

Is it Legitimate? Tips for Assessing Prescriptions for Controlled Substances

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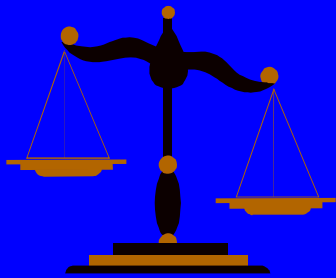
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Pain Management

Three Personal Views

- 1983 - Hospital Pharmacist
- 1999 - Son of Cancer Patient
- 2002 - Attorney for Pharmacist

Policy Goal

Achieve Balance

**Maximize
Legitimate
Medical Use
of Abusable
Drugs**



**While
Minimizing
Ability of
Abusers to
Obtain
These
Drugs**

Good and Bad Decisions

State of the World

Healthcare Provider Activity

	Patient Is Legitimate Pain Patient*	Patient NOT Legitimate Pain Patient
Opioids are prescribed/dispensed	Good Decision	Bad Decision
Opioids NOT prescribed/dispensed	Bad Decision	Good Decision

*Assume that opioids are appropriate therapy for the patient.

(Brushwood D, Carlson J. *Food Drug Cosmetic Law J*, 1991)

The Practitioner's Dilemma

- The therapeutic imperative:
“Always dispense opioid analgesics when they are appropriate for a patient.”
- The regulatory imperative:
“Never dispense opioid analgesics when they are inappropriate for a patient.”

Dual Roles

Law Enforcement:

- Drug diversion is a crime
- The prescribing and dispensing of controlled substances governed by the state and federal Controlled Substances Acts
- Controlled Substances Acts are criminal laws, not health care laws

Health Care Provider:

- Standard RI.1.2.8: “Patients have the right to appropriate assessment and management of pain.”
- Standard PE.1.4: “Pain is assessed in all patients.”
- Standard PF.1.7: “Patients are taught that pain management is a part of treatment.”

DEA: Don't Be Scammed By A Drug Abuser

Your Responsibilities:

- The abuse of prescription drugs--especially controlled substances--is a serious social and health problem in the United States today. As a healthcare professional, you share responsibility for solving the prescription drug abuse and diversion problem.

Your Responsibilities

- You have a legal and ethical responsibility to uphold the law and to help protect society from drug abuse.
- You have a professional responsibility to prescribe controlled substances appropriately, guarding against abuse while ensuring that your patients have medication available when they need it.
- You have a personal responsibility to protect your practice from becoming an easy target for drug diversion. You must become aware of the potential situations where drug diversion can occur and safeguards that can be enacted to prevent this diversion.

Message from the Administrator

Dear Pharmacist:

Your role in the proper dispensing of controlled substances is critical to the health of the patient and to safeguard society against drug abuse and diversion. Your adherence to the Controlled Substances Act, together with your voluntary compliance with its objectives, are a powerful resource for protecting the public health, assuring patient safety, and preventing the diversion of controlled substances and drug products containing listed chemicals.

Sincerely,

Donnie R. Marshall
Administrator
Drug Enforcement Administration

MODEL GUIDELINES FOR THE USE OF CONTROLLED
SUBSTANCES
FOR THE TREATMENT OF PAIN
THE FEDERATION OF STATE MEDICAL BOARDS OF
THE UNITED STATES, INC.
(Adopted May 2, 1998)

Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients.

MODEL GUIDELINES

The (*state medical board*) is obligated under the laws of the State of (*name of state*) to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

MODEL GUIDELINES

Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing, or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

MODEL GUIDELINES

Each case of prescribing for pain will be evaluated on an individual basis. The board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs including any improvement in functioning, and recognizing that some types of pain cannot be completely relieved.

National Association of Boards of Pharmacy

Letter from the NABP endorsing the Federation's Model Guidelines
Endorsed: March 26, 2001

At its recent meeting, the NABP Executive Committee reviewed the Model Guidelines for the Use of Controlled Substances for Treatment of Pain and adopted by the Federation of State Medical Boards. The Executive Committee endorsed the guidelines as a document that the state boards of pharmacy would find useful in their regulation of pain management therapies and medications.

By copy of this letter, we are forwarding this information to the state boards of pharmacy.

If I can be of further assistance, please feel free to contact me.

Cordially,

Carmen Catizone, MS, RPh

Executive Director/Secretary

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DEA, March, 2001 (8th Ed.)

DEA supports the 1998 "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain" prepared by the Federation of State Medical Boards of the United States, Inc. DEA believes that the "Model Guidelines" will protect legitimate medical uses of controlled substances while preventing drug diversion.

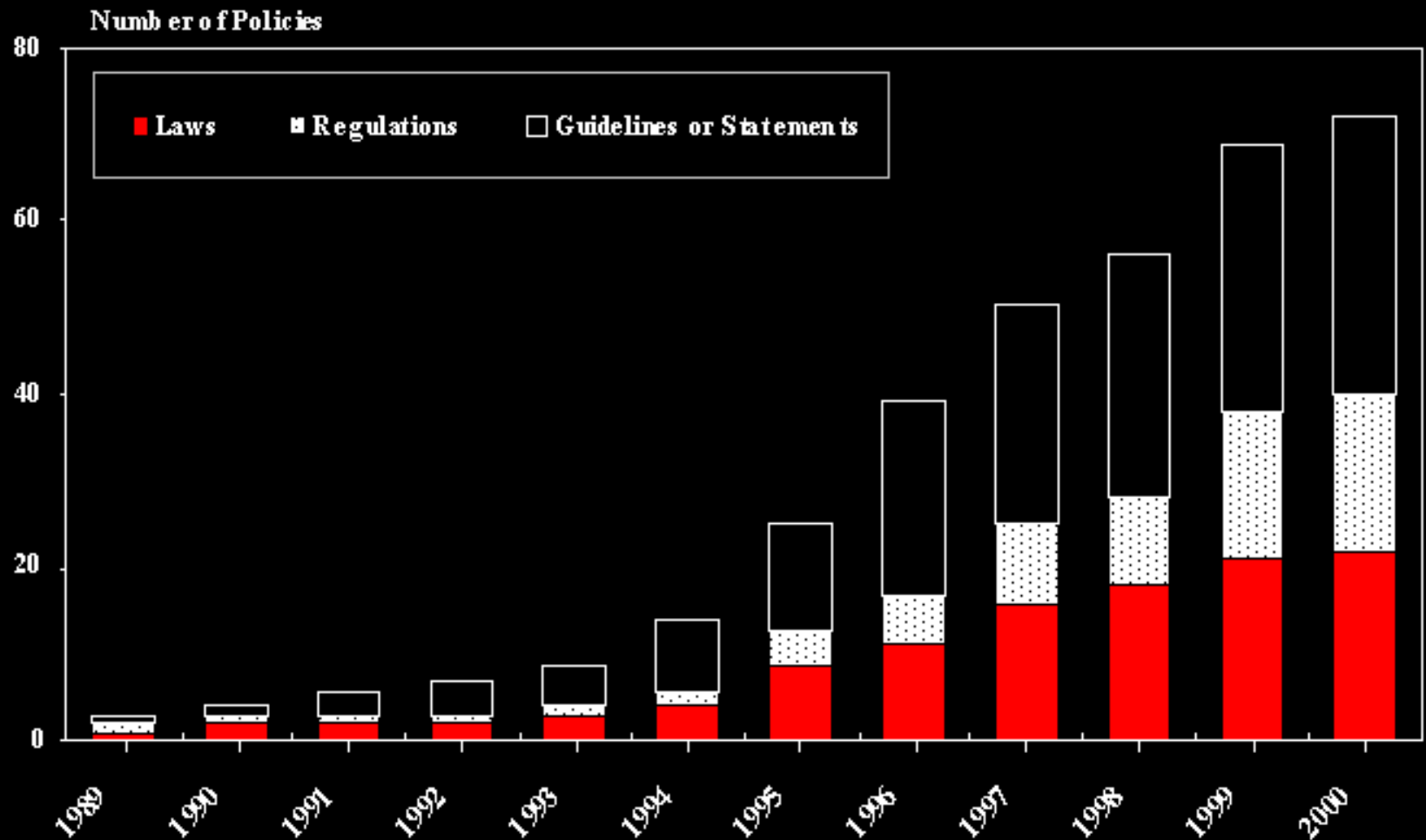
Guidelines Are Not Laws

- Most states have not enacted any pain – specific laws or regulations
- Many Pharmacy Board investigators have a law enforcement mentality
- Boards have a tendency to use 20/20 hindsight when reviewing cases

Figure 1

State Pain-Specific Policies

1989 - 2000



What is a CS “Prescription?”

A “Process” Definition

- ✱ an order for a CS drug
- ✱ issued by an individual state licensed prescriber
- ✱ who is registered with the DEA
- ✱ for a “patient”
- ✱ for a legitimate medical purpose
- ✱ in the usual course of professional treatment
- ✱ in the right “form”

What is the Law?

- Federal Controlled Substances Act
- Individual State Controlled Substances Acts
- Prescription Monitoring Laws
- Prescription Form Laws

“Prescription” defined

21 CFR § 1300.01(b)(35):

An order for medication
which is dispensed to or
for an ultimate user
(non-institutional).

21 CFR § 1306.05: The “form” of a prescription

- * CS prescriptions must be dated and signed that day, have patient’s name and address, prescriber’s DEA number and written in ink, indelible pencil or typewritten.
- * The pharmacist has a corresponding responsibility to determine that prescriptions are issued in this form.

Schedule II Prescriptions

- Must be in writing, except:
 - emergency situation
 - verbal ok
 - quantity limited to emergency
 - pharmacist reduces to writing
 - within 7 days, prescriber sends written Rx
 - facsimile may serve as original if:
 - prescription is for infusion therapy
 - patient is resident of LTCF
 - patient enrolled in hospice

Schedule II Prescriptions

- No refills
- Partial filling fully authorized
 - outpatient
 - must fill balance within 72 hours
 - LTCF or terminal illness
 - must fill balance within 60 days
 - must record each partial filling
- Rules are substantially relaxed for institutional pharmacies, where patients are administered drugs by licensed healthcare professionals

Other RX “Form” Issues

- Electronic Signatures in Global and National Commerce Act (ESIG)
 - Prohibits the government from requiring written signatures and records. It also requires governmental agencies, at both the state and federal levels, to accept electronic signatures and records as if they were written on hardcopy.
 - Sec. 101; 15 USC §A77001(b)(2)
- Individual State Electronic Signature Laws

Other RX “Form” Issues

- “A signature on a document cannot be denied legal effect solely because the signature or record is in electronic form”
- “All other statutes, regulations or rules of law requiring written signatures or written records are preempted”

What is NOT A CS Prescription?

- *an order for a CS drug...

- *that “purports” to BE a prescription...

 - *looks like a prescription

 - *has all the right information

 - *correct form

 - *not a “forgery”

 - *from a licensed prescriber

 - *for a “patient

- *not issued in the usual course of professional treatment.

Federal Law:

Corresponding Responsibility

21 CFR 1306.04 Purpose of Issue of Prescription

- (a) A prescription for a controlled substance to be effective must be issued for a ***legitimate medical purpose*** by an individual practitioner acting in the usual course of his professional practice.

Federal Law:

Corresponding Responsibility

The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

Federal Law:

Corresponding Responsibility

An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

What is a “legitimate
medical purpose”?

Principle No. 1

There is a distinction
between identifying “bad”
medicine, and identifying
“non-medicine”

United States vs. Hayes

(595 F.2d 258 [5th Cir. 1979])

- Issue: Whether a pharmacist who filled purported prescriptions violated the DEA “corresponding responsibility” rule
 - A “tremendous number” of prescriptions were filled by Hayes on the purported orders of just one doctor who, during the period involved, was an alcoholic and continually under the influence of alcohol and moving from one temporary lodging place to another.”

United States vs. Hayes

595 F.2d 258 (5th Cir. 1979)

“during one month Hayes filled [for one patient] 34 prescriptions for Dilaudid, representing 3400 pills for which [the patient] paid \$3,400, and 75 prescriptions for Preludin at \$75 each, or \$4,125. The following month Hayes filled [for the same patient] 101 prescriptions for Dilaudid and 137 for Preludin, for which he was paid, respectively, \$10,000 and \$10,825.”

United States vs. Hayes

- “Hayes contends that the regulation is unconstitutionally vague.”
- “A pharmacist, he argues, cannot have a ‘corresponding responsibility’ to that of a practitioner because he cannot prescribe but can only dispense.”
- “He points out that the most the pharmacist can do to verify the prescription is to check with the issuing practitioner.”

United States vs. Hayes

- “Verification by the issuing practitioner is evidence that the pharmacist lacks knowledge that the prescription was issued outside the scope of professional practice.”
- “not an insurance policy against a fact finder’s concluding that the pharmacist had the requisite knowledge despite a purported but false verification.”

United States vs. Hayes

“What is required is the responsibility to not fill an order that purports to be a prescription but is not. . . because he *knows* that the issuing practitioner issued it outside the scope of medical practice.”

Principle No. 2

Questioning every controlled substance prescription is not good pharmacy (and might get you fired)

Ryan vs. Dan's Food Stores, Inc.

972 P.2d 395 (Utah 1998)

- Issue: whether a pharmacist can be fired for being overly aggressive in questioning the legitimacy of controlled substance prescriptions
- “During the 18 months that Ryan worked full-time for Dan’s, many customers complained about Ryan’s treatment of them.”
- “Ryan received at least five letters . . . complimenting him on his thoroughness in detecting fraudulent prescriptions.”

Ryan vs. Dan's Food Stores, Inc.

- “Ryan argues that he was following a clear and substantial policy set out by 21 C.F.R. §1306.04.”
- “Ryan argues that this section clearly requires him to check on prescriptions that he believes are unusual.”

Ryan vs. Dan's Food Stores, Inc.

- “Section 1306.04 does contain a clear and substantial public policy, but it is a narrow one, one which only prohibits pharmacists from *knowingly* filling an improper prescription.”
- “Section 1306.04 does not mandate or even authorize a pharmacist to question every prescription or to conduct an investigation to determine whether an otherwise facially valid prescription has been issued other than in the usual course of the doctor’s practice.”

Principle No. 3

Common sense goes a long way, and if you fail to use it, you open yourself to criminal, regulatory, and civil liability

Hook's SuperX vs. McLaughlin

642 N.E.2d 514 (Ind. 1994)

- Issue: Whether a pharmacist can be liable to a patient for failure to detect too frequent refills
- What is a pharmacist's duty in "medical bartender" cases?
- Most common type of civil "failure to warn" claim

Hook's SuperX vs. McLaughlin

- Plaintiff was prescribed propoxyphene following a back injury
- Plaintiff consumed these drugs at a rate much faster than prescribed.
 - During one 60 day period, he received 24 separate refills totaling 1,072 tablets.
 - If consumed as prescribed, the prescription would have lasted a period of 138 days – he consumed the tablets almost two and one half times faster than the prescription ordered
 - During one month, Plaintiff or his wife appeared in the pharmacy once every 2 - 3 days for refills.

Hook's SuperX vs. McLaughlin

- Doctor cut him off when he became aware
- Plaintiff “cleaned up”, and then filed suit, alleging that the pharmacy breached its duty of care by failing to stop filling the prescriptions
- Alleged that the pharmacists knew or should have known that McLaughlin was consuming the drugs so frequently that it posed a threat to his health.

Hook's SuperX vs. McLaughlin

- Duty determined by factoring (1) the relationship between the parties, (2) foreseeability of the harm, and (3) public policy concerns
- “The duty imposed is simply a practical recognition of the relationship between pharmacist and customer.”

Hook's SuperX vs. McLaughlin

- Pharmacists have duties beyond technical accuracy to include prevention of drug overuse
- Pharmacists may be held accountable for the foreseeable consequences of what they do or fail to do

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The following criteria may indicate that a prescription was not issued for a legitimate medical purpose.

- The prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in your area.
- The patient appears to be returning too frequently. Prescription which should last for a month in legitimate use, is being refilled on a biweekly, weekly or even a daily basis.
- The prescriber writes prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time. Drug abusers often request prescriptions for "uppers and downers" at the same time.

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The following criteria may indicate that a prescription was not issued for a legitimate medical purpose (cont.)

- **Patient appears presenting prescriptions written in the names of other people.**
- **A number of people appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician.**
- **Numerous "strangers," people who are not regular patrons or residents of your community, suddenly show up with prescriptions from the same physician.**

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Note: The quantity of drugs prescribed and frequency of prescriptions filled are not alone indications of fraud or improper prescribing especially if the patient is being treated with opioids for pain management. Pharmacists should also recognize that drug tolerance and physical dependence may develop as a consequence of the patient's sustained use of opioid analgesics for the legitimate treatment of chronic pain.

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Types of Fraudulent Prescriptions

The practiced forger of prescriptions is usually very adept at the job. The forger knows what information is needed on the prescription to make it appear authentic. Pharmacists should be aware of the various kinds of forged prescriptions that may be presented for dispensing.

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Types of Fraudulent Prescriptions

Some patients, in an effort to obtain additional amounts of legitimately prescribed drugs, alter the physician's prescription. They will also have prescription pads printed using a legitimate doctor's name, but with a different call back number that is answered by an accomplice to verify the prescription. Also, drug seeking individuals will call in their own prescriptions and give their own telephone number as a call back confirmation.

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Types of Fraudulent Prescriptions

Legitimate prescription pads are stolen from physicians' offices and hospitals and prescriptions are written using fictitious patients names and addresses. In addition, individuals will go to emergency rooms complaining of pain in the hopes of receiving a controlled substance prescription. The prescription can then be altered or copied to be used again. Computers are often used to create prescriptions for nonexistent doctors or to copy legitimate doctors' prescriptions.

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Characteristics of Forged Prescriptions

1. Prescription looks "too good"; the prescriber's handwriting is too legible;
2. Quantities, directions or dosages differ from usual medical usage;
3. Prescription does not comply with the acceptable standard abbreviations or appear to be textbook presentations;
4. Prescription appears to be photocopied;
5. Directions written in full with no abbreviations;
6. Prescription written in different-color inks or written in different handwriting.
7. Apparent erasure marks.

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Prevention Techniques

Know the prescriber and his/her signature;

Know the prescriber's DEA registration number;

Know the patient;

Check the date on the prescription order. Has it been presented to you in a reasonable length of time since the prescriber wrote it?

When there is a question about any aspect of the prescription order, call the prescriber for verification or clarification. Should there be a discrepancy, the patient must have a plausible reason before the prescription medication is dispensed.

Any time you are in doubt, require proper identification. Although this procedure isn't foolproof (identification papers can also be stolen/forged), it does increase the drug abuser's risk.

If you believe that you have a forged, altered, or bogus prescription--don't dispense it--call your local police.

If you believe that you have discovered a pattern of prescription abuses, contact your State Board of Pharmacy or your local DEA office. Both DEA and state authorities consider retail-level diversion a priority issue.

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Proper Controls

Dispensing procedures, without control and professional caution, are an invitation to the drug abuser. Proper controls against bogus prescriptions can best be accomplished by following common sense, sound professional practice, and proper dispensing procedures and controls.

Have your pharmacy staff help protect your practice from becoming a source of prescription drug diversion. Become familiar with which drugs are popular for abuse and resale on the streets in your area. Drug abuse prevention must be an ongoing staff activity.

Encourage local pharmacists and physicians to develop a network, or at least a working relationship, which promotes teamwork and camaraderie. Discuss abuse problems with other pharmacists and physicians in the community. Most drug abusers seek out areas where communication and cooperation between health professionals are minimal because it makes their work so much easier.

QUESTIONS AND DISCUSSION