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POLICY BRIEF

OPIOID TREATMENT AGREEMENTS OR “CONTRACTS”:
PROCEED WITH CAUTION

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OPIOID TREATMENT AGREEMENTS OR “CONTRACTS”: PROCEED WITH CAUTION

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INTRODUCTION

Pain care in the United States presents a complex set of challenges. On the one hand, there is ample documentation that pain, especially chronic pain, is often not well managed, and that as the Institute of Medicine has stated, we need a “cultural transformation in how pain is judged, managed and treated” to advance pain care in the United States.¹ On the other hand, much of the pain care discussion has centered around a singular aspect of pain management, the so-called opioid analgesic “conundrum.” This conundrum relates to the notion that opioids are classified as “essential

medications” for medical practice, but may be abused and misused, sometimes with deadly consequences. For example, according to the Centers for Disease Control and Prevention, nearly three out of four of the 20,044 prescription drug overdose fatalities involve opioid analgesics, representing more overdose fatalities than cocaine and heroin combined.²

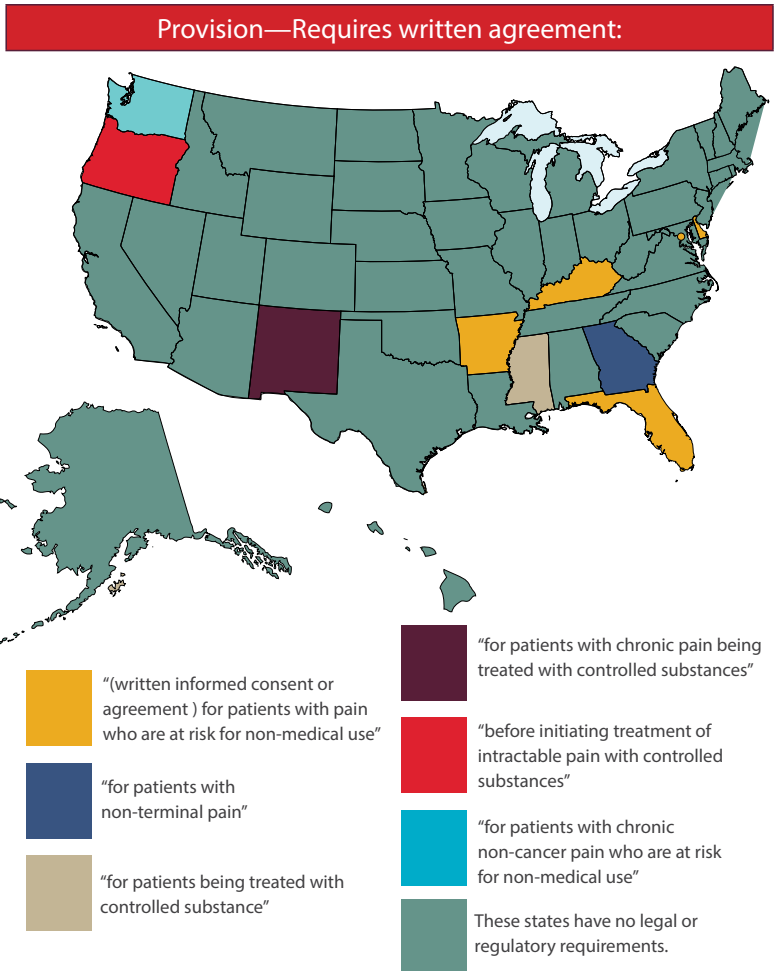
To address these complex problems, a series of policy solutions has been promulgated. One such policy is the use of prescription drug monitoring programs, now functioning in 47 of the 50 states (with New Hampshire and

Nebraska actively implementing theirs, and Missouri being the only state not to have passed enabling legislation). Another is the creation of model policies and guidelines for the use of opioids in the treatment of chronic pain, such as that written by the Federation of State Medical Boards.³ The Federation of State Medical Boards guidelines and several state departments of health specifically recommend the use of treatment agreements and so-called opioid “contracts” as part of their model policies. In some states, legislatures have directed licensing boards to write rules mandating the use of agreements. These rules vary somewhat in their degree of specificity with respect to the contents of such agreements. This PAINS policy brief addresses the pros and cons of the use of opioid treatment agreements or contracts for the management of chronic pain.

Opioid treatment agreements and contracts: definitions & elements

Ideally patient agreements or contracts are “verbal or written agreements that a patient makes with themselves, with healthcare practitioners ... where participants commit to a set of behaviors related to the care of the patient. Contracts aim to improve the patients’ adherence to treatment...”⁴ Although most healthcare providers typically do not advocate for the use of legal terminology in medical settings, and some have called for the elimination of the term “contract” because this language generally connotes legal and punitive measures and conveys a level of mistrust between patient and provider, nonetheless the term is used widely in clinical practice⁵ and is often used in ways that leverage the power of providers over patients in the medical encounter.⁶ Therefore in this brief, the terms “contract” and “treatment agreement” will be used interchangeably.

Perhaps the best way to think about opioid treatment agreements is as a form of (written) informed consent. Some have criticized the proliferation of opioid contracts because they



may become simple checklists that substitute for meaningful communication between patient and provider. When misused in this way, there are lost opportunities to assess whether the patient truly understands the options for treatment and to discuss patient preferences, which may or may not be incorporated into the written treatment agreement, including preferences that would lead them to choose one treatment over another.⁵ At a minimum, these documents should contain key elements of informed consent, such as:^{3,7}

- Clear statement of the medical and/or pain diagnosis
- Clear statement of the goals of therapy, especially regarding pain relief and restoration of function
- Risks and benefits associated with opioid therapy for chronic pain
- The risks and benefits of alternative treatments
- The risks and benefits of not receiving opioids



- Potential side effects of opioid therapy, including physical as well as cognitive side effects
- The likelihood of the development of tolerance and physical dependence
- The risk of opioid misuse, dependence, addiction and overdose
- Specific reasons for which drug therapy may be changed or discontinued
- The consequences of “contractual violation” on the part of the patient
- The description of the physician’s prescribing policies and expectations, including the number and frequency of prescription refills, the policy on early refills and replacement of lost or stolen medications, expectations about the use of a single pharmacy, etc.
- The patient’s responsibilities for the use of controlled substances (such as how the medications would be safeguarded at home)
- Policies and expectations regarding the use of random blood and urine drug testing

There are currently no standards for the use of language and terminology in opioid treatment agreements. Although some have argued that one can write opioid agreements or contracts with “patient-centered” language,⁸ in the absence of standard language, there has been criticism that the tone of the documents is often punitive and one-sided (only emphasizing the roles and responsibilities of patients, not providers), and are written for health literacy levels that are beyond the reach of most patients.⁹ Given the absence of uniform language for opioid treatment agreements or contracts, a working group of the FDA Safe Use Initiative is developing a checklist for review by patients and providers to assure that the most important information is shared and discussed.¹⁰

Opioid contracts: pros & cons

On the face of it, it seems quite reasonable to require that patients and providers sign on to a document that describes risks and benefits of any therapy, particularly therapies that are potentially dangerous. This sentiment seems even more salient given the current problems of prescription drug abuse and opioid-related deaths. In fact, advocates for promulgation of opioid treatment agreements argue that in the real world of concerns about under-treatment of pain and increasing opioid-related deaths, the only way to assure continued availability of opioids for legitimate medical needs is to utilize treatment agreements to minimize risky prescribing practices and use patterns.

However, the evidence for the efficacy of the use of opioid treatment agreements is quite weak,³ although not completely absent. This in itself is a reason to resist the widespread adoption of opioid treatment agreements or contracts, particularly since their use may increase the stigma associated with chronic pain. A second reason for caution is related to concerns about the many unintended consequences of injudicious widespread utilization of opioid treatment agreements for which there is little evidence for efficacy. It is important to note that the risk of unintended consequences of policy interventions in multifaceted situations like this are increased when there is relative ignorance of the complexity of the situation and when there is an “overemphasis of the immediate interests in solving a problem” that often allows one to overlook or neglect the possible long-term consequences of a new policy. Some of the feared unanticipated consequences of requiring opioid treatment agreements or contracts in all patients with chronic pain are:

- They may increase the risk of stigmatization of already highly stigmatized conditions, resulting in patients foregoing otherwise effective pain treatment.^{5,11}
- Their use implies distrust between patient and provider and may further compromise an increasingly tenuous doctor-patient relationship.⁵

- They may be applied or interpreted with discriminatory intent, which further exacerbates known racial and ethnically-based disparities in the treatment of chronic pain.
- Their use may not afford the legal protection that most physician providers assume.

To minimize bias in the use of opioid treatment agreements or contracts, some have advocated universal adoption, or use in every patient with chronic pain who requires an opioid prescription. Yet, others have warned that this may have not only the unintended effect to further stigmatize chronic pain patients and thus produce harm by having patients avoid otherwise useful therapy, but may also be associated with discriminatory application of opioid contract use.¹⁶ Furthermore, lawyers have warned that the use of opioid treatment agreements may not protect doctors from liability, particularly if written in ways as to constitute “unconscionable adhesion contracts,” or documents that are “prepared by one party, to be signed by the party in a weaker position, usually a consumer who has little choice (or little meaningful choice) about the terms.” Such contracts are typically unenforceable.¹⁷ At least one attorney general has warned that opioid contracts that require patients to be more responsible for safeguarding medications at home may be a harbinger of a slippery slope that makes physicians responsible in other contexts, for other threats to health in the home, such as, for example, the safe storage and use of firearms.¹⁸

The consequences attached to patients’ violations of the terms of these agreements also can be concerning. In many cases, agreements mandate dismissal of the patient from the prescriber’s practice if the patient strays from the path defined by that agreement—regardless of the severity or frequency of that violation or extenuating circumstances. Prescribers who ignore a patient’s violation of even a minor provision of the agreement place themselves at risk of being held liable in civil, administrative, or even criminal proceedings, if they fail to follow through on terminating their care for the patient, as mandated by the agreement. In some cases, prescribers may find that patients are able to be appropriately adherent if they are provided with greater structure, such as requiring that they



appear weekly to obtain new prescriptions, rather than monthly. In other cases, dismissing the patient from the practice means bypassing an opportunity to properly assess, and provide for treatment of, a substance use disorder. Thus, care must be exercised in outlining consequences for patients and prescribers, with some flexibility based on the prescriber's judgment being optimal. It is hard to imagine any other area of medicine where the detection of a new medical diagnosis (such as substance abuse disorder in the case of persons with pain) would result in termination of the patient's treatment. Language that mandates a "re-evaluation of the treatment plan and terms of treatment, up to, and including, termination of treatment" may be preferable and superior from an ethical standpoint to language that inflexibly "dismisses" the patient from the medical practice for any violation.

Recommendations for policy makers

Although the use of opioid treatment agreements or contracts are advocated widely, there is, in fact, little evidence for their efficacy, and there may be many unanticipated negative consequences of their widespread adaption. Given this, the following recommendations seem prudent:

1. There should be prospective study to answer the empiric questions concerning efficacy and pitfalls to the use of opioid treatment agreements as they affect outcomes in chronic pain patients.
2. Model policy agreements and clinical practice guidelines should not recommend widespread

or mandatory universal adoption of opioid treatment agreements or contracts in the absence of better evidence of efficacy.

3. In the absence of evidence of efficacy, current use of opioid treatment agreements or contracts should be restricted to patients at elevated risk for misuse or abuse of opioids and should be subjected to further study.
 - a. When opioid treatment agreements are used, they should be written in “patient-centered language” that is non-punitive in tone.
 - b. Generally, language that mandates a “re-evaluation of the treatment plan and terms of treatment, up to and including, termination of treatment” is preferable and superior to language that inflexibly “dismisses” the patient from the medical practice for any violation.
 - c. Opioid treatment agreements should be flexible in mandating the “one pharmacy limit” rule now present in most opioid treatment agreements. Although the need to track opioid use is made easier by applying this rule, it is not always realistic to obey this provision, even for the most compliant patient with no substance abuse diagnosis or motives if, for example, they live in rural or inner city areas or are caught in unexpected circumstances in which their primary pharmacy is simply not available to them or does not have the prescribed medication.
 - d. Opioid treatment agreements should specify the use of prescription monitoring programs if available.
4. We recommend thorough discussions (and even written statements) confirming informed consent conversations with patients about the risks and benefits of chronic opioid therapy in their specific circumstances. However, these informed consent documents differ from opioid treatment agreements in that they do not stipulate punishments for “violations” of a specific term or aspect of the prescribed treatment regimen. ■



REFERENCES

1. IOM report—Pain Care
2. Centers for Disease Control and Prevention (CDC) <http://www.cdc.gov/homeandrecreationalsafety/rxbrief/>. Accessed 3/14/14
3. Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain. Federation of State Medical Boards. July 2013. (<http://www.fsmb.org>). Accessed 3/24/14
4. Bosch-Capblanch X, Abba K, Prictor M, Garner P. Contracts between patients and healthcare practitioners for improving patients' adherence to treatment, prevention and health promotion activities. The Chronic Library 2007, Issue 2. (<http://www.thecochranelibrary.com>). Accessed 3/24/14
5. Payne R, Anderson E, Arnold R et al. A Rose by Any Other Name: Pain Contracts/Agreements. The American Journal of Bioethics 2010;10 (11):5-12.
6. Power and Control: Contracts and the Patient-Physician Relationship. Int. J Clin Pract 2011;65 (12):1214-1217
7. Cheatle MD, Savage, SR. Informed Consent in Opioid Therapy: A Potential Obligation and Opportunity. J Pain Symptom Manage 2012;44:105-116.
8. Savage S. The Patient-Centered Opioid Treatment Agreement. The American Journal of Bioethics. 2010; 10 (11):18-19
9. Roskos SE, Keenum AJ, Newman LM, Wallace LS. Literacy Demands and Formatting Characteristics of Opioid Contracts in Chronic Nonmalignant Pain Management. The Journal of Pain 2007; 8 (10):753-758
10. Personal communication from Dr. Robert Twillman.
11. Fishman SM, Gallagher RM, McCarberg BH. The Opioid Treatment Agreement: A Real-World Perspective. The American Journal of Bioethics 2010;10(11):14-15.
12. Starrels J, Becker W, Alford D, Kapoor A, Williams AR, Turner B. Systematic Review: Treatment Agreements and Urine Drug Testing to Reduce Opioid Misuse in Patients With Chronic Pain." Annals of Internal Medicine. 2010; 2010. 152 (11): 712-720.
13. Jashiree H, Lamb G, Neuner J. Long-Term Opioid Contract Use for Chronic Pain Management in Primary Care Practice: A Five Year Experience. Journal of General Internal Medicine.; 2007;22 (4): 485-490.
14. Merton RK. The Unanticipated Consequences of Purposive Social Action. American Sociological Review 1936;1(6):894-904
15. Heit HA, Gourlay DL. Tackling the Difficulty Problem of Prescription Opioid Misuse. Annals of Internal Medicine 2010;142 (11):747-748
16. Anderson E, Burris S. Opioid Treatment Agreements Are the Answer. What is the Question? The American Journal of Bioethics 2010;10 (11):15-17
17. Hausmann LRM, Gao S, Lee ES, Kwok CK. Racial Disparities in the Monitoring of Patients on Chronic Opioid Therapy. Pain 2013;154:46-52.
18. Edmondson WAD. Be Careful How you Help. The American Journal of Bioethics 2010;10 (11):1-2.
19. Collen M. Opioid Contracts and Random Drug Testing for People with Chronic Pain—Think Twice. Journal of Law, Medicine & Ethics.2009;37:841-845
20. Gourlay, D , Heit H, Abdulazlz A. Universal Precautions in Pain Medicine: A Rational Approach to the Treatment of Chronic Pain. Pain Medicine. 2005. 6 (2): 107-112.
21. Perillo JM. Corbin on Contracts. Matthew Bender and Company, Newark. 1998;376:387

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“OPIOID TREATMENT AGREEMENTS”

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