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RESOURCE GUIDE

Information about Regulatory Issues in Pain Management

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A. Introduction

I. Purpose Statement

The purpose of this Resource Guide is to provide information about pain-related policy and regulatory issues. It is not intended to be the response to specific legislative or regulatory situations in the states -- these require study and crafting of individualized responses to suit the unique circumstances.

The Resource Guide is part of an education and research project of the University of Wisconsin Pain & Policy Studies Group (PPSG) with support from the Robert Wood Johnson Foundation.

II. How the Resource Guide was Developed

PPSG organized a focus group at the 1997 National Meeting for State Cancer Pain Initiatives to obtain input on what pain-related policy and regulatory issues are important to practicing healthcare professionals, and therefore, what a resource guide should contain.

The proposed content was reviewed by the Resource Center for State Pain Initiatives, the American Alliance for Cancer Pain Initiatives, and by all the Cancer Pain Initiatives in the states.

III. Development of a List Server

In addition, the PPSG has created a "list server" to facilitate discussion of pain-related policy issues. A list server is an e-mail communications network with a limited subscribership.

The list server was used to obtain input on the development of the Resource Guide and will be tested to determine whether it is a useful method to discuss regulatory and policy issues. If warranted, the list server may be continued and the subscriber membership could be expanded to more participants who are interested in discussing regulatory issues, and in receiving new information and policy updates. If you are interested in joining this list server, please e-mail your request to ppsg@macc.wisc.edu.

IV. Robert Wood Johnson Grant: Pain Management and State Regulatory Policy: A

This grant supports the following projects. Additional information is available by contacting PPSG.

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Program of Research, Education, and Policy

- A content analysis of state medical board guidelines on prescribing for pain management to understand their similarities and differences, to gauge their potential effects on medical practice and patient care, and to identify possible model language.
- A second survey of state medical board members to study changes in members' knowledge, attitudes and beliefs about the use of opioids for pain.
- Six more workshops on pain management and public policy for state medical board members, in cooperation with the Federation of State Medical Boards of the United States.
- Surveys to assess physicians' knowledge and attitudes toward changes in pain-related policy and regulation in their states.
- A pilot survey to assess pharmacists' knowledge and attitudes regarding the use of opioids for pain management, controlled substances regulations, and the extent to which pharmacists have concerns about addiction and regulatory scrutiny when dispensing opioids for pain management.
- Evaluation of medical, nursing and pharmacy statutes, regulations, and guidelines related to pain, prescribing and professional practice.
- A study of national epidemiologic data to determine the extent to which opioid analgesics are part of the drug abuse problem.
- A collaborative project to explore ways that prescription monitoring programs (PMPs) and the pain management field can cooperate to prevent interference in legitimate prescribing for pain , and to identify ways the pain field can help PMPs to address drug diversion.
- A website to provide public access to a range of resource materials for pain management and public policy.

Pain & Policy Studies Group Website

The Pain & Policy Studies Group website has the pain-related laws, regulations and medical board guidelines for each state, articles about trends in pain policy, policy alerts, and a large section on international policy and opioid consumption trends.

It can be viewed at http://www.medsch.wisc.edu/painpolicy/. If you are involved in pain-related regulatory and policy issues, we recommend that you become familiar with the contents on this website.

For information about state laws as well as bills that have been introduced in the state legislatures, the National Conference of State Legislatures' website has links to each state's website at http://www.ncsl.org/public/sitesleg.htm#sites

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B. The Basics

1. Glossary

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Narcotic	"Narcotic" is a legal, not a scientific term. Under the Single Convention on Narcotic Drugs, 1961, and the U.S. Controlled Substances Act (CSA), substances such as opioids are classified as narcotics. However, marijuana and cocaine are also legally classified as "narcotics." When discussing pain relief, the use of "opiate" or "opioid" is preferred.
Opiate	"Opiate" refers to drugs whose origin is the opium poppy, including codeine and morphine.
Opioid	"Opioid" denotes both natural (codeine, morphine) and synthetic (methadone, fentanyl) drugs whose pharmacological effects are mediated by specific receptors in the nervous system.
Tolerance	"Tolerance" refers to the physical adaptation of the body to an opioid, where the dose needs to be increased to achieve the same response, or where there is a reduction in a response to a stable dose.
Physical dependence	"Physical dependence" is the physical adaptation to the presence of an opioid it is characterized by signs of withdrawal when use of an opioid is stopped or decreased, or when an opioid antagonist is administered.
Psychological dependence	"Psychological dependence" is a behavioral pattern characterized by a compulsion to use a drug for mood altering effects.
Addiction	"Addiction" is a sociologic term which refers to compulsive drug use, severe psychological dependence, and continuing use despite harm. Neither physical dependence nor tolerance are sufficient to define "addiction"; however, "addiction" is frequently and incorrectly equated with physical dependence and tolerance, resulting in confusing pain patients with addicts, stigmatization, and resulting in possible inadequate treatment of pain.
Pseudoaddiction	"Pseudoaddiction" is an iatrogenic syndrome characterized by a pattern of drug-seeking behavior in pain patients who are receiving inadequate pain management. Pseudoaddiction can be mistaken for "drug-seeking behavior and addiction.
Policy	"Policy" is a very broad term, and refers to rules of conduct and may be used generally to refer to laws, regulations, or guidelines.
Law	"Law" is a broad term that refers to rules of conduct with binding legal force, adopted by governments at the international, federal, state or local levels. Law can be found in treaties, constitutional provisions, decisions of the court, statutes and regulations. A number of laws have been adopted by the states concerning pain management.
Statute	"Statute" is a law created by a legislative body, whether federal, state, county or city. Statutes are commonly referred to as laws or acts.
Regulation	"Regulation" is an official rule or order issued by agencies of the executive branch of government. Regulations have the force of law, and are intended to implement a specific statute, often to establish what conduct is not acceptable for those regulated by the agency, for example, physicians, pharmacists, and nurses. Regulations of state agencies should not exceed the agency's statutory authority.
Guideline	"Guideline" means an official policy statement, which does not have the force of law. Guidelines may be issued by a professional association or a government agency to express the group's attitude about a particular matter. While guidelines themselves do not have binding legal force, they may outline the parameters of accepted standards of practice for those regulated by the agency. State medical boards have issued guidelines regarding the medical use of opioids which define the conduct which the board considers to be within the professional practice of medicine. Guidelines may also be called a position statement or policy statement; and these may appear in a position paper, report, article, letter or newsletter.

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II. Regulatory Systems and Pain Management 101

The purpose of this section is to describe briefly the regulatory systems and recent trends that affect pain management. References are provided for more extensive information.

There are several regulatory systems that influence access to and delivery of pain management. These include the regulation of patient care facilities, reimbursement, drug regulation, and the licensing of health professionals. This section discusses the latter two.

Drug regulation

There are three tiers of drug regulation: international, federal and state. The latter two will be discussed here; publications about international regulation of drugs are available elsewhere.[1],[2]

Federal and state law provide for three general levels of drug control, including "over-the-counter" drugs, "prescription" drugs and "controlled substances."[3] Under Federal and state laws, over-the-counter drugs such as aspirin are the least controlled, and are available directly to the consumer at a wide variety of retail establishments. Prescription drugs such as antibiotics, which have greater potency and risks, must be approved as both safe and effective for human use by the U.S. Food and Drug Administration (FDA), according to authority under the Federal Food, Drug and Cosmetic Act (FFDCA). Prescription drugs are also regulated at the state level by food and drug laws, or by pharmacy laws that are often administered by state pharmacy boards. Manufacturers are subject to restrictions regarding advertising and marketing prescription drugs. Federal and state laws provide penalties for obtaining prescription drugs without a prescription; however, lower dosages or combination products may be available "over-the-counter." As a class, prescription drugs may be prescribed for other than their specifically labeled indications if there is a medical rationale.

Controlled substances laws provide an additional layer of control over prescription drugs and illegal drugs that have a potential for producing psychological or physical dependence, in order to prevent abuse, trafficking and diversion. The federal Controlled Substances Act (CSA) contains numerous provisions regarding the possession, manufacture and trafficking in illicit controlled substances, for which criminal penalties are established; nevertheless, the CSA recognizes that controlled substances are necessary for public health and that their availability for medical and scientific purposes must be assured. Therefore, despite increased control, the requirements of the CSA are not to interfere with the medical uses of prescription drugs.[2] The CSA specifies five classification schedules which carry different penalties for unlawful uses; requirements for prescriptions also vary depending on the schedule. Schedule I contains all drugs that have no approved medical use such as opioids like heroin. Schedules II-IV contain drugs that have been approved by the FDA for medical use, including the opioids; opioids with the highest potential for abuse are in Schedule II, and include drugs such as morphine, hydromorphone, oxycodone, fentanyl. Opioids such as hydrocodone and codeine combinations are in Schedule III, while Schedule IV also contains codeine in smaller dosages. Schedule V contains some opioids in smaller amounts, which may be over-the-counter cough preparations.

Under the CSA, it is not lawful to prescribe narcotic drugs for the purpose of maintenance or detoxification of narcotic addiction; this activity requires registration as a Narcotic Treatment Program (NTP). NTPs may only use drugs approved for this purpose, such as methadone, and must comply with federal and state methadone program regulations.

Methadone, however, may be prescribed as an analgesic (in most states), just as one would prescribe another schedule II opioid analgesic.

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All persons or business entities must be registered with the Drug Enforcement Administration (and with state agencies in some states) to possess controlled substances. All registrants' purchases are made using a special triplicate order form (not a prescription form) to monitor all transfers of controlled substances within a "closed system". Prescriptions for Schedule II drugs must be in written form and may not be renewed, while five renewals are permitted for drugs in Schedules III and IV. Federal law allows oral prescriptions of controlled substances in Schedule II in medical emergencies under specific circumstances. Federal law also allows for the partial dispensing and faxing of prescriptions under certain circumstances. Federal laws and regulations do not limit the amount of the prescription nor the duration of prescribing. There are penalties, both criminal and civil, for violation of these requirements.

The states have adopted versions of the CSA which use the same classification system, using a model Uniform Controlled Substances Act (UCSA) prepared by the National Conference of Commissioners on Uniform State Laws.(4) All of the state Acts permit prescribing of controlled substances, although most do not specifically reflect the recognition by federal law of the medical uses of controlled substances. A revised model UCSA has been prepared to correct these deficiencies, but only a few states have adopted the changes.(5) The criminal provisions of the state Acts are enforced by state and local police agencies, while the drug regulatory aspects of state controlled substances laws are administered by a variety of state agencies, including departments of regulation and licensing and pharmacy examining boards. These agencies often have regulations that govern the prescription and dispensing of controlled substances more so than under federal law.(6) Penalties for violation of prescribing requirements vary. Some states also limit the amount that can be prescribed at one time, and limit the validity of a prescription to a few days. Some have overly broad definitions of "addict" which could include physically dependent pain patients; some states prohibit prescribing to such persons, or require they be reported to a state agency.

A few states have also adopted laws that require physicians and pharmacists to use special government forms when prescribing and dispensing certain controlled substances. These programs allow state health departments or law enforcement agencies to monitor prescriptions of drugs, usually those in Schedule II, to detect fraud and abuse. State special prescription programs differ considerably; they require use of either a triplicate form, duplicate or single copy; the extent to which the prescriptions are entered into computerized systems and are actually monitored varies greatly. Special prescription programs have been reported to affect negatively prescribing for legitimate purposes.(7),(8) Recently, states have begun to adopt electronic monitoring programs, as an alternative to special prescription programs. These are intended to be less intrusive and more efficient than serialized prescription forms. See Table 1 for a description of current prescription monitoring programs.

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Regulation of health professionals

The regulation of professional practice in medicine, nursing, pharmacy, social work and other professions occurs at the state, not federal level. State legislatures have adopted statutes to protect the public; these provide authority for a state agency to license and discipline members of the profession. Typically, the law creates a board, such as a Board of Medical Licensure, that manages the responsibility of licensing the members of the profession, as well as disciplining licensees for violation of standards of professional conduct which are usually expressed in the statute or in regulations. Boards have the power to adopt regulations to implement the law; its procedures are a matter for public input and public record. A fixed number of board members with staggered terms typically are appointed by the Governor, sometimes in consultation with the profession's state society. Board investigation of a licensee is typically initiated by a complaint. Boards differ greatly as to the procedures used for inquiry and investigation into complaints; some boards, by law, are

required to investigate each complaint received; others can exercise discretion. Investigations may or may not be prompt, and may be dropped due to insufficient evidence, or may proceed to disciplinary action, which may range from a warning, to education, to a limitation or removal of prescribing privilege or the professional license. Board disciplinary actions may be reviewed by the state courts. Boards also manage programs to assist in the identification, treatment and recovery of impaired licensees.

Each professional category of licensing board has a national organization which serves all the state boards; for medical boards, it is the Federation of State Medical Boards; for pharmacy boards, it is the National Association of Boards of Pharmacy; for nursing boards, it is the National Council of Boards of Nursing. The associations can be involved in a number of activities, such as: (1) the sponsorship of annual meetings, (2) the appointment of study task forces to address specific issues relevant to the regulation of that profession, and (3) a range of other technical assistance and information activities, including newsletters, statistics about licenses and discipline, and preparation of model laws and regulations.

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Recent trends in state pain policy

In the last ten years, concerns about inappropriate discipline of physicians for use of opioid analgesics for treatment of chronic pain has led to changes in state laws, medical board regulations, and guidelines.[9] (see Figure I) Although new state intractable pain treatment laws are intended to improve access to pain management, they typically do not contain provisions which do this. Further, IPTAs pose more requirements and restrictions on the prescribing of opioids for pain. Recently, state medical boards have participated in pain management workshops and have begun adopting guidelines (and in a few cases, regulations) to encourage improved pain management and to dispel physicians' fear of discipline.[7],[11] Additional workshops for state medical boards are scheduled during 1998. To promote consistency in state medical policy, the Federation of State Medical Boards has adopted a "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain." The trend in new state medical policy in pain management is likely to continue and may also affect pharmacy and nursing practice regulation.

In the last several years new state-level initiatives to improve pain management[11] end-of-life care have also emerged.[12] These initiatives often involve the study of barriers to care, and are likely to precipitate changes in state pain-related laws, regulations and other policies for the next several years.

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Figure 1. Cumulative Pain-Related Policies in Effect, 1980-1997

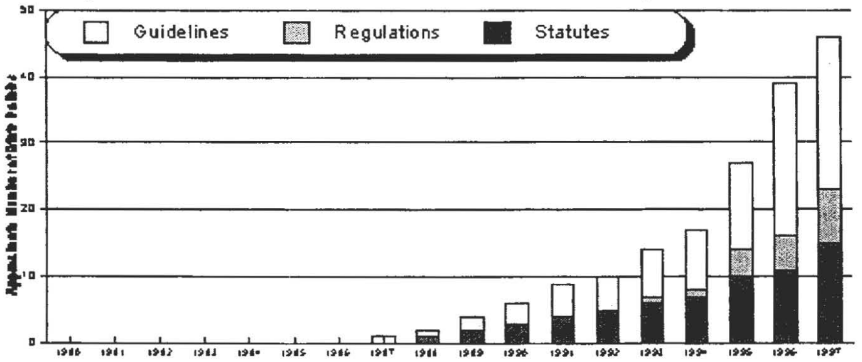

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Table 1

States with Prescription Monitoring Programs for Controlled Substances

Special Prescription Program	Type of Program	Year Enacted
California*	Triplicate - Schedule II	1940
Idaho	Triplicate - Schedule II	1967
Illinois	Triplicate - Schedule II	1961
Michigan**	Single copy - Schedule II	1995
New York*	Triplicate - Schedule II and benzodiazepines	1977
Texas**	Triplicate - Schedule II	1997
Washington (for disciplinary purposes only)	Triplicate	1989
Electronic Data Transmission (EDT) programs		
Hawaii	Schedule II	1994
Indiana	Schedule II	1995
Massachusetts	Schedule II	1992
Nevada	Schedules II - IV	1997
Oklahoma	Schedule II	1990
Rhode Island	Schedule II	1997
Utah	Schedules II - V	1996
West Virginia	Schedule II	1996

* Considering moving to EDT program

** Also EDT

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III. What Can State Legislatures Do to Improve Pain Management

Response: the most crucial step is to study the problem; the problems and solutions differ from state to state.

Create a multidisciplinary task force, commission or committee with public hearings to study carefully the barriers to pain management for all types of pain patients in the state (cancer, chronic non-cancer, post-surgical, sickle cell, AIDS, etc.); review relevant state policies outlined below; make and implement recommendations in legislation (policy, budget), in leadership, public information, education, training, program development, etc.

1. Drug, pharmacy, controlled substances policy **8700112307**

Does the state controlled substances act recognize the essential medical uses of controlled substances as in federal law and as recommended by the National Conference of Commissioners on Uniform

State Laws?

Does state law or regulation unduly restrict prescribing of controlled substances, e.g., government-required prescription forms; exclusion of addicts even if they have pain; require second opinion, consultation or informed consent; legal terminology confusing addicts with pain patients/addict reporting; limit number of dosage units of controlled substances (e.g., opioids) that can be prescribed at one time; or limit unrealistically the period of validity of a prescription for a scheduled substance?

Does state policy allow physicians and pharmacists to take full advantage of the flexibility in federal controlled substances regulation regarding faxing and partial dispensing of controlled substances prescriptions?

2. Medical policy

Does the medical practice act or regulation contain any policies with regard to prescribing controlled substances which are unduly restrictive or confusing when applied to the prescribing of controlled substances for the treatment of pain? (i.e., no prescribing to addicts, even if they have pain?)

Does the medical board have a policy statement or guidelines which clarifies that the board recognizes that the use of controlled substances for the treatment of chronic pain is accepted medical practice and clarifies the principles which a physician can follow to confidently avoid the risk of discipline or arrest by any agency in the state?

3. Facility regulation (hospice, nursing home, home care, etc.)

What is the attitude of the state facility regulators: is pain a priority or is the priority only to reduce the use of controlled drugs; do certification and inspection criteria include assessment and treatment of pain and training of patient care staff; is technical assistance on pain and symptom management available?

4. State health policy

Does the state cancer control program include a funded emphasis on pain management and palliative care for cancer patients in the state?

Is there a state Cancer Pain Initiative and does it have adequate membership and financial support?

Does the public have access to information about pain and symptom management including chronic non-cancer pain, and where to go for help?

Does the 800 number for cancer information also include information about pain management?

Do managed care organizations have adequate policies: pain assessment, treatment, reimbursement, appropriate access to specialists?

Does state Medicaid policy adequately reimburse the controlled drugs used in pain and symptom management?

Does Workers Compensation adequately address the needs of people with chronic severe pain?

5. Drug enforcement policy **8700112308**

Do the state agencies which are involved in drug law enforcement and monitoring of controlled

substances prescribing, dispensing and patient use have adequate safeguards against the inappropriate scrutiny of practitioners who legitimately prescribe and dispense controlled substances?

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Are intractable pain treatment acts what we need?

A number of states have adopted legislation called "intractable pain treatment acts" (IPTAs).(9) The 1997 Supreme Court decision on assisted suicide is likely to stimulate even more interest in state legislation to address inadequate pain management, including IPTAs.

IPTAs are often modeled after the highly publicized Texas Act which was passed in 1989. The main goal of these laws was to address physician reluctance to prescribe opioids for the treatment of chronic pain, due to their concern about regulatory scrutiny, by providing immunity from discipline by state medical boards. These immunity laws are stimulated by patients and physicians who are concerned about the undertreatment of chronic non-cancer pain; nevertheless, most IPTAs apply to prescribing for any intractable pain patient, including those with cancer or AIDS.

However, IPTAs may not be the most direct way to address the desirable goal of relieving physician concern about regulatory scrutiny. They also may create additional barriers for physicians and for patients. For example, the language used in IPTAs implies that opioids are a last resort, and that use of opioids is not considered part of ordinary medical practice. The use of the term "intractable" implies pain that is not treatable, even though chronic pain is treatable. IPTAs exclude pain patients who use drugs "nontherapeutically", and they may impose additional requirements, such as required consultation with another physician, and signed informed consent. Some states have adopted the Texas IPTA and have thus added new restrictions and requirements for prescribing opioids for "intractable pain." Subsequently, the Texas legislature corrected the deficiencies in its IPTA.

Further, IPTAs do not directly address the critical issue of how to improve patient access to pain treatment or improve education of health professionals about pain management. The potential benefits and risks of IPTAs are discussed in an article about the current status of intractable pain treatment policy.(9)

A number of state medical boards have taken steps to improve pain management including clarification of policy to address physician reluctance to prescribe. Working with state medical boards is a more direct approach than legislation to clarify state opioid prescribing policy and to encourage better pain management.(10)

Governments' increasing interest in pain is an opportunity to make lasting improvements in pain management and to provide better patient access to pain care. Several states have created pain study commissions or task forces.(11) This is a promising approach. It avoids "quick fix" legislation and more importantly, it is a mechanism to study the unique needs of individual states, and respond appropriately. A number of government agencies and professional organizations can be involved in the study process. A commission or task force can take the time to identify the needs of a state, including regulatory barriers that might otherwise be overlooked in simply adopting an IPTA.

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