CME CREDIT ***EDUCATIONAL OBJECTIVE:*** Readers will use controlled-substance agreements with their patients on chronic opioid therapy

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Breaking the pain contract: A better controlled-substance agreement for patients on chronic opioid therapy

ABSTRACT

"Pain contracts" for patients receiving long-term opioid therapy, though well-intentioned, often stigmatize the patient and erode trust between patient and physician. This article discusses how to improve these agreements to promote adherence, safety, trust, and shared decision-making.

KEY POINTS

Both chronic pain and opioid therapy impose costs and risks. Though controversial, long-term opioid therapy will probably have a role for the foreseeable future.

The term "controlled-substance agreement" is preferable to "pain contract" or "narcotic contract."

Controlled-substance agreements should be used only in the context of personalized patient counseling and shared decision-making.

Objectives of controlled-substance agreements are to improve adherence, obtain informed consent, outline the prescribing policies of the practice, and mitigate risk.

doi:10.3949/ccjm.83a.15172

Regulatory bodies and professional societies have encouraged or mandated written pain treatment agreements for over a decade as a way to establish informed consent, improve adherence, and mitigate risk. Unfortunately, the content of these agreements varies, their efficacy is uncertain, and some are stigmatizing or coercive and jeopardize trust. Additionally, many are written at reading levels beyond most patients' understanding. However, we believe a well-written agreement is still an important tool in chronic pain management.

In this article, we explore common limitations of current pain treatment "contracts" and propose strategies to improve their usefulness and acceptance.

PAIN AND ITS TREATMENT HAVE COSTS

Chronic pain affects 100 million US adults and is estimated to cost $635 billion each year in treatment, lost wages, and reduced productivity.[1]

Opioid therapy for chronic noncancer pain is being called into question,[2–5] and a 2016 guideline from the US Centers for Disease Control and Prevention has called for more limited and judicious use of opioids in primary care.[6] Nevertheless, long-term opioid therapy is probably helpful in some circumstances and will likely continue to have a role in chronic pain management for the foreseeable future.[7]

Concerns about opioids include risks of overdose and death. Unintentional drug overdoses, typically with opioids, exceeded motor

vehicle accidents in 2009 as the leading cause of accidental death in the United States[8]; by 2014, nearly one and a half times as many people were dying of a drug overdose than of a car accident.[9] Even when used appropriately, opioids are associated with sedation, falls, motor vehicle accidents, addiction, and unintended overdose.[10]

The potential harm extends beyond the patient to the community at large. Diversion of prescription drugs for nonmedical use is common[11] and, after marijuana and alcohol abuse, is the most common form of drug abuse in the United States.[12] Misuse of prescription drugs costs health insurers an estimated $72.5 billion each year—a cost largely passed on to consumers through higher premiums.[13] Most individuals who abuse prescription opioids get them from friends and family, sometimes by stealing them.[14]

THE SPECIAL ROLE OF THE PRIMARY CARE PHYSICIAN

Chronic pain is extremely prevalent in general internal medicine and primary care practice.[15,16] It has tremendous associated medical, social, and economic costs.[1]

Drug overdose deaths exceed deaths from car crashes

In light of the risks and complexity of opioid use and the increasing regulatory requirements for safe prescribing, some primary care physicians have stopped prescribing opioids altogether and refer patients elsewhere for pain management.

This does a disservice to patients. Primary care physicians cannot entirely avoid chronic pain management or absolutely refuse to prescribe opioids in all circumstances and still provide quality care. And although some primary care physicians may need more training in prescribing opioids, their comprehensive understanding of the patient's other health issues enables them to address the psychosocial generators and consequences of the patient's chronic pain more fully than a specialist can.

Furthermore, access to board-certified pain specialists is limited. There are only four such specialists for every 100,000 patients with chronic pain,[17] and those who are available often restrict the types of insurance they accept, disproportionately excluding Medicaid patients.

We encourage primary care physicians to undertake continuing medical education and professional development as needed to prescribe opioids as safely and effectively as possible.

A CONTROLLED-SUBSTANCE AGREEMENT INSTEAD OF A 'NARCOTIC CONTRACT'

To address the challenges of long-term opioid therapy, many state officials, medical licensing boards, professional societies, and other regulatory bodies recommend proactive monitoring and management of prescribing risks. Often promoted and sometimes mandated is the use of a written pain treatment agreement, sometimes called a "pain contract" or "narcotic contract," in which the patient and the physician ostensibly agree to various conditions under which opioids will be prescribed or discontinued. Although well-intentioned, these documents can cause several problems.

Contracts were being advocated in treating opiate addiction as early as 1981.[18] Since then, the term "narcotic contract" has become widely used, even as most professional guidelines have now moved away from using it. A Google search for the term on November 27, 2015, yielded 2,000 results, with numerous examples of the documents in clinical use.

But the phrase is misleading, and we believe physicians should avoid using it. Clinically, the word "narcotic" is imprecise and can refer to substances other than opioids. For example, the US Controlled Substances Act lists cocaine as a narcotic.[19] The word also carries a stigma, as law enforcement agencies and drug abuse programs commonly use phrases such as "narcotic task force" or "narcotic treatment program." On the other hand, the more accurate term "opioid" may be unfamiliar to patients. We recommend using the term "controlled substance" instead.

Similarly, the word "contract" can be perceived as coercive, can erode physician-patient trust, and implies that failure to agree to it will result in loss of access to pain medications.[20–23]

For these reasons, we encourage physicians to adopt the phrase "controlled-substance agreement" or something similar. This label accurately reflects the specificity of the treatment and connotes a partnership between pa-

tient and physician. Furthermore, it allows the physician to use the agreement when prescribing other controlled substances such as benzodiazepines and stimulants that also carry a risk of addiction, misuse, and adverse effects.

STIGMATIZING THE PATIENT

Although no studies have systematically assessed the style and tone of available treatment agreements, many of the agreements seem to stigmatize the patient, using language that is mistrustful, accusatory, and even confrontational and that implies that the patient will misuse or abuse the medications.[21,24] For example, "Failure to comply with the terms of the contract will risk loss of medication or discharge from the medical practice" is inflammatory and coercive, but variations of this phrase appear in many of the results of the aforementioned Google search.

Such language defeats attempts to communicate openly and implies a deprecatory attitude towards patients. Stigmatization may result in undertreatment of pain, physician refusal to prescribe opioids, and patient refusal to submit to the terms of a one-sided agreement perceived as unfair. Therefore, poorly written opioid agreements impair the trust necessary for a therapeutic physician-patient relationship and can interfere with optimal pain management.[20–23]

Some physicians stigmatize inadvertently. Believing that they can identify which patients will misuse their prescriptions, they use controlled-substance agreements only in this subgroup. But in fact, physicians are notoriously poor at predicting which patients will misuse prescription opioids or suffer adverse effects.[25] Therefore, it is important to be transparent and consistent with monitoring practices for all patients on chronic opioid therapy.[26]

Framing the controlled-substance agreement in terms of safety and using it universally can minimize miscommunication and unintentional stigmatization.

SHARED DECISION-MAKING AND CHRONIC OPIOID THERAPY

We recommend using controlled-substance agreements only in the context of personalized patient counseling and shared decision-making.

Shared decision-making promotes mutual respect between patients and physicians, is feasible to implement in primary care, and may improve health outcomes.[27,28] A study found that physicians who received 2 hours of training in shared decision-making for chronic opioid therapy were more likely to complete treatment agreements and set mutually agreed-upon functional goals with patients, and they felt more confident, competent, and comfortable treating chronic pain.[29] Additionally, after learning about the risks, some patients may choose to forgo opioid therapy.

To be consistent with shared decision-making, the controlled-substance agreement must:

TABLE 1

Essential elements of shared decision-making

1 Define the problem
How is the pain affecting the patient's quality of life and ability to function?

2 Present and discuss treatment options
Consider nonpharmacologic (eg, physical therapy), pharmacologic, and procedural options

3 Discuss benefits, risks, and costs
Consider efficacy, adverse effects, availability, monitoring needs, and other risks

4 Explore the patient's values and preferences
Discuss ideas, concerns, and outcome expectations

5 Discuss the physician's treatment recommendations
Base recommendations on medical knowledge and patient preferences

6 Discuss the patient's ability to follow through on the treatment plan
Can the patient realistically adhere to appointments, tests, and referral plans?

7 Clarify understanding
Consider the patient's health literacy and assess the patient's understanding of options

8 Make or defer decision
Make a treatment plan or delay until additional input (eg, from family) can be gathered

9 Arrange follow-up
Create a plan to follow up and modify or continue the treatment decision

- Engage the patient, emphasizing the shared, reciprocal obligations of physician and patient
- Address goals of treatment that are personalized and mutually agreed-upon and that incorporate the patient's values and preferences
- Explain treatment options in a way that is understandable and informative for the patient.

Table 1 outlines other key elements in detail.[27,30,31]

Shared decision-making is especially useful when the balance between the risks and benefits of a treatment plan is uncertain. It is not a substitute for medical expertise, and a patient's preferences do not override the physician's clinical judgment. A physician should not offer or implement chronic opioid therapy if he or she believes it is not indicated or is contraindicated, or that the risks for that patient clearly outweigh the benefits.[32]

THE CONTROLLED-SUBSTANCE AGREEMENT: FOUR OBJECTIVES

Some primary care physicians have stopped prescribing opioids altogether

Stigmatizing language in the controlled-substance agreement may result from physician ambivalence regarding its intent and objectives. For example, some may perceive the agreement as a way to facilitate communication, while others may use it in a possibly unethical manner to control patient behavior with the threat of cutting off access to pain medication.[33]

Controlled-substance agreements have four commonly identified objectives,[34] explored further below:

- To improve adherence with the safe use of controlled substances while reducing aberrant behaviors
- To obtain informed consent
- To outline the prescribing policies of the practice
- To mitigate the prescriber's legal risk.

Improving adherence

Many authors say that the primary goal of the controlled-substance agreement is to promote the use of the medication as prescribed, without variance, and from one physician only.[35–38] This goal seems reasonable. However, many other classes of medications are also risky when used aberrantly, and we do not ask the patient to sign an agreement when we prescribe them. This double standard may reflect both the inherently higher risks associated with controlled substances and physician ambivalence regarding their use.

Regardless, the efficacy of controlled-substance agreements in improving safe-use adherence and reducing aberrant medication-taking behaviors is uncertain. A 2010 systematic review based on observational and largely poor-quality studies concluded that using treatment agreements along with urine drug testing modestly reduced opioid misuse,[39] while other reports have called their efficacy into question.[40] We remain optimistic that well-written controlled-substance agreements can advance this objective, and that absence of evidence is not evidence of absence—ie, lack of efficacy. However, the data are not yet clear.

Interestingly, a 2014 survey found that most primary care physicians thought that controlled-substance agreements do not meaningfully reduce opioid misuse but do give a sense of protection against liability.[41] Additionally, these documents are associated with a greater sense of physician satisfaction and mastery,[42] and for some physicians these reasons may be enough to justify their use.

Somewhat alarmingly though, one study suggests that many patients do not even know that they signed a treatment agreement.[43] Using a controlled-substance agreement without the full awareness and engagement of the patient cannot promote adherence and is likely counterproductive.

Obtaining informed consent

It is essential to discuss possible benefits and risks so that informed and shared decision-making can occur.

Controlled-substance agreements may advance this aim if carefully written, although medical practices often design them for use across a spectrum of patients with varying indications, contraindications, and risks, making these documents inherently inflexible. A one-size-fits-all document does not allow for meaningful personalization and is insufficient without patient-centered counseling.

We strongly recommend that treatment

TABLE 2

A checklist for chronic opioid therapy

Both the physician and the patient should initial each point.

Provider initials	Patient initials	Shared responsibilities
		1 We talked about how my pain affects me and how opioids may help me function. We agreed to work toward the following goals: (Table 1, elements 1, 4, and 8) Goal #1: Goal #2: Goal #3:
		2 We talked about other treatment choices. We decided together to use opioids, but my doctor also recommends starting or continuing the following: (Table 1, elements 2, 5, and 8) Physical therapy: Yes/No Talk therapy: Yes/No Exercise: Yes/No Counseling: Yes/No Massage, chiropractor treatment, acupuncture: Yes/No Other pain medications: Yes/No
		3 We talked about possible side effects and the risk of overdose. We also talked about what to do if this happens. (Table 1, element 3)
		4 We agreed to be honest with each other. We both have the same goal—to safely control my pain. (Table 1, element 4)
		5 We talked about the cost of my medication and which drugstore I will use. We also talked about other choices if they become too expensive. (Table 1, elements 3 and 6)
		6 We agreed that opioids can be dangerous, especially if used in the wrong way. For my safety, we agreed that my doctor needs to monitor my pain treatment. This may include: (Table 1, element 9) a) Pill counts, to be sure the number of pills used is correct b) Urine ("pee") or blood tests, to be sure I am taking my medication correctly and no unsafe drugs are present c) Checking the state "prescription monitoring program" to be sure the drugstore is filling pain pills only when they are due and only from this doctor's office.
		7 We agreed that I would take only the number and type of pills prescribed to me. We will work together to change them if they are not meeting our agreed-upon goals. (Table 1, elements 7 and 9)

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Physicians are notoriously poor at predicting which patients will misuse opioids

agreements complement but not replace personalized patient-centered counseling about individual risks and benefits. Well-written controlled-substance agreements may reduce the chance of overlooking key risks and launch further customized discussion. Additionally, they can be written in a manner that allows patients and physicians to agree on and document personalized goals (**Table 2**).

Furthermore, when crafted within a risk-benefit framework, a controlled-substance agreement can help to clarify an ethically important concept, ie, that the physician is judging the safety and appropriateness of the treatment, not the character of the patient.[44] The prescriber can focus on evaluating the risks

TABLE 2 (CONTINUED FROM PAGE 832)

Provider initial	Patient initials	Patient responsibilities
		8 I will tell my doctor about all the pills I am taking and any new medication given to me by someone else. (Table 1, element 2)
		9 My doctor has the right name, address, and phone numbers for me. I will let my doctor know if they change. (Table 1, element 6)
		10 If I have a problem, or if my pain medication is not working, I will talk to my doctor before I do anything different with my pills. (Table 1, element 9)
		11 I agree to take my pills the way the doctor tells me. If I do not understand the directions, I will ask questions. (Table 1, element 7)
		12 My doctor explained that opioids are even more dangerous when they are mixed with other drugs or alcohol or used in the wrong way. For safety, I understand that I should not: (Table 1, elements 3, 5, and 6) a) Use illegal or recreational drugs, including marijuana b) Take medications not prescribed to me c) Drink more alcohol than my doctor thinks is safe for me d) Take extra pills or ask for early refills e) Get opioids from other doctors or the emergency room f) Give or sell my pills to someone else g) Drive a car until I know how the pills affect me.
		13 I understand that my pills are for me only. I will keep them in a safe place away from children and other people. I will also get rid of leftover pills only in the way my doctor or pharmacist teaches me. (Table 1, element 3)
		14 I will tell my doctor right away if I am pregnant. I know that my medications may need to change to keep me and my baby safe. (Table 1, elements 3 and 9)
		Physician responsibilities
		15 I will listen to my patient's stories about living with pain. I will keep their personal goals in mind when recommending treatment. (Table 1, element 5)
		16 I will keep learning about how to treat pain and recognize when opioids are causing more harm than good. (Table 1, element 5)
		17 I will make sure my patient has the right phone numbers for my office and the hospital. (Table 1, element 9)
		18 My office and I will be available to my patients when they need help. (Table 1, element 9)
		19 I will make sure my patient knows my office rules about how and when to ask for refills. (Table 1, element 7)
		20 I will teach my patients how to take their pills safely. I will have them show me to be sure they are doing it right. (Table 1, element 7)
		21 If I believe opioids are no longer safe or helping my patient, I will carefully stop prescribing them and use other treatments. (Table 1, elements 5 and 9)

Shared decision-making is not a substitute for clinical judgment

and benefits of treatment choices, not being a police officer or a judge of how "deserving" of opioid therapy the patient is.

Importantly, for patients to provide meaningful informed consent, the agreement must be understandable. A study of 162 opioid treatment agreements found that on average, they were written at a 14th grade level, which is beyond the reading comprehension of most patients.[45] Another study evaluated patients' ability to understand and follow instructions on labels for common prescriptions; even though 70% of the patients could read the labels, only 34.7% could demonstrate the instructions "take two tablets by mouth twice daily."[46]

We recommend analyzing all controlled-substance agreements for readability by assessing their Flesch-Kincaid grade level or a similar literacy assessment, using readily available computer apps. The average education level of the patients cared for in each practice will vary based on the demographic served, and the controlled-substance agreement can be modified accordingly, but typically writing the document at the 6th- to 7th-grade reading level is suggested.

Outlining practice policies

Opioids are federally controlled substances with prescribing restrictions that vary based on the drug's Drug Enforcement Agency schedule. State laws and regulations also govern opioid prescribing and are constantly evolving.[47]

Refilling opioid prescriptions should be a deliberate process during which the prescriber reviews the appropriateness of the medication and issues the prescription as safely as possible.

To promote practice consistency and to share expectations transparently with patients, we recommend spelling out in the agreement your policies on:

- Who can manage this patient's opioid therapy
- How to handle refill requests after hours and on weekends
- When and how patients should request opioid refills
- Which pharmacies patients will use
- Whether the practice allows others to pick up refills for the patient.

This not only serves as a reference for patients, who keep a copy for their records, it also reduces the risk of inconsistent processes within the office, which will quickly lead to chaos and confusion among patients and physicians alike. Inconsistent prescription and refill practices can give the impression that a double standard exists and that some patients get more leeway than others, without apparent justification.

There is little evidence that this approach truly improves practice efficiency,[34,48] but we believe that it may avert future confusion and conflict.

Mitigating the prescriber's risk

Most licensing boards and clinical guidelines recommend controlled-substance agreements as part of opioid risk mitigation. These documents are now the standard of care, with many bodies recommending or mandating them, including the Federation of State Medical Boards,[49] many states,[50] Physicians for Responsible Opioid Prescribing,[51] the American Academy of Pain Management,[52] and the American Pain Society along with the American Academy of Pain Medicine.[53]

Many patients do not even know that they signed a treatment agreement

Historically, primary care physicians have used controlled-substance agreements inconsistently and primarily for patients believed to be at high risk of misuse.[54] However, because physicians cannot accurately predict who will misuse or divert medications,[25] controlled-substance agreements should be used universally, ie, for all patients prescribed controlled substances.

A controlled-substance agreement can serve as documentation. The patient can keep a copy for future reference, and a cosigned document is evidence that a discussion took place and may lower the risk of malpractice litigation.[55] Further, if a state requires physicians to check their prescription monitoring database before prescribing opioids, the controlled-substance agreement can serve to both inform patients about this obligation and to obtain their consent when required.

At a minimum, we recommend that prescribers learn about the regulatory framework in their state and use controlled-substance agreements as legislatively mandated.

A CHECKLIST FOR THE PHYSICIAN AND PATIENT

To facilitate the development and use of ethically appropriate controlled-substance agreements with a focus on shared decision-making, we offer a sample tool in the form of a checklist (**Table 2**). It can be modified and implemented instead of a traditional controlled-substance agreement or can be used alongside other more comprehensive documents to facilitate discussion.

The model presents critical information for the patient and physician to discuss and acknowledge (initial) in writing. It is divided into three sections: shared responsibilities, patient responsibilities, and physician responsibilities. Each contains an approximately equal number of items; this is deliberate and visually conveys the notion of equivalent and shared responsibilities for patient and physician. The patient, physician, or both should initial each item to indicate their agreement.

The document is customizable for the specific treatment prescribed. It is written at a Flesch-Kincaid grade level of 6.8, consistent with current health literacy recommendations, and avoids medical jargon and complex compound sentences as much as possible.

We indicate key elements of shared decision-making[27,30,31] in parentheses in **Table 2** and cross-reference them with **Table 1**, which describes them more fully.

A BETTER TOOL

Both chronic pain and prescription drug abuse are highly prevalent and carry serious consequences. These overlapping epidemics put the prescriber in the difficult position of trying to prevent misuse, abuse, and diversion while simultaneously adequately treating pain.

Physicians and policy makers look to controlled-substance agreements as tools to help them balance the benefits and risks, but frequently at the expense of eroding trust between the patient and physician, stigmatizing the patient, using pejorative and coercive language, not adhering to health literacy guidelines, and failing to share decisions.

We believe a better tool is possible and suggest that controlled-substance agreements be universally applied, use deliberate and understandable language, be framed in terms of safety, and be implemented according to the principles of shared decision-making.

REFERENCES

1. **Committee on Advancing Pain Research Care, Institute of Medicine**. Relieving Pain In America: A Blueprint For Transforming Prevention, Care, Education, and Research. Washington, DC: National Academies Press; 2011. 030921484X.
2. **Von Korff M, Kolodny A, Deyo RA, Chou R**. Long-term opioid therapy reconsidered. Ann Intern Med 2011; 155:325–328.
3. **Chou R, Turner JA, Devine EB, et al**. The effectiveness and risks of long-term opioid therapy for chronic pain: a systematic review for a national institutes of health pathways to prevention workshop. Ann Intern Med 2015; 162:276–286.
4. **Manchikanti L, Vallejo R, Manchikanti KN, Benyamin RM, Datta S, Christo PJ**. Effectiveness of long-term opioid therapy for chronic non-cancer pain. Pain Physician 2011; 14:E133–E156.
5. **Trescot AM, Glaser SE, Hansen H, Benyamin R, Patel S, Manchikanti L**. Effectiveness of opioids in the treatment of chronic non-cancer pain. Pain Physician 2008; 11(suppl):S181–S200.
6. **Dowell D, Haegerich TM, Chou R**. CDC Guideline for prescribing opioids for chronic pain—United States, 2016. MMWR Recomm Rep 2016; 65(1):1–49.
7. **Brooks A, Kominek C, Pham TC, Fudin J**. Exploring the use of chronic opioid therapy for chronic pain: when, how, and for whom? Med Clin North Am 2016; 100:81–102.
8. **Paulozzi L, Dellinger A, Degutis L**. Lessons from the past. Injury Prev 2012; 18:70.
9. **Rudd RA, Aleshire N, Zibbell JE, Gladden RM**. Increases in drug and opioid overdose deaths - United States, 2000-2014. MMWR Morb Mortal Wkly Rep 2016; 64(50-51):1378–1382.
10. **Vowles KE, McEntee ML, Julnes PS, Frohe T, Ney JP, van der Goes DN**. Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis. Pain 2015; 156:569–576.
11. **Cicero TJ, Kurtz SP, Surratt HL, et al**. Multiple determinants of specific modes of prescription opioid diversion. J Drug Issues 2011; 41:283–304.
12. **SAMHSA**. Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings. HHS Publication No. (SMA) 14-4863. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2014: www.samhsa.gov/data/sites/default/files/NSDUHresultsPDFWHTML2013/Web/NSDUHresults2013.htm. Accessed October 10, 2015.
13. **National Drug Intelligence Center, Drug Enforcement Administration**. National Prescription Drug Threat Assessment. 2009.
14. **Jones CM, Paulozzi LJ, Mack KA**. Sources of prescription opioid pain relievers by frequency of past-year nonmedical use: United States, 2008-2011. JAMA Intern Med 2014; 174:802–803.
15. **Clark JD**. Chronic pain prevalence and analgesic prescribing in a general medical population. J Pain Symptom Manage 2002; 23:131–137.
16. **American Academy of Family Physicians**. Pain management and opioid abuse: a public health concern. Position paper, executive summary. 2012; www.aafp.org/content/dam/AAFP/documents/patient_care/pain_management/opioid-abuse-position-paper.pdf. Accessed October 10, 2015.
17. **Breuer B, Pappagallo M, Tai JY, Portenoy RK**. U.S. board-certified pain physician practices: uniformity and census data of their locations. J Pain 2007; 8:244–250.
18. **Rush AJ, Shaw BF**. Psychotherapeutic treatment of opiate addiction. Am J Psychother 1981; 35:61–75.
19. U.S. Department of Justice, Office of Diversion Control, Title 21 Code of Federal Regulations - Part 1300 - Definitions. 2015; www.deadiversion.usdoj.gov/21cfr/cfr/1300/1300_01.htm. Accessed Octo-

ber 10, 2016.
20. **McGee S, Silverman RD**. Treatment agreements, informed consent, and the role of state medical boards in opioid prescribing. Pain Med 2015; 16:25–29.
21. **Buchman DZ, Ho A**. What's trust got to do with it? Revisiting opioid contracts. J Med Ethics 2014; 40:673–677.
22. **Deep K**. Use of narcotics contracts. Virtual Mentor 2013; 15:416–420.
23. **Payne R, Anderson E, Arnold R, et al**. A rose by any other name: pain contracts/agreements. Am J Bioethics 2010; 10:5–12.
24. **Goldberg DSDS**. Job and the stigmatization of chronic pain. Perspect Biol Med 2010; 53:425–438.
25. **Bronstein K PS, Munitz L, Leider H**. Can clinicians accurately predict which patients are misusing their medications? American Pain Society 30th Annual Scientific Meeting; May 18–21, 2011, 2011; Austin, TX.
26. **Gourlay DL, Heit HA, Almahrezi A**. Universal precautions in pain medicine: a rational approach to the treatment of chronic pain. Pain Med 2005; 6:107–112.
27. **Charles C, Gafni A, Whelan T**. Shared decision-making in the medical encounter: what does it mean? (or it takes at least two to tango). Soc Sci Med 1997; 44:681–692.
28. **Murray E, Charles C, Gafni A**. Shared decision-making in primary care: tailoring the Charles et al model to fit the context of general practice. Patient Educ Couns 2006; 62:205–211.
29. **Sullivan MD, Leigh J, Gaster B**. Brief report: training internists in shared decision making about chronic opioid treatment for noncancer pain. J Gen Intern Med 2006; 21:360–362.
30. **Charles C, Gafni A, Whelan T**. Decision-making in the physician-patient encounter: revisiting the shared treatment decision-making model. Soc Sci Med 1999; 49:651–661.
31. **Makoul G, Clayman ML**. An integrative model of shared decision making in medical encounters. Patient Educ Couns 2006; 60:301–312.
32. **Savage S**. The patient-centered opioid treatment agreement. Am J Bioethics 2010; 10:18–19.
33. **Crowley-Matoka M**. How to parse the protective, the punitive and the prejudicial in chronic opioid therapy? Pain 2013; 154:5–6.
34. **Arnold RM, Han PK, Seltzer D**. Opioid contracts in chronic nonmalignant pain management: objectives and uncertainties. Am J Med 2006; 119:292–296.
35. **Kirkpatrick AF, Derasari M, Kovacs PL, Lamb BD, Miller R, Reading A**. A protocol-contract for opioid use in patients with chronic pain not due to malignancy. J Clin Anesth 1998; 10:435–443.
36. **Fishman SM, Bandman TB, Edwards A, Borsook D**. The opioid contract in the management of chronic pain. J Pain Symptom Manage 1999; 18:27–37.
37. **Hariharan J, Lamb GC, Neuner JM**. Long-term opioid contract use for chronic pain management in primary care practice. A five year experience. J Gen Intern Med 2007; 22:485–490.
38. **Fishman SM, Wilsey B, Yang J, Reisfield GM, Bandman TB, Borsook D**. Adherence monitoring and drug surveillance in chronic opioid therapy. J Pain Symptom Manage 2000; 20:293–307.
39. **Starrels JL, Becker WC, Alford DP, Kapoor A, Williams AR, Turner BJ**. Systematic review: treatment agreements and urine drug testing to reduce opioid misuse in patients with chronic pain. Ann Intern Med 2010; 152:712–720.
40. **King S**. How useful are patient opioid agreements and urine drug testing? Psychiatric Times March 2, 2011; www.psychiatrictimes.com/how-useful-are-patient-opioid-agreements-and-urine-drug-testing. Accessed August 2, 2015.
41. **Starrels JL, Wu B, Peyser D, et al**. It made my life a little easier: primary care providers' beliefs and attitudes about using opioid treatment agreements. J Opioid Manag 2014; 10:95–102.
42. **Touchet BK, Yates WR, Coon KA**. Opioid contract use is associated with physician training level and practice specialty. J Opioid Manage 2005; 1:195–200.
43. **Penko J, Mattson J, Miaskowski C, Kushel M**. Do patients know they are on pain medication agreements? Results from a sample of high-risk patients on chronic opioid therapy. Pain Med 2012; 13:1174–1180.
44. **Nicolaidis C**. Police officer, deal-maker, or health care provider? Moving to a patient-centered framework for chronic opioid management. Pain Med 2011; 12:890–897.
45. **Roskos SE, Keenum AJ, Newman LM, Wallace LS**. Literacy demands and formatting characteristics of opioid contracts in chronic nonmalignant pain management. J Pain 2007; 8:753–758.
46. **Davis TC, Wolf MS, Bass PF 3rd, et al**. Low literacy impairs comprehension of prescription drug warning labels. J Gen Intern Med 2006; 21:847–851.
47. **American Academy of Pain Medicine**. State legislative updates. www.painmed.org/advocacy/state-updates/. Accessed August 5, 2016.
48. **Burchman SL, Pagel PS**. Implementation of a formal treatment agreement for outpatient management of chronic nonmalignant pain with opioid analgesics. J Pain Symptom Manage 1995; 10:556–563.
49. **Federation of State Medical Boards**. Model policy on the use of opioid analgesics in the treatment of chronic pain. 2013; www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/pain_policy_july2013.pdf. Accessed August 2, 2016.
50. **University of Wisconsin-Madison**. Pain & Policy Studies Group. Database of statutes, regulations, & other policies for pain management. www.painpolicy.wisc.edu/database-statutes-regulations-other-policies-pain-management. Accessed August 3, 2016.
51. **Cameron KA, Rintamaki LS, Kamanda-Kosseh M, Noskin GA, Baker DW, Makoul G**. Using theoretical constructs to identify key issues for targeted message design: African American seniors' perceptions about influenza and influenza vaccination. Health Commun 2009; 24:316–326.
52. **Kandula NR, Nsiah-Kumi PA, Makoul G, et al**. The relationship between health literacy and knowledge improvement after a multimedia type 2 diabetes education program. Patient Educ Couns 2009; 75:321–327.
53. **Chou R, Fanciullo GJ, Fine PG, et al**. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. J Pain 2009; 10:113–130.
54. **Adams NJ, Plane MB, Fleming MF, Mundt MP, Saunders LA, Stauffacher EA**. Opioids and the treatment of chronic pain in a primary care sample. J Pain Symptom Manage 2001; 22:791–796.
55. **Richeimer SH**. Opioids for pain: risk management. Semin Anesthesia Periop Med Pain 2005; 24:165–169.

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