# Controlled Substance Agreements and Other Best Opioid Prescription Practices

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**KEYWORDS**

- Controlled substance agreements • Opioid prescribing best practices
- Chronic opioid prescription

**KEY POINTS**

- Prescription of controlled substances for chronic pain is complex, and given the known detrimental side effects, requires careful management between patient and provider.
- Part of responsible prescription of controlled substances for chronic pain can include a controlled substance agreement, which serves as an educational tool and an agreement between patient and provider.
- Best practices for chronic opioid prescription include ongoing monitoring for correct use, including routine drug screening, evaluating ongoing need for narcotic medications, and regularly reviewing the prescription monitoring program.

## INTRODUCTION

Acute and chronic pain are common symptoms among patients presenting to surgical providers. At the initial consultation, patients may be opioid naïve or they may be on chronic analgesic therapy.[1] It is important for the surgical provider to evaluate both the current and potential postoperative pain needs of each patient to develop a personalized therapeutic plan for the perioperative future. For patients requiring chronic opioids, controlled substance agreements constitute a nonlegally binding agreement between the physician and provider outlining treatment goals and guidelines. Best prescription practices and expectations are outlined in the controlled substance agreement, including informed consent, regular checks of prescription drug monitoring program, regular toxicology screening, adhering to 1 provider/1 pharmacy, and regular reassessment of risk/benefit analysis of the treatment.

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Otolaryngol Clin N Am 53 (2020) 877–883
https://doi.org/10.1016/j.otc.2020.05.017
oto.theclinics.com

## CONTROLLED SUBSTANCE AGREEMENTS AND OTHER BEST OPIOID PRESCRIBING PRACTICES

Controlled substances, including opioids and benzodiazepines, are common medications that are used in the perioperative period. It is not uncommon for surgical procedures to represent the first time that patients may be exposed to opioids or other controlled substances. Yet, these substances can pose significant risk to patients. In 2016, drug overdose resulted in the death of an estimated 63,600 people in the United States, which was an increase of 21% from 2015, with more than 60% involving opioids.[2] Experts estimate that one-half of these overdoses were related to prescription opioids.[2] Given that 1 in 16 patients may become chronic users of opioids after surgical procedures, it is imperative that providers follow best practices when managing their pain.[2]

The US Department of Health and Human Services estimates that the cost of both acute and chronic pain to the United States is between $560 billion and $635 billion annually. Because many patients present to a variety of physician providers for management of their pain, management can prove difficult. Controlled substance use, in particular opioids, and their potential adverse consequences have increased since the 1990s. This escalation has been termed the "opioid epidemic" and drug-related deaths have tripled from 1999 to 2015.[3] Although these alarming statistics include prescribed sources, they also include alternative, nonprescription sources. In October 2017, a public health emergency was declared and in 2018 the "Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand" was released.

Despite these striking statistics, many controlled substances remain important components of acute, perioperative, and chronic pain management. However, providers may feel increasingly uncomfortable with prescribing these medications to patients. To this end, the rate of opioid prescriptions has been decreasing and greater numbers of providers are refusing to provide prescriptions for these medications.[1] Therefore, with their high potential for misuse, it is important for providers to understand current guidelines for both prescribing and monitoring appropriate use of these medications.

The initial approach to patients who may benefit from use of a controlled substance involves a careful evaluation of their underlying condition, with establishment of a clear diagnosis, involving obtaining a relevant workup and potentially offering surgical or other definitive intervention, should it be deemed appropriate. A comprehensive treatment plan should be established with clear, measurable outcomes that can be tracked over time, involving important clinical metrics, such as PEG score, improvements in quality of life, the ability to perform activities of daily living, or functional status (**Table 1**).[3] A multimodal and multidisciplinary treatment plan should be established, which may include medications, interventional pain management techniques, and physical or occupational therapy.[1] Providers should perform risk assessment while devising a personalized treatment plan for patients. This assessment should help to identify risk factors from relevant patient or family history and current biopsychosocial factors that may impact their ability to comply with different aspects of treatment plans.[1]

Once a provider has determined that a controlled substance is a necessary component of a patient's chronic treatment plan, they should enter into a mutual treatment agreement with the patient with clearly outlined goals and guidelines for their care (**Box 1**). This step is important for both providers and patients to understand responsible use of these medications and provide a framework for discussion before treatment initiation as well as should any potential discrepancies arise. This previously

**Table 1**
**PEG score: used to assess pain and functioning**

| During the past week, | |
|---|---|
| 1. What number best describes your *P*ain? | |
| 0 = no pain | 10 = worst pain imaginable |
| 2. What number best describes how much your pain interfered with your *E*njoyment of life? | |
| 0 = no interference | 10 = complete interference |
| 3. What number describes how much pain interfered with your *G*eneral activity? | |
| 0 = no interference | 10 = complete interference |

The PEG score may be tracked to gauge benefit from chronic opioid use. To calculate PEG score, average scores from questions 1 through 3.

*From* Checklist for prescribing opioids for chronic pain. CDC. Available at: https://www.cdc.gov/drugoverdose/pdf/pdo_checklist-a.pdf.

has been described as a narcotic contract; however, this term carries significant stigma and does not encompass all potential agents for misuse, dependence, or addiction. Additionally, the use of the term contract can suggest legal connotations, so this language is discouraged. Therefore, many in the pain treatment community advocate for the term controlled substance agreement.

One of the most important tenants of a controlled substance agreement is the belief in shared decision making between the patient and the provider. A candid discussion should occur with the patient where information is provided regarding the risks, benefits, and alternatives to controlled substance use. The patient and provider should have a frank discussion regarding expectations of disease progression and functional goals of treatment. This patient-centric discussion should aim to incorporate the patient's values and preferences regarding their care in the setting of physician-guided treatment recommendations. During this discussion, it is important to assess each

**Box 1**
**Common components of controlled substance agreements**

Goals of treatment (improved functional status, benefits outweigh risks, reevaluation)

Risks of opioid treatment

Safe medication storage

No early refills (file police report if stolen)

Safe medication disposal

Regular toxicology screens/pill counts

No refills on nights/weekends

No illicit substances

No diversion

One prescribing provider only

One pharmacy for medications only

*Data from* G., Keough Forte, K., & Johnson McGee, S. (2016). Breaking the pain contract: A better controlled-substance agreement for patients on chronic opioid therapy. Cleve Clin J Med, 83(11), 827-35.

patient's health literacy and ensure that all essential medical information is communicated in a clear, understandable format. The provider should attempt to identify and educate the patient regarding any potential gaps in understanding.

It is important that the language that is used both during the discussion and with the formal controlled substance agreement highlights the partnership between the patient and the physician. Providers should avoid using language that promotes mistrust or is accusatory in nature. This style of communication may undermine the trust-building component of the agreement that is essential to a successful treatment plan and successful treatment of patients' pain. Instead, a focus on patient safety and shared decision making with an understanding of mutual respect can facilitate these goals can help establish a therapeutic alliance between patient and physician.

The goals of treatment should be outlined in the controlled substance agreement. It should be clear that the benefits versus the risks of opioids and other analgesics will continue to be reevaluated at regular time intervals, and the decision to wean off opioids may occur if the risks outweigh the benefits.

The controlled substance agreement can also serve as an important educational tool for the patient regarding not only appropriate use of the prescribed pharmacologic agent, but also other potential agents that can interact with the controlled substance. The agreement should clarify guidelines from the provider regarding the avoidance of other substances, such as alcohol and illicit drugs, while undergoing this type of therapy. The dangerous adverse effects, including respiratory depression and death, should be highlighted from concomitant use of the substances and agreement should be established between patient and provider regarding their use.

Plans for follow-up should be established so that patients and providers can have an ongoing dialogue and discussion regarding the treatment plan. Decisions can be made at these points regarding whether modification of the plan is necessary. Patients should be notified of the importance of keeping regular appointments with their provider while they are participating in a controlled substance agreement and that this is a requirement of continued prescription therapy.

Within the controlled substance agreement, best practices for these substances should be outlined and adhered to at subsequent patient visits as well as outlining practice policies (**Box 2**). One key element of this involves obtaining informed consent, including education regarding the potential risks and benefits of opioids. It is essential that patients understand the risks of overdose and death with the use of certain controlled substances. Clear guidelines should be given if overdose is suspected.

**Box 2**
**Best practices for chronic opioid prescribing**

- Discuss risks/benefits of opioids
- Complete a controlled substance agreement
- Perform regular urine toxicology screening
- Prescribe refills at office visits
- Check prescription drug monitoring program
- Assess PEG or other measurement of functional status
- Consider naloxone prescription for patients on 50mg oral morphine equivalents or higher daily

*Data from* Dowell, D., Haegerich, T. M., & Chou, R. (2016). CDC guideline for prescribing opioids for chronic pain—United States, 2016. Jama, 315(15), 1624-1645.

The provider should consider prescribing naloxone to be used in case of accidental overdose to patients at higher risk. This includes patients with a history of overdose, history of substance use disorder, those concurrently taking benzodiazepines, and those on 50mg oral morphine equivalents daily or higher. The patient and those living in the household should be educated regarding naloxone use.[4]

There are several objectives of the physician–patient controlled substance agreement, among which is improved compliance with appropriate use of these medications by patients. A meta-analysis of various practice settings prescribing controlled substances showed modest improvement in patient compliance after the institution of controlled substance agreement.[5] A study looking at pain adherence in patients who had controlled substance agreement in a pain practice showed that this metric improved by 50% in patients.[6] After the introduction of controlled substance agreement in the treatment of noncancer chronic pain, patients were shown to have fewer primary care visits, fewer hospitalizations, and fewer specialty care visits.[7]

Physicians should review with the patient what their preferred pharmacy is and an agreement should be made to only fill controlled substance prescriptions at this location and only at the appropriately prescribed intervals with no early refills. Expectations should be described, including how refill requests are managed after hours and on weekends. An agreement should be established regarding management if medication is lost, stolen, or misplaced, with an understanding that a police report must be filed. Physicians should routinely review the prescription drug monitoring program to ensure that patients are compliant. As a part of the controlled substance agreement, patients should understand that their prescribing physician will be routinely reviewing this information. In accordance with this, both the patient and the physician should agree that the physician involved in the controlled substance agreement should be the only provider prescribing controlled substances and the patient should not attempt to obtain these medications from outside sources.

Additional measures may be used, including pill counts, where patients should be instructed to bring in their medications and providers can count the remaining pills. This measure can help to ensure that patients are taking the pills throughout the prescription interval at an appropriate rate as prescribed. It is important for patients to understand that they should not be taking the controlled substance more frequently than prescribed. Patients should be instructed that they should bring their medications in their original packaging for this counting to occur.

Patients should also be counseled regarding the appropriate disposal of controlled substances, should they have excess. Patients should be educated regarding the inappropriateness and illegal nature of giving or selling their medications to other individuals. They should be counseled on keeping their medications in a secure location, where others do not have access. Part of the controlled substance agreement should include routine urine screening for both the presence of the prescribed agent as well as the absence of other nonprescribed agents.

The controlled substance agreement should outline whom the physician is able to communicate with regarding the patient's use of certain pharmacologic agents. Many of these agreements inform patients that the physician will be able to communicate with the patient's primary care provider and other consultants. These details should be clearly agreed upon before treatment initiation.

Both the prescribing physician and the patient should be provided with a copy of the agreed-upon controlled substance agreement. This step can provide the patient with a reference in case questions arise, as well as promote standard office practices. This document may aid in avoiding both conflict and confusion between patients and

providers. This step can help the patient to understand standard practices and destigmatize regular toxicology screenings and other protocols. Guidelines may outline appropriate contact with office staff members and require the avoidance of combative, coercive, or abusive behavior toward these individuals.

It is important for physicians prescribing controlled substances to be transparent in their controlled substance agreement policies and apply them universally to the patients who they treat using the aforementioned medications. Studies have shown that physicians' ability to predict which patients will misuse controlled substances is only slightly better than chance alone.[8]

An additional benefit of obtaining a controlled substance agreement is that it can provide documentation that informed consent was obtained. Patients should understand both the potential benefits of pain relief and the known adverse consequences associated with controlled substance use. These agreements should outline issues such as respiratory depression, tolerance, dependence, addiction, and constipation. Females of child-bearing age should understand the risk of the controlled substance in case of pregnancy. Patients should also understand that controlled substances may provide incomplete relief of their pain and that their treatment expectations should be established. Patients should be counseled about avoiding abrupt discontinuation of these agents. Discussion should ensue regarding the symptoms and risks of withdrawal with certain agents. The controlled substance agreement may be a potential opportunity to give instructions regarding the potential dangers of driving or operating heavy machinery while using controlled substances. The controlled substance agreement can also set the expectation that the controlled substance would be discontinued if the controlled substance agreement is violated.

As a part of their ongoing care, patients and providers should routinely evaluate the continued need of controlled substances as a part of their care plan. Alternative therapies should always be sought, and providers and patients should discuss the potential for tapering off the controlled substance at the earliest possible point in time.

The controlled substance agreement is another potential avenue to outline the multimodal nature of a treatment plan for the patient. As part of the therapeutic alliance, the providers may request or require that the patient is compliant with other aspects of pain treatment. This process can include a variety of other modalities, including physical therapy, psychotherapy, or behavioral counseling.[9]

## SUMMARY

The controlled substance agreement is a nonlegal agreement between the provider and the patient that serves as a valuable tool for setting expectations and guidelines for chronic opioid therapy. It may be used to outline best opioid prescription practices and destigmatize practice policies, such as regular monitoring of prescription drug monitoring program and regular toxicology screenings. It can also outline treatment guidelines, such as regular reassessment of treatment benefits versus risks. It may set expectations for discontinuation of therapy if deemed appropriate. Because many surgical patients present with acute or chronic pain, the surgeon must be versed in best opioid prescription guidelines for the safe management of these medications.

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