

Responsible Opioid Prescribing for Chronic Pain: Interpreting the CDC Guideline, Understanding New Rhode Island Regulations

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ABSTRACT

New Rhode Island regulations require physicians and other licensed practitioners to make significant adjustments to comply with new requirements for prescribing narcotics for chronic pain. Responding to the opioid epidemic, the new rules are intended to improve patient safety by changing physicians' prescribing patterns. However, the new rules may overlook the importance of treatment-access problems and the importance of buprenorphine products for treating pain and opioid dependence. Empirical data have demonstrated the safety and efficacy of buprenorphine in treating opioid-dependent patients with chronic pain, including those with and without substance abuse histories, but access to buprenorphine treatment remains limited throughout the state. The new regulations call upon physicians to make use of consultation services, which are also of limited availability. Although well intentioned, the new rules may contribute to treatment-access problems, and patients with chronic pain may resort to higher-risk "street" drugs when they are unable to access safe but effective medical treatment.

KEYWORDS: analgesics, opioid, buprenorphine, social control, formal, chronic pain, referral and consultation

INTRODUCTION

New Rhode Island regulations¹ require physicians and other licensed practitioners to make significant adjustments to comply with new requirements for prescribing narcotics for chronic pain. The rules, issued by the state Department of Health and filed with the Secretary of State, contain requirements for multiple stages in the treatment of patients with chronic pain, including the initial evaluation (§ 3.1); minimum requirements for documentation of the treatment plan in the medical record (§ 3.2); maximum limits for morphine milligram equivalent (MME) dosing in initial prescriptions for acute pain (§ 3.3(b)); use of the Prescription Monitoring Program (PMP) (§§ 3.5, 3.7(c), 3.13(a)); minimum disclosure requirements for informed consent (§ 3.4); a written Patient Treatment Agreement documented in the medical record for any chronic pain patients receiving an opioid prescription (§ 3.6); periodic review of treatment compliance, efficacy,

etc. (§ 3.7); circumstances requiring consultation with a Pain Medicine Physician (§ 3.9(c)); care transitions (§ 3.10); and processes for transmitting prescriptions to pharmacies (§ 3.11). The regulations also include detailed rules for the prescription of long-acting opioids such as methadone (§ 3.12), training requirements for practitioners who prescribe Schedule II opioids (§ 3.14), and registration with the Department of Health (§ 4). Violations of the regulations are considered equivalent to violations of the Uniform Controlled Substances Act.² The new Rhode Island regulations are intended to improve patient safety by drastically reducing the frequency and amount of prescribed narcotic analgesics that have been associated with increased abuse, morbidity and mortality.

BACKGROUND: UNDERSTANDING THE OPIOID EPIDEMIC

The national epidemic of deaths related to opioid abuse and dependence is recognized as a crisis of historic proportions, and Rhode Island has not escaped its effects. Drug overdose death rates are roughly five times greater than they were in the early 1980s, and the percentage of fatal overdoses involving opioids roughly doubled within the first 10 years of the 21st Century.³ In 2009, deaths from drug overdoses exceeded those from motor vehicle accidents in the U.S. for the first time, with a significant portion of these deaths involving opioids.³ Because many of the overdose deaths occurred in patients who had originally obtained opioid prescriptions, many states have been developing new or revised legislation to control physician prescribing practices.

The opioids that have been associated with the highest morbidity and mortality include oxycodone, hydrocodone, and methadone,³ which are all full opioid agonists.⁴ These are often taken in combination with alcohol or other drugs, frequently benzodiazepines.³ Concurrent use of opioids with benzodiazepines increases the risk of overdose.⁵

The Centers for Disease Control and Prevention (CDC) issued a new Guideline for Prescribing Opioids for Chronic Pain⁶ in March 2016, intended to help curb the rate of opioid overdose deaths and the rising tide of opioid dependence in the U.S. The Guideline provided recommendations aimed mainly towards primary care physicians treating adult patients with chronic non-cancer pain. The recommendations were also targeted primarily for new prescriptions

rather than toward the treatment of patients who are already on long-term opioid treatment.

Legislation like that of the new Rhode Island rules represents a well-intentioned effort among regulatory bodies to improve patient safety and to reverse some of the worrying trends seen in recent years with opioid use and abuse. However, new and additional regulations carry the risk of unintended and undesirable consequences for patients and healthcare providers. The new regulations may contribute to existing problems with treatment access among patients with opioid dependence.

THE ROLE OF BUPRENORPHINE IN MANAGING THE OPIOID CRISIS

There are safer ways to help patients with chronic pain, but access problems are significant. Empirical data support the safety and efficacy of buprenorphine in treating patients with chronic pain, including those with a history of substance abuse, but access to buprenorphine treatment is limited. In contrast to full opioid agonists, buprenorphine products, which are potent partial opioid agonists,⁴ have not been implicated in life-threatening overdoses. In fact, buprenorphine products have a significant protective mechanism through their stronger binding to opioid receptors.⁷ This results in less sedation and respiratory depression compared to full opioid agonists.⁸

Several open studies have observed that buprenorphine products are highly effective for treating chronic pain.^{9,10,11} This effectiveness has been demonstrated both in opioid-dependent and non-dependent patients. Malinoff and colleagues evaluated the treatment of 95 patients with chronic pain who were referred for detoxification from opioid analgesics.⁹ Buprenorphine treatment was successful in 86% of patients, including measured improvements in mood, functioning, and subjective difficulty with pain.⁹ In a study of 143 veterans with chronic pain and opioid dependence treated with buprenorphine/naloxone, Pade and colleagues observed high treatment retention and “modest but statistically significant improvement” in pain scores on buprenorphine/naloxone.^{10, p.446}

Streltzer et al. studied the treatment of comorbid opioid dependence and pain in primary care, exploring whether treatment response differs between patients with and without a history of substance abuse.¹¹ Patients in the sample had chronic pain that was difficult to manage, were taking morphine equivalent doses of at least 120 mg (except for three patients), and most had been diagnosed with opioid dependence. Following treatment with buprenorphine, patients reported high levels of treatment satisfaction and “much less preoccupation with pain.”^{11, p.357} There was no significant difference in treatment outcome between patients with and without substance abuse history.¹¹

THE ROLE OF CONSULTATION SERVICES

The above findings are consistent with the experience of this author, who has been providing consultation to Rhode Island community physicians who have become uncomfortable managing difficult chronic pain with opioid treatment. In the current climate of prescription narcotic abuse, physicians are increasingly uncomfortable prescribing opioid analgesics.¹² In light of this, the new regulations recommend utilizing consultation services.¹³

RESOURCES AND OBSTACLES TO OBTAINING TREATMENT

Consultation and treatment services are of limited availability. There are several pain management clinics identified in the community, as well as other physicians with the qualifications to provide consultation. Unfortunately, these resources generally do not appear to manage patients identified as needing to be tapered or discontinued from high-dose opioid analgesics, even when they are clinically indicated. Regulations should be revised or clarified to allow for treatment and reimbursement in a substance abuse treatment setting if there are no other available treatment settings.

This author has been providing consultation primarily in the context of hospital-based dual-diagnosis programs at Butler Hospital. Patients have been primarily evaluated for their potential to either detox completely from opioids or transition from high-dose full-agonist opioids with induction to buprenorphine products. Many of these patients meet the criteria for opioid dependence and substance use disorder, past or present. Because of the medical complexity and high morphine equivalent dosing, buprenorphine induction takes place in a dual-diagnosis outpatient (and, on occasion, inpatient) hospital-based setting. Clinical outcomes in Butler Hospital’s dual-diagnosis program have generally been remarkably positive, with patient reports of pain reduction and increased functioning and quality of life.

Dual-diagnosis hospital-based detox clinics are one of the only available settings for discontinuing narcotic analgesics and/or transitioning with induction to buprenorphine products. This raises the question as to what settings are available for a patient without an Opioid Use Disorder (OUD), but still requiring the protocol for buprenorphine induction to transition to the safer product. In order to access treatment in a substance abuse treatment center, a diagnostic code of OUD is required for meeting criteria and therefore reimbursement. In many cases, a comorbid diagnosis of OUD is appropriate, but there are times that there is no apparent comorbid OUD. These patients find themselves without an available setting for this important treatment option. Buprenorphine induction may be clinically indicated for patients without a history of opioid abuse and raises questions as to whether an OUD diagnostic code should be required.

CONCLUSION

Just as the CDC Guideline provided a major step toward bringing the medical community together in order to address the opioid abuse and overdose epidemic, the new Rhode Island regulations represent another effort to improve patient safety. However, the guidelines do not differentiate between different types of prescription opioids, which may lead more physicians to avoid the use of safer products like buprenorphine, even when they are clinically indicated. There needs to be physician education to increase awareness that the use of buprenorphine products is approved when clinically indicated. Prescriptions only require the stipulation that the prescription is for pain. No special waiver is required. New regulations should aim to increase the availability of Medication-Assisted Treatment (MAT) for OUD and buprenorphine products for chronic pain. When MAT and safer opioids (like buprenorphine) are unavailable to mitigate withdrawal, patients may resort to street drugs with a higher potential for abuse and fatal overdose. New regulations should make it easier for physicians to utilize safe and effective treatment for patients with chronic pain. Regulations should be revised or clarified to allow for treatment in a substance abuse treatment setting, even if there is no diagnosis of an opioid use disorder, if there are no other available treatment site options.

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