find samples on the Academy's website at www.painmed.org.
18. American Academy of Pain Medicine: *Position Statement on Opioid Therapy, Consent for Chronic Opioid Therapy*. American Academy of Pain Medicine Web site. Available at www.painmed.org/productpub/statements/sample.html.
19. Title 21, Code of Federal Regulations, Section 1306.04.
20. North Carolina Board of Medicine: *Policy for the Use of Controlled Substances for the Treatment of Pain*. (Adopted September 1996 as *Management of Chronic Non-Malignant Pain*; redone July 2005 based on the Federation of State Medical Board's *Model Policy for the Use of Controlled Substances for the Treatment of Pain*, as amended by the FSMB in 2004.) North Carolina Board of Medicine Web site. Available at <http://www.ncmedboard.org/>. Accessed June 10, 2006.
21. Fishman S, Mahajan G, Jung SW, et al.: The trilateral opioid contract. Bridging the pain clinic and the primary care physician through the opioid contract. *J Pain Symptom Manage*. 2002; 24(3): 335-344.
22. The DAST-20 is available at www.chronicpainnetwork.com.
23. The SOAPP® Tool is available at www.painedu.org/soap.asp.
24. The Opioid Risk Tool is available at www.emergingsolutionsinpain.com.
25. Colorado State Board of Medical Examiners: *Policy for the Use of Controlled Substances for the Treatment of Pain* (as revised November 18, 2004). State of Colorado Department of Regulatory Agencies Web site. Available at www.dora.state.co.us/medical/Policy10-14.htm. Accessed June 10, 2006. Accompanying sample patient contract, "Using Opioid Pain Medication in Chronic Pain," available at www.dora.state.co.us/medical/Policy10-14SampleContract.doc. Accessed June 10, 2006.
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27. Fishman SM, Bandman TB, Edwards A, et al.: The opioid contract in the management of chronic pain. *J Pain Symptom Manage*. 1999; 18: 27-37.
28. Heit H: Creating and Implementing Opioid Agreements. *CareManagement* Web site. Available at www.jcaremanagement.com/html/pain__creating_and_implementin.html. Accessed June 22, 2006.
29. Check your state law to make sure there is no requirement in pain management to implement "random" urine or serum drug testing. Usually, the randomness requirement is limited to employment or workplace drug testing, the nature of which is *very* different from that of urine drug testing in pain management.

APPENDIX 1. FROM *THE LEGAL SIDE OF PAIN*®—A BASIC CHECKLIST ON INFORMED CONSENT AND AGREEMENT FOR TREATMENT RELATED TO THE USE OF CONTROLLED SUBSTANCES TO TREAT PAIN

Does your state have a GUIDELINE or POSITION STATEMENT OR REGULATION or RULE OR BOTH related to the Use of Controlled Substances for the Treatment of Pain?

Write down the title of your state's document(s): _____

Does this document use the term "Controlled Substances" throughout? ___ Yes ___ No

What other terms does the document use to refer to controlled substances? _____

What term does your state use to refer to Informed Consent? _____

Does your state say you MUST or SHOULD perform Informed Consent? _____

What elements do you find in your state's Informed Consent language? (risks, benefits, etc.) _____

Does your state say you MUST or SHOULD use a boundary document with patients when you prescribe controlled substances for the treatment of chronic and/or intractable pain? ___ Yes ___ No

What term does your state use to refer to such a boundary document? (Agreement for Treatment, Treatment Agreement, Opioid Contract, etc) _____

With whom does your state suggest you use such a boundary document? (Open discretion, all patients, high-risk patients, does not say) _____

If your state suggests you use a boundary document with *high-risk* patients, do you have a tool you regularly use to rank or otherwise decide whether a patient is *high risk*? If so, which one? (DAST-20, SOAPP®, ORT, other): _____ If not, select one to try.

Does your state suggest the use of any specific boundary terms (one physician and one pharmacy for controlled substances, urine drug testing, family conferences, etc.) in a boundary document? If so, list them here: _____

Make sure you remove language that limits your discretion—change "you will be discharged" to "we *may* change your treatment plan or discharge you from our practice." Also, change "you may be subject to *random* urine drug tests" to "you agree to provide a urine sample *when requested*." You always want to retain your discretion to request a test whenever you think it is appropriate to do so and you do not want to add an unnecessary legal burden to your medical practice—the inappropriate use of the terms "random" or "unannounced" may do just that.²⁹

Make sure your introductory language is proper for both your Informed Consent form and your Agreement for Treatment document.

For both Informed Consent and Agreement for Treatment, make sure you obtain the patient's signature, give the patient a copy of the document, and keep the original in the patient's medical record.

Make sure you address patient behaviors that are contrary to the promises made to you by the patient.

Make sure you document your efforts.