GUIDELINES FOR MEDICAL BOARD INVESTIGATORS AND CONSULTANTS DEALING WITH DISTRESSED PAIN MEDICINE PRACTICES

David G. Greenberg, M.D., M.P.H.

ABSTRACT

During the past decade, the federal government has approved the development and marketing of powerful oral and transdermal narcotic preparations whose unit dose amounts often contain a much greater amount of active ingredient than ever previously allowed in a single dose of such medication. Although these changes have been beneficial in allowing patients suffering from severe chronic pain syndromes to have better access to higher doses of narcotic analgesics, in a minority of cases substance abusing and drug diverting patients have contributed to increases in their own and the public's morbidity and mortality. Medical and other related regulatory boards have experienced significant difficulties in adapting their regulatory activities to recent increases in the prescribing of high unit dose narcotic preparations. Complicating this problem is the fact that the vast majority of practicing physicians have had little or no formal training in the fields of chronic pain or addiction medicine; and that most physicians completed their training long before the fairly recent approval and marketing of high dosage narcotic medications. These and other factors can contribute to dangerous prescribing practices. The author wishes to assist medical board staff in conducting thorough, consistent and fair investigations of cases involving suspected inappropriate prescribing of chronic pain medications. The attempt has been made to provide a possible approach for adjudicating board members that incorporates accepted modern methods for the compassionate diagnosis, treatment and ongoing monitoring of chronic pain patients that also serves to protect patients, the public, prescribing physicians and the regulatory boards.

INTRODUCTION

State medical regulatory boards were unfortunately not included in the recent momentous bureaucratic process during which the federal government made unprecedented decisions to allow for the mass marketing of extremely high dosage Schedule II oral narcotic preparations. As a result, state boards and provincial colleges were caught off guard when some of their licentiates began to prescribe such around-the-clock narcotic preparations to patients with non-malignant pain symptoms. This article attempts to address these new regulatory challenges in a practical, safe and compassionate manner while also serving as a guide for medical investigators evaluating complaints concerning chronic pain medical practitioners.

During the past several years, North American medical prescribing practices regarding chronic pain diagnoses have undergone dramatic change. More physicians are prescribing Schedule II narcotics to a larger number of patients while the doses of narcotics prescribed to individual patients have inflated markedly. These increases follow a significant policy change in which federal regulators have approved previously unheard of high dosage levels of certain oral narcotic preparations. In addition, much of the increase in narcotic prescribing follows significant detailing efforts by a relative handful of large pharmaceutical houses.

As an example, in the recent past a common Rx for severe pain was 5 mg oxycodone with 325 mg of acetaminophen (Percocet) to be taken as 1-2 tablets every 4-6 hours for pain. The "maximum" amount to be taken was approximately 10 tablets per day or 50 mg of oxycodone per day. Because of the large amount of acetaminophen in this preparation, it was not easily abused by injection or snorting and wise physicians were reticent to prescribe greater numbers of tablets because of their concern for liver toxicity secondary to acetaminophen.

A common current prescription for severe pain with new "long-acting" drugs can be as much as 80 mg oxycodone

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taken 3-4 times per day. The new "maximum" amount to be taken per day is 240-320 mg. This is an increase in narcotic dosing of approximately 600 percent per day over just five years ago. Many of these "long-acting" pills are easily abused and transformed into rapid-acting narcotics by chewing or crushing to snort or inject. Furthermore, the author's experience has been that long-acting narcotic preparations are frequently not effective when taken every 12 hours as advertised. Many patients require such "long acting" medicines three or even four times per day and/or must take short-acting narcotics for "breakthrough pain."

An inadvertent consequence of such prolific narcotic prescribing has been an easily demonstrable increase in drug abuse and drug diversion by patients being treated for chronic pain. This surge of drug abuse and drug diversion by some chronic pain patients is easily missed by many physicians who, for whatever reasons, choose to practice medicine in a manner that ignores or discounts problems involving patients who abuse or divert their chronic pain prescriptions. The author firmly believes curtailing drug abuse and drug diversion can be accomplished without unduly impeding the compassionate use of narcotic analgesics in the treatment of properly diagnosed and managed chronic pain patients. The goals of this article are to:

1. Briefly describe the workings of a successful large chronic pain treatment clinic that incorporated many policies and procedures that served to promote rational treatments and minimize drug abuse and diversion.
2. Delineate common serious problems found in many chronic pain practices that decrease the quality of patient care and may endanger society at large from drug diversion and abuse. In so doing, medical investigators will then be able to recognize and document potential problems in a medical practice under review.
3. Propose clinical and administrative approaches to the management of chronic pain patients to improve their quality of care and decrease the incidence of drug abuse and diversion in this population. Such proposed changes may provide the framework for remediating a distressed chronic pain practice.
4. Explore risk management issues commonly found in certain chronic pain practices. Both medical boards and liability insurers may be keen to detect and reduce the risks entailed by the actions and omissions of distressed chronic pain providers.

PAST LESSONS

From 1985 through 1990, the author served as the medical director for an interdisciplinary chronic pain clinic serving a staff model HMO with approximately 300,000 members in the state of Arizona. The clinical team included members from the specialties of psychiatry, psychology, neurology, anesthesiology, addiction medicine, pharmacy and master's level mental health counselors. Other specialists such as neurosurgeons, orthopaedists, and rheumatologists were utilized on an as-needed basis.

All patients were subject to complete historical review and appropriate diagnostic workups. After diagnosis and informed consent, the patients benefited from a full spectrum of treatments guided by a rational treatment plan and a comprehensive chronic pain treatment contract. Bear in mind the proper diagnoses and rational treatments are as important in pain medicine as they are in other specialties such as surgery and internal medicine. The list in Table 1 details some of the critical components of the aforementioned interdisciplinary clinic's approach to chronic pain.

Table 1

Diagnostic Strategies for Chronic Pain

1. History
2. Verification of history
3. Physical exam
4. Laboratory studies
5. Other diagnostic studies
6. Specialty consultations

Components of a Treatment Plan

1. Problem
2. Diagnosis
3. Intervention
4. Goals of intervention
5. How to assess accomplishment of goals

Non-Narcotic Pain Treatments

1. Medications other than narcotics
2. Physical therapy
3. Occupational therapy
4. Stretching and exercise programs
5. Weight loss
6. Smoking cessation
7. Counseling
8. Biofeedback
9. Nerve blocks
10. Support groups

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11. Vocational rehab
12. Alternative medicine

The majority of the clinic's patients were diagnosed with disorders in which narcotic medications were indicated along with other treatments. In choosing a narcotic for chronic pain treatment, the prescribing physicians endeavored to start with the drug that had the best combination of effectiveness, low abuse potential, low diversion potential, and competitive price. In an opiate naïve individual, it was found to almost always be best to begin narcotic therapy with a low dosage Schedule III preparation. When stronger preparations were indicated, the patients were routinely placed on an upwardly controlled titration of liquid methadone 1 mg/cc. This regimen allowed for superior pain control in a safe and effective manner that minimized drug abuse and diversion. Methadone is usually less euphorogenic than many other Schedule II narcotics and, in liquid form, it is less likely to be commercially diverted. Methadone also has the advantage of being an inherently long-acting chemical that does not require any attempts at producing specialized formulations to slow its absorption from the gastrointestinal tract.

In this practice, narcotic analgesics were prescribed to the great majority of patients in a judicious and compassionate manner. However, approximately 25 percent of the patients were successfully treated without using narcotics or only using intermittent narcotic medications. On occasion, other Schedule II narcotics (other than methadone) were prescribed in a fashion that also emphasized efficacious pain relief, decreased possibility for abuse or diversion, and that took into account the affordability of the medication. Liquid preparations were the predominant initial Schedule II drug prescribed because these were so easily titrated in order to achieve adequate pain control with minimal side effects compared to fixed dosage pills. These preparations provided excellent analgesia and the maximum dose of methadone required rarely exceeded 60 mg/day. The program maintained a high degree of vigilance insofar as detecting drug abuse and diversion via patient history, physical exam, and laboratory tests. Patients detected to have active drug abuse were referred for substance abuse treatment, whereas drug diverters had controlled substances eliminated from their regimens. Of note, all patients were required to utilize appropriate non-narcotic treatments as indicated.

Key lessons learned were:

1. The initial workup and stabilization of complex chronic pain patients is labor intensive, consuming an average of four hours of total physician time in the first 90 days. Thereafter, pain physician time and consultant time dropped to less than one hour per month on average.
2. Most patients could be returned to their primary care physicians for their ongoing care after diagnosis and stabilization by the interdisciplinary chronic pain treatment team. These patients were scheduled for at least one pain clinic follow-up appointment per year.
3. Approximately 20 percent of all patients presenting to the pain clinic were detected to be active drug abusers and/or diverters during their 90-day workup and stabilization period. Another five percent were detected to be diverters or abusers during their first year in the program. It should be noted approximately five percent of all patients referred to the clinic refused to make an appointment when they heard that the clinic performed drug testing on all patients.
4. Patients with a substance abuse history could be successfully treated for their chronic pain complaints although their treatment rarely included continuous Schedule II narcotic analgesics. The successful treatment of this group of patients dramatically and sustainably decreased their utilization of all other healthcare resources. The savings incurred by treating these patients properly more than paid for the cost of running the interdisciplinary pain clinic.

PROBLEMS FOUND IN MANY CONTEMPORARY PAIN PRACTICES

It is not difficult to ascertain the reasons why so many chronic pain medical practices are distressed. Currently, most North American physicians who write "long-acting" Schedule II narcotic prescriptions for chronic pain patients have little if any formal training in the management of chronic pain. For the most part, they are busy primary care providers without resources or expertise in this area. Recently, a trend appears to be developing in which doctors who have failed to flourish in their respective specialties are transforming themselves into being self-declared chronic pain specialists, again without any formal training or prior experience in diagnosing or managing complex chronic pain patients. These physicians often prescribe high dosage "long-acting" medications for many of their pain patients. They may also believe chronic pain patients can be managed easily within the context of a busy outpatient practice. Drug company detailers may tend to minimize the potential problems of drug abuse and diversion by giving the message to physicians that drug abuse and diversion occur very

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rarely and such problems should not keep the doctors from prescribing high dosage "long-acting" opiates to those patients who could benefit from them. Also, primary care physicians are now subject to increased patient demand for strong narcotics to treat an ever-expanding list of chronic pain complaints. Finally, it appears a significant minority of self declared pain specialists are all to willing to become ongoing targets of drug diverting and drug abusing patients. Table 2 documents common problems in many chronic pain practices:

Table 2

Common Deficiencies in Pain Medicine Practices

1. Failure to allocate necessary time to work up the case adequately.
2. Failure to obtain a general medical history and an in-depth history of the patient's chronic pain problem(s) as well as failure to obtain a substance abuse history.
3. Failure to corroborate the patient's history with prime sourced documents and/or phone contact with past care providers.
4. Failure to perform and document an appropriate physical examination.
5. Failure to order an appropriate pre-treatment urine drug screen.
6. Failure to order indicated diagnostic studies and specialty consultations.
7. Prematurely prescribing controlled substances to patients.
8. Failing to properly prescribe non-narcotic medications and other potentially useful treatments or procedures.
9. Failure to properly address depression and other psychiatric issues.
10. Failure to utilize *and enforce* an appropriate pain treatment contract that includes informed consent.
11. Failure to rationally prescribe narcotics and other controlled substances.
12. Failure to monitor patients for substance abuse, diversion, and compliance with ordered diagnostic and therapeutic trials with modalities other than controlled substances.
13. Failure to design and implement a logical treatment plan.
14. Failure to meet with and examine patients at appropriate intervals.
15. Failure to document ways the patients' pain complaints have been helped by implemented treatments.
16. Failure to arrange competent coverage during practitioner absences such as vacation, CME activities, and sickness.
17. Failure to abide by federal and state statutes regarding the prescribing of controlled substances.
18. Failure to implement policies that assure safe practice insofar as counting or destroying a patient's prescribed medicines.
19. Failure to make a good faith attempt to help drug-abusing patents obtain detoxification and rehabilitation services.
20. Failure to notify risk manager/liability carrier re: situations or events that require timely notification.
21. Failure to follow accepted safe practices when terminating the doctor-patient relationship.

SUGGESTED CHRONIC PAIN PRESCRIBING CHECKLISTS

Table 3 includes suggestions medical boards and other entities may wish to consider as guidelines for practitioners of chronic pain medicine as well as for their investigators. Such guidelines are potentially useful when dealing with a distressed chronic pain practitioner who desires to upgrade his or her clinical approach. It should be noted that thousands of knowledgeable chronic pain specialists have routinely incorporated many of these principles into their practices during the past several years. The author recognizes experienced and well-trained and ethical chronic pain specialists may not need to strictly follow such guidelines as these in order to properly treat chronic pain patients and help prevent drug abuse and diversion. Nevertheless, distressed chronic pain practitioners and their patients can benefit tremendously by embracing these suggested approaches. Needless to say, liability carriers and others involved in medical risk management might also consider recommending part or all of the following to some of their clinicians who have recently chose to declare themselves to be chronic pain specialists.

Table 3

First Appointment Prior to Prescribing Controlled Substances

1. Take a complete general medical and pain treatment history. Directly explore any substance abuse history, including alcohol. Ascertain who has prescribed pain medicines in the past as well as who is prescribing pain medicine for the patient currently. Ask the patient what pharmacies he or she has used in the past two years. Request that the patient pres-

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ent an accepted picture I.D. such as a driver's license when the patient presents for their first appointment.
2. Obtain proper releases, get past medical records and read them. Speak with previous providers via telephone if indicated. Verify reports of past diagnostic and treatment efforts performed by other practitioners.
3. Perform a thorough exam with the patient undressed and gowned. Identify all critical physical examination findings needed to support your diagnosis. Accurately document. Examine the patient for signs of substance abuse.
4. Order a pre-treatment urine drug screen (UDS) with a proper chain of custody and gas chromatography/mass spectroscopy (GC/MS) confirmation. Be certain to test for street drugs and all commonly prescribed controlled substances, e.g., oxycodone, hydrocodone, propoxyphene, meperidine, hydromorphone, codeine, methadone, common stimulants and such sedative hypnotic medications as benzodiazepines and barbiturates.
5. Order any diagnostic studies and consultations that are indicated to help establish a diagnosis. Directly ask your consultants to comment in their reports on whether they believe that long-term controlled substance prescribing is appropriate for the patient's pathology.
6. Do not jump into prescribing narcotics. If the patient is currently on narcotics from another provider, instruct them to continue to obtain their narcotics from that provider until your workup is complete. If this is not possible, call the previous prescribing physician and verify the patient's story. Utilize the World Health Organization's (WHO) analgesic stepladder approach after the diagnosis has been reached:
   - Step 1. Non-narcotic medications and other treatment modalities
   - Step 2. Non-narcotic medications, other treatment modalities, plus mild opiate medication
   - Step 3. Non-narcotic medications, other treatment modalities, plus stronger opiate medication
7. Give the patient a copy of both the Chronic Pain Treatment Contract and the informed consent and instruct them to read it carefully and write down any questions they may have prior to their next appointment.

Second Appointment After Completion of Initial Assessment

1. Answer patient's questions regarding the Chronic Pain Treatment Contract and the informed consent document. Then, ask the patient to initial each item and sign the documents with both the M.D. and another witness countersigning.
2. Determine the best indicated treatment modalities other than narcotics, utilizing the WHO guidelines or other respected medical sources. Insist such non-narcotic treatments be part of the comprehensive pain treatment plan.
3. If narcotics are indicated, begin by choosing the safest cost-effective drug with the least propensity for abuse and/or diversion. Choose drugs and dosages as scientifically as possible. Do not unnecessarily complicate management by placing a patient on multiple simultaneous narcotic drugs unless this is absolutely required.
4. Formulate a written pain treatment plan with specific goals.

Follow-up Visits

1. See and examine chronic pain patients who have been placed on continuous opiate therapy at least monthly during the first year. Document any symptoms or signs of substances abuse and then respectfully confront the patient as is appropriate.
2. Obtain at least one additional random urine drug screen (UDS) per year with proper chain of custody and GC/MS confirmation.
3. Ask patients specifically if they are taking all of their pain medications as directed and when they last took their pain medications. Document this in the chart prior to sending the patient for UDS.
4. Patients should utilize appropriately prescribed non-narcotic medications and other treatment modalities. Note: Patients who refuse to engage in PT, OT, exercise regimens, weight loss regimens, smoking cessation programs, counseling, biofeedback, nerve blocks, etc. may be in violation of their pain treatment contracts. Check for compliance with non-narcotic prescriptions via urine testing, blood testing, or pharmacy records.
5. Post-dated prescriptions are illegal in many jurisdictions. Do not use post-dated prescriptions.
6. Carefully document how various pain treatments are helping the patient and also document any side effects. Make sure you note in the chart any measures taken to decrease patient side effects.

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7. Covering physicians who help manage another physician's pain patients during absences (vacation, CME, etc.) should read the patient's chart and examine the patient prior to prescribing. "Blind" telephone prescribing of controlled substances is poor practice.
8. Do not touch a patient's controlled substances. Should you desire to see a patient's medications and count them, have the patient count their medicines in front of you. If medications need to be destroyed, have the patient flush their medications down the toilet in the presence of yourself and another witness. Document this in the chart.
9. Patients refusing to participate in appropriate non-narcotic treatments and/or further indicated diagnostic evaluations are in violation of their chronic pain treatment contracts and may be candidates to be appropriately weaned off of their controlled substances prescriptions.
10. Patients with active substance abuse should be referred for detox and rehab or to appropriate maintenance programs for addicts. You may approve a 24-hour supply of medications for a three-day period while a patient arranges for this substance abuse treatment.
11. Patients who are diverting controlled substances should be terminated from one's practice. (A letter requesting guidance on this issue was forwarded to the Arizona Attorney General and the U.S. Department of Justice some months ago. The question placed before the attorneys: Do practitioners have a duty to report suspected criminal diversion of controlled substances?)
12. Keep in mind a situation in which a patient's pain is not responding to narcotics is a strong indication that other diagnostic and treatment modalities must be explored. Do not simply keep increasing the dosage of narcotics hoping for possible pain relief.

REMEDIATION OF DISTRESSED CHRONIC PAIN PRACTICES

Physicians and other practitioners with problematic chronic pain prescribing practices often respond well to simple and direct interventions in their practices. Many physicians are surprised to see how inadequate and potentially dangerous their past practice of pain management has been. In retrospect, many of these physicians will admit readily they received insufficient training in the fields of chronic pain management and addiction medicine during medical school and residency. Certain physicians may need to discontinue the chronic pain portion of their practices and refer their pain patients to reputable pain specialists. Some problematic pain treatment physicians will be found to be suffering from substance abuse disorders. These doctors require a full course of treatment prior to being monitored while resuming work in a medical practice that poses a lower risk for substance abuse relapse. Other physicians may be suffering from a psychiatric problem that requires treatment before they can safely return to the practice of medicine. Finally, a tiny fraction of practitioners will end up being criminally prosecuted for commercial or sexual drug diversion related violations.

Table 4

A Suggested Approach to the Distressed Chronic Pain Practice

1. Understand the concerns of both the involved physician and the referring colleagues, institution or agency.
2. Review involved state's laws regarding controlled substance prescribing, administration and dispensing.
3. Obtain an accurate history of the physician's career and his qualifications to practice pain management.
4. Review client identified charts as well as randomly selected charts.
5. Interview key office staff and become acquainted with patient flow and office procedures. Document in detail how controlled substances are handled in the office, i.e., dispensing, administration, storage of meds and samples, and destruction of controlled substances.
6. Interview the physician and go over selected charts together.
7. If there is any concern over the physical or mental well being of the physician in question, he should be requested to participate voluntarily and immediately in an evaluation of his physical and mental health to include appropriate laboratory testing, other studies, and consultations.
8. The consultant and the physician together should see both follow-up and new patients for one to three days in the physician's practice.
9. On occasion, it will be helpful to interview selected patients without the physician present.
10. If indicated, the physician should be given verbal guidance as to how to improve his practice of pain management and a recommended CME program.

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11. Prepare and submit any reports requested. This is where the proposed written remediation plan is introduced which includes and expands upon any verbal suggestions.
12. Arrange a brief follow-up visit with the doctor in approximately 30-90 days or at least arrange a telephonic chart review as a follow-up measure.
13. Many severely distressed chronic pain practitioners benefit from a longer period of post consultation monitoring in order to detect backsliding or any new problems. It is not unreasonable for such long-term monitoring to be performed on a monthly or quarterly basis for as long as one to two years with status reports forwarded to regulatory entities as required.

CONCLUSION

The landscape of opiate prescribing in the U.S. has undergone significant change in response to the needs to an aging population, increased awareness and compassion of physicians, pharmaceutical marketing programs, and a vastly more permissive posture of federal regulatory and enforcement agencies. The implementation of continuous opiate prescribing is best accomplished by utilizing proper medical judgment in the diagnosis, treatment and maintenance of chronic pain patients. In doing so, the well-trained, alert physician can reduce suffering in a compassionate manner while also providing excellent medical care and protecting the public's safety.

The current situation regarding medical regulatory board scrutiny of alleged inappropriate pain prescribing is complex. Many patient advocacy organizations bristle at any attempt by regulators to scrutinize pain practitioners. Medical boards might wish to consider utilizing a consistent, fair and scientific approach in their investigations of alleged inappropriate prescribing of controlled substances as suggested in this article. Appropriately supervised medical board investigators can be trained to perform the majority of the work entailed in the investigation of distressed chronic pain medical practices. The basic components of this approach can readily be adapted to conform to various state and provincial laws as well as to the specific organizations' personnel and procedures. Individualized agency flow sheets can then be developed to systematically and fairly cover the phases of investigation, remediation, and monitoring. It should be noted that even in situations where remediation is not possible, an approach such as this may lend itself to a more consistent regimen of discipline that will likely stand up well to challenges in the arenas of both the courts and the media.

While it is true certain pain advocacy groups and others will be opposed to many of the approaches used in this article, it is the author's experience the most of the detractors can be won over. Once they see the methods utilized are based on the principles of quality scientific medical care and that said principles genuinely help protect the doctors' privileges to compassionately prescribe controlled substances for pain patients, the great majority of the detractors become supporters. It should also be noted most of the pharmaceutical companies that distribute controlled substances also now strongly support programs aimed at improving diagnosis and compliance, while at the same time reducing the incidence of drug abuse and diversion.

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