

# Cases Involving Discipline for Inappropriate Prescribing of Controlled Substances

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## Background

Of the approximately 350 disciplinary orders issued by the Medical Examining Board (MEB) between 1988 and mid-1996, 8% involved a principal allegation of inappropriate prescribing of controlled substances. During the same period, 3% of the 127 Dentistry Examining Board's disciplinary orders related to similar allegations. All 36 cases involving prescribing practices of MD and DO physicians (n=29), physician assistants (n=1), podiatrists (n=0), and dentists (n=5) between 1988 and mid-1996 were examined. Excluded were cases involving impaired physicians (those who may have also committed unprofessional conduct through self-prescribing, but for whom such conduct was likely a product of the impairment or addiction, as opposed to those who self-prescribed for recreational or purported treatment purposes). All but 1 of the 36 cases examined was a "negotiated settlement," meaning that the practitioner had agreed that the board (MEB or Dentistry Examining Board) could make the findings and impose disci-

pline without a full trial.

Use of such decisions does not reliably provide a complete picture of the disciplined practitioner's problems, because such decisions are frequently the product of negotiations between counsel for the practitioner and the prosecuting attorney. Such negotiations often "tone down" the wording to remove full descriptions of the practitioner's conduct, or delete references to other patients who may have been treated in a similar fashion. Compromise language may lead to desirable results by reducing the cost of litigation and speeding the final outcome, but it comes at the cost of a full description of the practitioner's conduct.

Of the 36 cases, 24 were for prescribing excessive (under the circumstances) quantities of controlled substances (CS) for patients, or for prescribing CS for patients whose conditions did not require such prescribing. (It is often difficult to tell from the text of the orders which of these descriptions is more applicable.) Three were for prescribing maintenance dosages of narcotics, including methadone, without being registered as a treatment program (the physicians claimed to be unaware of this requirement). Two were for self-prescribing. Two were for violating the "amphetamine rule" which restricts the prescription of C-II

amphetamines to limited situations, and which was adopted in response to the widespread abuse of amphetamines for weight loss and their diversion into the drug-abusing culture. One was for prescribing anabolic steroids for non-medical purposes, one for permitting a pharmacist-relative to prescribe in the physician's name, one for failure to diagnose a clear case of substance abuse in a hospitalized patient, one for enabling a physician-spouse to abuse, and one, involving a dentist, for failing to keep proper records when dispensing CS samples.

## Record-keeping

Many cases of overprescribing or inappropriate prescribing were accompanied by findings that the practitioner's chart was inadequate, that a physical examination or history was inadequate, or that there was inadequate monitoring or follow-up. Indeed, it appears to me that inadequate charting is the heart of most such violations, but that the charts were inadequate because there was not adequate content for the chart. The physician simply failed to do the appropriate work, and therefore had nothing to put in the chart. Had the appropriate work been done and charted, the inappropriate prescribing would probably not have occurred. The lack of referrals for consultation and failure to obtain charts from previous providers was also frequently

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noted. Other technical violations, such as issuing postdated prescriptions, were also noted in several cases.

### **Disciplinary Outcomes**

The disciplinary outcomes in these cases exhibit wide variation, as some practitioners who were at or near retirement chose to sur-

any other practitioner. Adequate charting, clear functional goals, and other elements of sound practice protect both physician and patient. (*See sidebar.*) In the most extreme case to date, the MEB considered a benign chronic pain case involving administration of up to 16,000 mg per day of morphine to a patient, and

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render their licenses, while others who wanted to continue practice and who appeared to have made significant changes in their practices were only reprimanded. Most commonly, the practitioners were required to take a significant CME course in prescribing controlled substances, such as the 45 hour course at the New Jersey School of Medicine and Dentistry or the 40-hour course at Case Western Reserve University School of Medicine.

Notwithstanding these cases, I emphasize that judicious use of opioid therapy for pain is well within the standard of care, including very high doses, especially in terminal malignant disease cases. Indeed, failure to provide adequate analgesic therapy may subject a physician to disciplinary action, as happened in a particularly egregious case in Oregon.

With respect to chronic benign pain cases, the MEB has taken no official position regarding the use of opioids or other controlled substance therapy. Cases are handled on an individual basis. In general, it appears that a practitioner meeting the standard of care, including having a written pain agreement if the patient has a history of substance abuse, is no more likely to be disciplined than

after reviewing the extensive documentation, found that no violation had occurred.

Controlled substances are classified as such because they have significant potential for abuse, and are thus more subject than ordinary prescription (“legend”) drugs to diversion to the illicit market. There is little street value in penicillin or insulin, but substantial value in opioids, benzodiazepines, amphetamines, and barbiturates. Thus, the prescribing of these drugs is restricted by both state and federal law, for the express purposes of making it more difficult for patients to get them, reducing the quantities available to patients at any one time, and generally discouraging their use where alternatives are available. While the desirability of using controlled substances for analgesia, for psychiatric case management, for Attention Deficit Disorder or weight loss, or for other legitimate medical purposes is beyond question in individual cases, it is also unquestionably appropriate for there to be a substantial public policy concern about the availability of such drugs to potential abusers.

In the course of 10 years of handling disciplinary cases for the MEB relating to prescribing,

I have been impressed by the general lack of knowledge of the basic legal requirements for prescribing controlled substances. To cover these basics, I offer the following review of federal and state law. In general, Wisconsin has adopted the Federal Drug Enforcement Administration’s (DEA) rules: the major departure is the “34-day rule” discussed below. The state rules are included in the “Blue Book” (Wisconsin Statutes and Administrative Code Relating to the Practice of Medicine), which every MEB licensee receives when applying for licensure. The most recent edition is dated April, 2001, and every physician should maintain a current copy. The Blue Book is updated at least annually. Dentistry Examining Board and Board of Nursing licensees have similar books.

### **Prescription Requirements**

A prescription for a controlled substance in any schedule, if in writing, must be signed and dated on the date it is issued. It is unlawful to postdate a prescription, or to put a signed and undated prescription in the file for the patient to pick up at a later date. A prescription must have the prescriber’s name typed or printed, and be hand-signed by the practitioner: the use of a rubber stamp for the signature is not permitted under either state or federal law. A C-II prescription must be presented to the pharmacist within 7 days of its issue. All CS prescriptions must state dosage instructions (“take as directed” is not sufficient, although a PRN instruction is permitted so long as a maximum dose and frequency of use per day is included). In Wisconsin, only a 34-day supply may be dispensed to a patient at a time, except that Schedule III and IV anti-convulsants may be dispensed in 90 day supplies. Many

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insurance companies will not pay for more than a 30 day supply at a time, so this limitation is not considered an impediment to proper care. An MEB administrative rule that limited CS prescribing to 120 dosage units per prescription order was repealed in 1992.

Because of the increasing number of persons receiving long-term Schedule II drugs such as methylphenidate and some analgesics, the Wisconsin Pharmacy Examining Board has issued an interpretation which permits pharmacists to accept C-II prescriptions which are dated

mailed prescriptions are now legal in Wisconsin, provided there is a "secure method of validation" and other requirements are met (§ Phar 7.08, Wis. Adm. Code). DEA is said to be working on rules for e-mailing C-III and IV prescriptions.

An MEB rule requires that all prescriptions and medications directly dispensed, including samples, be recorded in the patient's chart (§ Med 17.05, Wis. Adm. Code), and this has been the accepted standard of practice in dentistry for many years.

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For a Schedule II drug (e.g. oxycodone, hydromorphone, morphine, meperidine, fentanyl, methadone, methylphenidate), all prescriptions must be in writing under federal and state law. If there is an emergency and a written prescription cannot be delivered, an oral prescription may be telephoned or an e-mail prescription sent for a limited quantity to cover the time it takes to get a written prescription to the pharmacy. Further, the prescriber is obligated to write a prescription to cover the oral order and include the words "authorization for emergency dispensing." The prescriber must send this to the pharmacy within 7 days or the pharmacist is required to report the prescriber to the MEB. A fax is not a written order within the meaning of the federal and state rules (which are identical) because a fax received by the pharmacist does not contain the original signature of the prescriber. Faxed orders are permitted in certain nursing home and hospice cases. A fax is not considered an oral order because it does not allow for immediate interaction and questions between the prescriber and the pharmacist.

on the date of issue, but intended for future dispensing. Under this interpretation, the prescriber issues three prescriptions for the medication, all dated on the date of issue. One is intended for immediate dispensing, one is marked "dispense in 30 days" and one is marked "dispense in 60 days." All 3 are presented to the pharmacist at the same time to comply with the 7-day rule. The pharmacist would then keep all three on file, and dispense one each month. By doing this, the physician can issue a 90-day prescription series, a convenience for all concerned. The Pharmacy Examining Board does not expect that this will be done in all cases, as some patients need to be seen more frequently and prescriptions should not be written for a period beyond the next practitioner-patient contact. However, for the stable maintenance patient, this will be a time and money-saver.

#### **Telephone/FAX/E-mail Prescribing**

Telephoned (including faxed) prescriptions are permitted for all non-C-II CS prescriptions, just as they are for legend drugs. E-

#### **Self-prescribing**

Self-prescribing is absolutely prohibited, and is a criminal offense:

§961.38(5), Wis. Stats.: No practitioner shall prescribe, orally or in writing, or take without a prescription, a controlled substance included in schedule I, II, III or IV for the practitioner's own personal use.

§961.435, Wis. Stats.: Any person who violates s.961.38(5) may be fined not more than \$500 or imprisoned not more than 30 days or both.

Self-prescribing by such methods as forging a prescription on another practitioner's pad, prescribing for a fictitious patient, etc., are more serious offenses and generally come under the heading of forgery, a felony.

#### **Maintenance/Tapering Prescriptions**

It is unlawful to provide maintenance or tapering prescriptions (including, but not limited to, methadone) for a narcotic to a patient who is addicted to controlled substances, unless the prescriber is registered with the DEA as a treatment program. Most commonly this refers to methadone clinics, but the rule applies to any addiction treatment and any narcotic CS.

## Elements of sound prescribing of opioids for chronic benign pain

- **Diagnosis:** is there a supportable diagnosis for the patient's condition?
- **Exam:** is there an appropriate physical examination in the chart?
- **Consultation:** have consultation reports been received from appropriate programs or physicians, including both physical medicine and mental health practitioners? Have you spoken with others who have or are treating the patient?
- **Alternatives:** has serious consideration been given to alternative modes of treatment, including unconventional or alternative medicine? Is this documented in the chart?
- **History:** is there an adequate history, including an AODA history, fully charted?
- **Med Sheet:** is there a medication sheet, tracking the actual usage of the patient?
- **Functional Goals:** do you have functional goals for the patient's daily life that are measurable in some reasonably objective manner?
- **Pain Scale:** are you tracking the patient's pain levels in a consistent manner?
- **Effectiveness:** can you document that treatment is effective in achieving the goals you have, both in controlling the pain and in enabling function?
- **Agreement:** do you have an agreement that the patient will receive CS *only* from you, and *only* from one pharmacy? If the patient has any AODA history, is that agreement in writing, and signed by you, the patient, and the pharmacist?
- **Pharmacy:** are you collaborating with the pharmacist in caring for the patient?
- **Collateral Information:** have you confirmed the patient's accounts with family or others with first-hand knowledge?
- **Pharmacology:** are you using long-acting agents to be taken on a scheduled basis with short-acting agents prescribed only PRN for breakthrough pain, and have you considered methadone?
- **Monitoring:** are you obtaining laboratory results which verify that the patient is, in fact, taking the medication as prescribed, and not taking un-prescribed drugs?
- **Suspicion:** are you maintaining an adequate level of suspicion concerning possible abuse, appropriate to the patient's history and status?
- **Education:** have you attended any of the several CME courses in prescribing controlled substances, or reviewed the literature in this area?
- **Replacement/refills:** do you have a clearly communicated policy that lost CS will not be replaced, and that no early refills will be given?
- **Pseudo addiction:** are you prescribing enough for your patient to avoid drug-seeking because of inadequate pain relief?

Controlled substances are controlled because they are abusible. They have great value on the street. Your patient may not be personally abusing, but may have family, friends or caregivers who are. It is the duty of a prescriber to authorize CS to those who need them, in quantities adequate to their legitimate needs, and to know when to stop.

21 CFR §1306.04(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule for "detoxification treatment" or "maintenance treatment" as defined in section 102 of the Act (21 USC 802).

21 USC 802(29) The term "maintenance treatment" means the dispensing, for a period in excess of 21 days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

21 USC 802(30) The term "detoxification treatment" means the dispensing, for

a period not in excess of 180 days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.

21 CFR §1306.07(b) Nothing in this section shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering

(but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than 3 days and may not be renewed or extended.

"Narcotic" is defined for these purposes as being all those drugs which are opiates or derived from the poppy, and the synthetic opioids, cocaine, and ecgonine.

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On the other hand, it is entirely proper to prescribe methadone for chronic pain, and because it is very inexpensive, practitioners should consider this alternative.

Use of buprenorphine for treatment of addiction is not yet approved by the FDA, although such approval is expected. At that time, physicians with specialized training and certification will be permitted to prescribe buprenorphine for this purpose in their office, i.e. without being a separate "methadone clinic" type operation.

### **Controlled Substance Dispensing**

Practitioners who receive CS samples or who buy CS to dispense directly to patients must comply with record-keeping provisions similar to those applicable to pharmacies. Ch. Med 17, Wis.

Adm. Code, sets these forth. A practitioner's dispensing records must be kept for 5 years, and may be inspected by the Department of Regulation & Licensing and the DEA.

When obtaining CS from a pharmacy for office dispensing purposes, federal law provides that a prescription may not be used:

21 CFR §1306.04(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

Such drugs must be obtained by ordering them from a pharmacy or drug distributor on separate forms, and in the case of C-II drugs, by the use of a DEA-

222 form. Additional requirements apply if the practitioner then re-sells or shares his office dispensing supply with other practitioners: such activities may require a separate license as a drug distributor. Contact the DEA or Wisconsin Department of Regulation & Licensing, Bureau of Health Professions, for details. Whether obtained by purchase or in the form of free samples, there are storage security requirements, requirements that the DEA be notified of any theft or other loss, biennial inventory requirements, and other technical requirements.

*Editor's Note: The views expressed are those of the author, and not necessarily those of the Department of Regulation and Licensing, the MEB or any other board attached to the Department.*



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