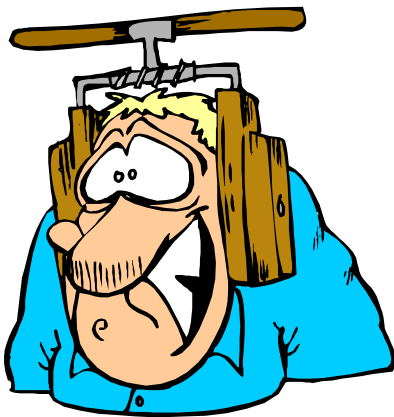


Ohio Law and Intractable Pain Treatment

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Goals:

The goal of this program is to inform pharmacists of the rules under which a physician can treat a patient for intractable pain with what, under normal circumstances, would seem inappropriate drug therapy.

Objectives:

1. To familiarize the pharmacist with the causes of intractable pain;
2. To offer the pharmacist an evaluation of the rules established and enforced by the State Medical Board of Ohio in respect to treating patients with intractable pain;
3. To provide a discussion on how the pharmacist can assist the physician in treating patients treated for intractable pain.

We believe the material presented in this educational module to be accurate and current at the time of publication. We remind the reader, however, that he or she is responsible for using professional judgment and for confirming or interpreting the findings presented here before utilizing the information.

The treatment of chronic and intractable pain has always been controversial. It was hoped that the controversy would be lessened with the publication of a Drug Enforcement Agency (DEA) guidance document published in August, 2004.

In the introduction of this document the DEA and the expert panels involved stated the purpose of the guidelines was to provide information to health care providers and professionals in law enforcement and regulatory communities about the medical treatment of pain. The goal of the guidelines was to achieve a better balance in addressing the treatment of pain while preventing abuse and diversion. These, of course, are also the goals of physicians and pharmacists.

However, the guidelines quickly became as controversial as the problems they were meant to address. Within two months of issue the DEA withdrew the guidance document from their Web site, providing little information on why except that the document contained 'misstatements' and that the 31-page document 'was not approved as an official statement of the agency.'

Why were the guidelines controversial?

The guidelines were developed over several years as a consensus statement formulated as the responses of the DEA and a panel of experts to what they considered the most frequently-asked-questions (FAQs) concerning pain treatment with controlled substances.

An immediate problem arose concerning the questions and responses appearing in Section VI of the document entitled, "other legal and regulatory considerations". The responses to the FAQs apparently appealed to the legal defense team representing a physician on trial for drug trafficking and they wanted to introduce the guidelines as evidence in the trial. In countering this, the Justice Department lawyers prosecuting the case filed a motion asking the court to exclude the guidelines as evidence. This legal maneuvering was followed in just a few weeks by the DEA's withdrawal of the guidelines, saying they did not represent official policy.

Though uncertain it is likely that this occurred due to the response to FAQ 30, "Do the number of patients in a practice who receive opioids, the number of tablets prescribed for each patient, or the duration of therapy with these drugs by themselves indicate abuse or diversion?" The response stated these factors, "do not, by themselves, indicate a problem and they should not be used as a sole basis for an investigation by regulators or law enforcement." The defense attorney countered that if the Justice Department had followed the guidelines there would have been no reason to arrest the physician and charge him with drug trafficking.

The DEA tried to clarify the response in the November 16, 2004 Federal Register (FR Doc 04-25469). In discussing the commencement of an investigation the

response to FAQ 30 was nullified by stating that, “in fact, each of the foregoing factors –though not necessarily determinative – may indeed be indicative of diversion. The DEA further stated that, “moreover, it is a long standing legal principle that the Government ‘can investigate merely on suspension that the law is being violated, or even just because it wants assurances that it is not’. It would be incorrect to suggest that the DEA must meet some arbitrary standard or threshold evidentiary requirement to commence an investigation of a possible violation of the controlled Substances Act (CSA).”

The same can be said for the understaffed local and state regulatory and enforcement agencies nationwide.

What impact does this have on physician and pharmacists

One can see why physicians remain confused and perhaps hesitant in treating real patients with very real pain management problems. The guidelines were to provide guidance, to provide clarity, to enable appropriate treatment of pain for those patients suffering on a daily basis. Initially, it seemed the focus would be on providing the legitimate use of prescription narcotics for pain management; but with ensuing controversy and the response of the DEA to the controversy it seems that the emphasis again reverted to law enforcement. In effect, nothing was done to reduce the hesitancy of physicians to use appropriate therapy when such therapy might arouse the suspicions of law enforcement and possibly lead to their investigation and, worse, even prosecution.

FAQ 24 and the response provided in the guidelines are especially important to pharmacist. The question was, “What requirements must physicians and pharmacists meet to comply with federal and state laws regulating opioids?”

One part of the lengthy response addressed the question of whether the physician can write multiple prescriptions for the same drug for the same patient on the same day. Any prescription to be dispensed at a later date would bear a future date when the pharmacist can dispense the prescribed medication. Except where prohibited by state law, this has long been a common practice among pain management physicians for patients in whom the level of pain and medication therapy are stabilized and the patient does not need to be seen as frequently. This, for example, would not be prohibited in Ohio as long as the medication is prescribed for a legitimate medical purpose.

The initial DEA response to FAQ 24 supported this practice: “Schedule II prescriptions may not be refilled; however, a physician may prepare multiple prescriptions on the same day with instructions to fill on different dates.”

When the DEA withdrew the guidelines, the response to the question, as apparently did the responses to many other of the FAQs, underwent agency scrutiny. The DEA’S inclusion in November 16, 2004 Federal Register (FR Doc

04-25469) reversed the initial response, stating, “The initial response as a ‘misstatement’. The DEA then went on to say that, “ for a physician to prepare multiple prescriptions on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a schedule II controlled substance”. It even states that this very practice is a recurring tactic among physicians who seek to avoid detection when dispensing controlled substances for unlawful (non-medical) purposes.

Federal agencies often solicit comments from the public and professionals before finalizing statements. This has been the case in this controversy. In response to received comments the DEA then published again in the January 18, 2005 Federal Register (FR Doc DEA-271N) what they assumed were further clarification for patients caught up in the controversy. Many of these patients had been receiving prescriptions for schedule II controlled prescriptions for several years (for example, for the treatment of severe pain or attention hyperactivity disorder) and had gotten into the routine of seeing their physicians once every three months. The assumption is that the health condition of these patients was stable and there was no need that he or she be seen on a more frequent basis. Many of those who commented were very upset, thinking they would now have to see their physician every month, which would likely have been the reality conveyed to them by the physicians. The DEA, with its insertion in the Register wanted to allay such fears. After all, the DEA commented, there is no prohibition against the physician mailing monthly prescriptions to the patient or pharmacy.

What impact does this have on patients

Interestingly, the Ohio State Board of Pharmacy had in the past, and for the convenience of patients and care givers, instructed physicians and pharmacists treating children with ADHD that it was an acceptable practice to write multiple prescriptions to be filled on different dates provided the patient was stable on the prescribed medication therapy. This procedure was proposed, as mentioned, for the convenience of the patient – it promotes good and acceptable drug therapy and improves patient compliance to that therapy. Both of these purposes are just as necessary in treating chronic and intractable pain. The DEA FAQ document and responses left patients confused as shown in the comments received from many of them.

It is estimated that thirty million Americans suffer from intractable pain. According to the National Foundation for the Treatment of Pain certain barriers and societal stigmas and taboos continue to block patients from receiving the benefits of medications that can significantly reduce the pain and discomfort of intractable pain. For many patients the recommended treatment for severe intractable pain will be opioid therapy. Once it is determined that intractable pain is a legitimate diagnosis, and once it is determined that opioid therapy is appropriate, the **drug of choice, dose, and duration of therapy** must be determined on an individual patient basis. It is not helpful when these factors must be determined with the

possibility that the decisions may violate the law or be the basis for regulatory investigation. This is especially true when one considers the following: Assuming that the need for treatment is based on a legitimate diagnosis of intractable pain,

1. Less than 1% of chronic pain patients become addicted or experience long-term physiological damage as a result of prolonged, controlled opioid pain treatment.
2. When pain patients receive adequate pain treatment that relieves their chronic pain and associated depression, patients can lead relatively normal, productive lives.
3. When pain patients continue to ask for increased pain medication, they are not addicted but experiencing increased pain. Once patients receive adequate doses of appropriate pain medication they stop asking for increased levels of medication.

Source: National Foundation for the Treatment of Pain

Current events

Currently, the DEA proposed rule changes that were published in the Federal Register (Wednesday, 9/6/2006) stating that “an individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided the following conditions are met:

1. The individual practitioner properly determines there is a legitimate medical purpose for the patient to be prescribed that controlled substance and the individual practitioner is acting in the usual course of professional practice.
2. The individual practitioner writes instructions on each prescription (other than the first prescription, if the practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill the prescription;
3. The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create as undue risk of diversion or abuse.
4. The issuance of multiple prescriptions as described in this section is permissible under the applicable state laws; and
5. The individual practitioner complies with all other applicable requirements under the Act (the Controlled Substances Act) and these regulations as well as any additional requirements under state law.

As mentioned, these changes are not finalized and pharmacists will need to wait for the final approved changes and instructions on compliance from the State Board of Pharmacy.

Fortunately many states, including Ohio, already have established laws and rules to guide physicians and pharmacists in the appropriate treatment of patients with intractable pain. This program will now discuss these laws and rules in detail.

The Ohio State Medical Board first issued a position paper on treating chronic benign pain (CBP) in 1996. The paper was timely because providing relief to patients experiencing CBP can be problematic. For the physician, the risks include failing to control pain for the patient, failing to return the individual to a more normal life and contributing to patient dependence. For the patient the risk of inadequate therapy can be continued pain and suffering, and drug addiction.

The Board acknowledged effective methods for treating CBP, including:

- ? Mild analgesics such as caffeine-free acetylsalicylic acid and acetaminophen
- ? Nonsteroidal anti-inflammatory drugs
- ? Antidepressants
- ? Anticonvulsants
- ? Physical therapy
- ? Manipulative therapy (including osteopathic)
- ? Transcutaneous nerve stimulation (TENS)
- ? Nerve block
- ? Mild analgesics with caffeine (non-narcotic)
- ? Psychiatric care or psychological counseling
- ? Biofeedback relaxation techniques
- ? Surgical techniques

At the same time the board acknowledged that scheduled drugs, including opiates, could be appropriately used for the treatment of CBP.

One reason for the position paper was that the board realized that physicians might be reluctant to prescribe potentially addictive analgesics, fearing that law enforcement agencies and the State Medical Board may prosecute them for what appear to be inappropriate therapy. The purpose of the position paper was to clarify that no such fear should exist with appropriate and legitimate use.

The Board provided diagnostic criteria for CBP, provided guidance on therapies to be tried before the physician utilized scheduled substances, and patient care guidelines to assure patient benefit while minimizing the problem of abuse.

The position paper was followed by promulgation of Rule 4731-21-01 in 1998 that defined the means of treating intractable pain. The purpose of Rule 4731-21-01 is not explicitly given, but it is to provide physicians with reasonable guidelines to treat patients who otherwise might not be treated effectively because the physician feels that his/her efforts might be scrutinized by others, especially state and federal agencies. Joranson ¹, for instance, cites several reasons why

physicians might feel this way. Anti-drug efforts are directed not only at the illegal controlled substances such as marijuana, heroin, and cocaine, but also legal controlled substances that have important medical uses. These efforts involve media campaigns against perceived overprescribing, vigorous enforcement efforts against suspect prescribers, regulations to increase restrictions on prescribing, and federal proposals to monitor all prescribing to patients of all controlled substances. In addition, third-party payers have initiated measures to scrutinize prescribing that varies from what is considered normal usage. Physicians also know that intractable pain is not necessarily associated with terminal illness and this, in part, is why treatment of patients with intractable pain may invite scrutiny.

Pain lasting beyond six months is generally characterized as chronic pain. Chronic pain may be the result of disease, as well as injury or surgery. It negatively impacts all aspects of life, including emotional, vocational, financial and social elements². Many patients experiencing chronic pain become isolated and depression, a common side effect, can add to the isolation experienced by these patients. A listing of potential causes of chronic pain will help pharmacists understand that any one of their patients might experience this problem.

Causes of chronic pain

Arachnoiditis	Avascular Necrosis	Brachial plexopathy	Cancer pain	Crohn's Disease
Degenerative Disc Disease	Diabetic Neuropathy	Endometriosis	Fibromyalgia & Fibromyositis	Interstitial Cystitis
Irritable Bowel Syndrome	Headache	Low Back Pain	Lyme Disease	Migraine
Multiple Sclerosis	Myofascial pain anydremia	Osteoarthritis	Osteoporosis	Pancreatitis
Pelvic Pain	Peripheral Neuropathy	Stump & Phantom Limb Pain	Plantar Dacoities	Psoriatic Arthritis
Raynaud's Syndrome	Reflex Sympathetic Dystrophy	Rheumatoid Arthritis	Scoliosis	Shingles and post-herpetic neuralgia
Systemic Lupus	TMJ	Trigeminal Neuralgia	Vulvodynia	

Most people suffering chronic pain will not suffer intractable pain. The pain and emotional stress associated with chronic pain will usually yield to conventional therapies. A few patients, however, will experience intractable pain, pain that is determined, after reasonable medical efforts have been made to relieve the pain or cure its cause, to have a cause for which no treatment or cure is possible or for which none have been found.

Ohio Revised Code (ORC) **4731.052** was approved in 1998 and provides the basis for the Management of Intractable Pain with Dangerous Drugs. It is the law that empowered the State Medical Board to develop the rules found in the Administrative Code, which are discussed later.

4731.052

(A) As used in this section:

(1) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

(2) "Intractable pain" means a state of pain that is determined, after reasonable medical efforts have been made to relieve the pain or cure its cause, to have a cause for which no treatment or cure is possible or for which none has been found.

(3) "Physician" means an individual authorized under this chapter to practice medicine and surgery or osteopathic medicine and surgery.

(B) The state medical board shall adopt rules in accordance with Chapter 119. of the Revised Code that establish standards and procedures to be followed by physicians in the diagnosis and treatment of intractable pain, including standards for managing intractable pain by prescribing, personally furnishing, or administering dangerous drugs in amounts or combinations that may not be appropriate when treating other medical conditions. In developing the rules, the board shall consult with and permit review by physicians who are experienced in the diagnosis and treatment of intractable pain.

(C) When a physician diagnoses an individual as having intractable pain, the physician may treat the pain by managing it with dangerous drugs in amounts or combinations that may not be appropriate when treating other medical conditions. The physician's diagnosis shall be made after having the individual evaluated by one or more other physicians who specialize in the treatment of the area, system, or organ of the body perceived as the source of the pain. The physician's diagnosis and treatment decisions shall be made according to accepted and prevailing standards for medical care. The physician shall maintain a record of all of the following:

(1) Medical history and physical examination of the individual;

(2) The diagnosis of intractable pain, including signs, symptoms, and causes;

(3) The plan of treatment proposed, the patient's response to treatment, and any modification to the plan of treatment;

(4) The dates on which dangerous drugs were prescribed, furnished, or administered, the name and address of the individual to or for whom the dangerous drugs were prescribed, dispensed, or administered, and the amounts and dosage forms for the dangerous drugs prescribed, furnished, or administered;

(5) A copy of the report made by the physician or the physician to whom referral for evaluation was made under this division.

(D) A physician who treats intractable pain by managing it with dangerous drugs is not subject to disciplinary action by the board under section 4731.22 of the Revised Code solely because the physician treated the intractable pain with dangerous drugs. The physician is subject to disciplinary action only if the dangerous drugs are not prescribed, furnished, or administered in accordance with this section and the rules adopted under it.

As one will notice the law tends to be general in nature, whereas the rules (Ohio Administrative Code) enacted by the regulatory entity that oversees compliance to the law are much more detailed and guidance oriented. In this case the regulatory entity, the state medical board enacted certain rules to ensure compliance with the law, the most important of which is Rule 4731-21-01.

The rule begins with a list of definitions. To help the reader these definitions are found at the end of the following discussion. The author has taken the liberty of italicizing and underlining the words as they appear for the first time in the text of the rule. Author's comments are placed within text boxes in the discussion so they are not confused with the text of the rule. **The reader is reminded that the author is not an attorney and any questions arising while reading this discussion should be clarified with the Ohio State Board of Pharmacy or the Medical Board of Ohio.**

Rule 4731-21-02 Utilizing prescription drugs for the treatment of intractable pain (OAC: 11/11/98)

(A) When utilizing any prescription drug for the treatment of intractable pain on a protracted basis or when managing intractable pain with prescription drugs in amounts or combinations that may not be appropriate when treating other medical conditions, a practitioner shall comply with accepted and prevailing standards of care which shall include, but not be limited to, the following:

Accepted and prevailing standards of care implies that the practitioner has a good understanding of what other practitioners treating similar patients under similar conditions consider prudent, e.g. it would probably be considered prudent to begin treatment with non-opioids before initiating treatment with opioid analgesics.

- (1) An initial evaluation of the patient shall be conducted and documented in the patient's record that includes a relevant history, including complete medical, pain, alcohol and substance abuse histories; an assessment of the impact of pain on the patient's physical and psychological functions; a review of previous diagnostic studies and previously utilized therapies; an assessment of coexisting illnesses, diseases or conditions; and an appropriate physical examination;

A patient experiencing intractable pain may not understand the need for such an extensive initial evaluation; however, it enables the practitioner to establish all important baseline values. Since psychological dysfunction and coexisting illnesses can exacerbate pain, it is important during the initial assessment that one considers these factors. In many cases this might require consultation with specialists.

- (2) A medical diagnosis shall be established and documented in the patient's medical record that indicates not only the presence of intractable pain but also the signs, symptoms, and causes and, if determinable, the nature of the underlying disease mechanism;

It is important the patient understands the diagnosis and that the intractable pain may be the result of the underlying disease mechanism. This understanding can make the patient a partner in his or her therapy. It is important, for instance, that the patient helps identify and subsequently avoid anything that triggers episodes involving worsening of pain.

- (3) An individualized treatment plan shall be formulated and documented in the patient's medical record. The treatment plan shall specify the medical justification of the treatment of intractable pain by utilizing prescription drugs on a protracted basis or in amounts or combinations that may not be appropriate when treating other medical conditions, the intended role of prescription drug therapy within the overall plan, and, when applicable, documentation that other medically reasonable treatments for relief of the patient's intractable pain have been offered or attempted without adequate or reasonable success. The prescription drug therapy shall be tailored to the individual medical needs of each patient. The practitioner shall document the patient's response to treatment and, as necessary, modify the treatment plan.

From the pharmacist's perspective, it is important to note that the practitioner is to tailor prescription drug therapy to the medical needs of individual patients. It should be unusual, for instance, to see a practitioner routinely begin therapy with unusually high doses of opioids. On the other hand, it should be recognized that very high doses may be necessary to treat certain patients. One would expect to see a reasonable progression to dosing levels that would seem inappropriate under normal circumstances.

- (4)(a) The practitioner's diagnosis of intractable pain shall be made after having the patient evaluated by one or more other practitioners who specialize in the treatment of the anatomic area, system, or organ of the body perceived as the source of the pain. For purposes of this rule, a practitioner "specializes" if the practitioner limits the whole or part of his or her practice, and is qualified by advanced training or experience to so limit his or her practice, to the particular anatomic area, system, or organ of the body perceived as the source of the pain. The evaluation shall include review of all available medical records of prior treatment of the intractable pain or the condition underlying the intractable pain; a thorough history and physical examination; and testing as required by accepted and prevailing standards of care. The practitioner shall maintain a copy of any report made by any practitioner to whom referral for evaluation was made under this paragraph. A practitioner shall not provide an evaluation under this paragraph if that practitioner would be prohibited by sections 4731.65 to 4731.69 of the Revised Code or any other rule adopted by the board from providing a designated health service upon referral by the treating practitioner; and
- (b) The practitioner shall not be required to obtain such an evaluation, if the practitioner obtains a copy of medical records or a detailed written summary thereof showing that the patient has been evaluated and treated within a reasonable period of time by one or more other practitioners who specialize in the treatment of the anatomic area, system, or organ of the body perceived as the source of the pain and the treating practitioner is satisfied that he or she can rely on that evaluation for purposes of meeting the further requirements of this chapter of the Administrative Code. The practitioner shall obtain and review available medical records or detailed written summaries thereof of prior treatment of the intractable pain or the condition underlying the intractable pain. The practitioner shall maintain a copy of any record or report of any practitioner on which the practitioner relied for purposes of meeting the requirements under this paragraph; and
- (5) The practitioner shall ensure and document in the patient's record that the patient or other individual who has the authority to provide consent to treatment on behalf of that patient gives consent to treatment after being informed of the benefits and risks of receiving prescription drug therapy on a protracted basis or in amounts or combinations that may not be appropriate when treating other medical conditions, and after being informed of available treatment alternatives.

Comment on 4 above: It is now generally recognized that the patient is not to be treated paternalistically. Whenever possible the patient should participate fully in decisions that concerns the management of his or her health. The very practical reason, however, is that protracted pain is something the patient must face and deal with on a very personal basis. The patient will be better able to deal with the pain and assist in the appropriate choice of therapy only if fully informed. Even the occasional patient who wishes to be treated paternalistically, perhaps because he has a preconceived role definition for the physician, should be encouraged to participate in decision making.

Interesting note: If the practitioner is a specialist as described above it is unclear whether evaluation by another practitioner is required. It would, however, it would seem that a prudent practitioner would want this to be the case. It would especially be helpful to have another qualified individual review all medical records of prior treatment and conduct an independent physical evaluation.

ORC reference in (4)(a) above: The section within 4731.65 to 4731.69 that seems most appropriate:

§ 4731.66 Prohibited referrals and cross-referrals for designated health service.

Text of Statute

(A) Except as provided in sections [4731.67](#) and [4731.68](#) of the Revised Code, no holder of a certificate under this chapter to practice medicine and surgery, osteopathic medicine and surgery, or podiatry shall refer a patient to a person for a designated health service if the certificate holder, or a member of the certificate holder's immediate family, has either of the following financial relationships with the person:

(1) An ownership or investment interest in the person whether through debt, equity, or other means;

(2) Any compensation arrangement involving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind.

(B) No person to which a certificate holder has referred a patient in violation of division (A) of this section shall bill the patient, any third-party payer, any governmental health care program, or any other person or governmental entity for the designated health service rendered pursuant to the referral.

(C) No person shall knowingly enter into an arrangement or scheme, including a cross-referral arrangement, that has a principal purpose of assuring referrals by a certificate holder to a particular person that, if the certificate holder directly made referrals to such person, would violate division (A) of this section.

For your information, ORC can be searched at

<http://codes.ohio.gov/>

Simply choose the link to ORC or OAC and search

What follows in paragraph B below is a powerful statement that the practitioner is expected to adhere to prevailing standards of care once it is determined to utilize prescription drugs for a patient experiencing intractable pain. This statement is followed by examples of what is considered prevailing standards. Note that prevailing standards are considered dynamic when it is stated that the listing, “*shall include, but not be limited to, the following:*” In other words it is appropriate to consider the standards as minimal. The practitioner may find that he has to (or should have) initiated more restrictive or more numerous standards in the care of certain patients.

(B) Upon completion and satisfaction of the conditions prescribed in paragraph (A) of this rule, and upon a practitioner's judgment that the continued utilization of prescription drugs is medically warranted for the treatment of intractable pain, a practitioner may utilize prescription drugs on a protracted basis or in amounts or combinations that may not be appropriate when treating other medical conditions, provided that the practitioner continues to adhere to accepted and prevailing standards of care which shall include, but not be limited to, the following:

- (1) Patients shall be seen by the practitioner at appropriate periodic intervals to assess the efficacy of treatment, assure that prescription drug therapy remains indicated, evaluate the patient's progress toward treatment objectives and note any adverse drug effects. During each visit, attention shall be given to changes in the patient's ability to function or the patient's quality of life as a result of prescription drug usage, as well as indications of possible addiction, drug abuse or diversion. Compliance with this paragraph of the rule shall be documented in the patient's medical record.

The pharmacist is an important resource for much of the information in this task. The pharmacist should be proactive in discussing the issues listed with the physician if adverse effects are suspected, or if there appears to be possible addiction, drug abuse, or diversion.

- (2) Some patients with intractable pain may be at risk of developing increasing prescription drug consumption without improvement in functional status. Subjective reports by the patient should be supported by objective data. Objective measures in the patient's condition are determined by an ongoing assessment of the patient's functional status, including the ability to engage in work or gainful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities, and physical activity of the patient. Compliance with this paragraph of the rule shall be documented in the patient's medical record.

- (3) Based on evidence or behavioral indications of addiction or drug abuse, the practitioner may obtain a drug screen on the patient. It is within the practitioner's discretion to decide the nature of the screen and which type of drug(s) to be screened. If the practitioner obtains a drug screen for the reasons described in this paragraph, the practitioner shall document the results of the drug screen in the patient's medical record. If the patient refuses to consent to a drug screen ordered by the practitioner, the practitioner shall make a referral as provided in paragraph (C) [below] of this rule.

The practitioner may turn to the pharmacist for advice or information concerning drug screens and the interpretation of results. This information can generally be obtained from the manufacturer or a drug and poison information center. The pharmacist should document any such communication with a practitioner and keep copies in the patient file or a general

- (4) The practitioner shall document in the patient's medical record the medical necessity for utilizing more than one controlled substance in the management of a patient's intractable pain; and

There may be a number of reasons for this standard, including (1) the dose of a drug should probably be maximized before switching to or adding another drug or drug class, (2) increasing the number of drugs may lead to compliance problems, (3) it may be that a combination of controlled and non-controlled drugs may be as effective, (4) in some individuals adding additional controlled substances may increase the likelihood of abuse.

- (5) The practitioner shall document in the patient's medical record the name and address of the patient to or for whom the prescription drugs were prescribed, dispensed, or administered, the dates on which prescription drugs were prescribed, dispensed, or administered, and the amounts and dosage forms of the prescription drugs prescribed, dispensed, or administered, including refills.

This is a labor-intensive and complex standard. One senses that it is especially critical to dispensing physicians. This is appropriate since this activity can more easily result in abuse and diversion. It is critical that the prescriber maintains thorough documentation in the event his/her prescribing activities are ever questioned.

- (C) If the practitioner believes or has reason to believe that the patient is suffering from addiction or drug abuse, the practitioner shall immediately consult with an addiction medicine or other substance abuse specialist. For purposes of this rule, "addiction or substance abuse specialist" means a physician who is qualified by advanced formal training in addiction medicine or other substance abuse specialty, and includes a medical doctor or doctor of osteopathic medicine who is certified by a specialty examining board to so limit the whole or part of his or her practice. Prescription drug therapy may be continued consistent with recommendations of the consultation, including, if the consulting addiction medicine or other substance abuse specialist recommends that it is necessary, prompt referral to an addiction medicine or other substance abuse specialist for physical examination and evaluation of the patient and a review of the referring practitioner's medical records of the patient. The practitioner shall continue to actively monitor the patient for signs and symptoms of addiction, drug abuse or diversion. The practitioner shall maintain a copy of any written report made by any practitioner to whom referral for evaluation was made under this paragraph.

Paragraph C above points out a real concern in treating patients with intractable pain. Without patient counseling, education and cooperation, medication alone is not likely to provide sufficient relief. Drug seeking behavior, which can lead to abuse and possible addiction, is a complex process with a strong psychological basis. If a patient is carefully monitored one can see signals of drug seeking behavior developing. This is especially true if health care professionals treating the patient communicate. The pharmacist should certainly communicate with the physician anytime he or she suspects a patient may exhibit such behavior.

There are some important rules that facilitate Rule 4731-21-02. Rule 4731-21-04, for instance clarifies that physical dependence and tolerance are possible with extended opioid therapy. The rule states that "*physical dependence and tolerance by themselves do not indicate addiction*", and that "*physical dependence and tolerance are normal physiological consequences of extended opioid therapy, and do not, in the absence of other indicators of drug abuse or addiction, require reduction or cessation of opioid therapy*". Tolerance does not mean that the patient is making unreasonable or unwarranted requests for more potent medication or more frequent prescribing of larger quantities. It means, simply, that the dose and frequency of dose is no longer capable of controlling the pain, or preventing the pain from causing a deterioration in ability of the patient to participate in daily activities. As described in rule 4731-21-02 the

practitioner is to assess, at appropriate periodic intervals, the efficacy of treatment. It is stressed that during the assessment the subjective reports of the patient should be supported by objective data. At this time, too, the practitioner is expected to consider possible addiction, drug abuse or diversion. If the pharmacist is aware of any problems that might indicate possible addiction, drug abuse or diversion it would certainly be appropriate to communicate such concerns to the practitioner.

In Rule 4731-21-03 the board encourages "*those practitioners who encounter patients with intractable pain in the usual course of their practices to complete continuing medical education related to the treatment of intractable pain, including coursework related to pharmacology, alternative methods of pain management and treatment, and addiction medicine*". One could argue that this rule ought to encourage all physicians to consider such continuing education.

Rule 4731-21-05 states that violation of any rule in this chapter (4731-21) of the Administrative Code, as determined by the board, shall constitute "*failure to use reasonable care discrimination in the administration of drugs,*" as that clause is used in division (B)(2) of section 4731.22 of the Revised Code; "*selling, prescribing, giving away, or administering drugs for other than legal and legitimate therapeutic purposes,*" as that clause is used in division (B)(3) of section 4731.22 of the Revised Code, if done knowingly or recklessly, as those words are defined in section 2901.22 of the Revised Code; and "a departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

Chapter 4731.22 of the Revised Code discusses grounds for discipline and investigations

(B)(2) states that the board can refuse license to an individual who fails to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease.

(B)(3) states that the board can refuse license to those selling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes. This applies also to those convicted of any federal or state law regulating the possession, distribution, or use of any drug.

(B)(6) states that the board can refuse license to individuals in the event of departure from, or failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established.

Rule 4731-21-06 allows for exceptions so that a practitioner who treats pain by utilizing prescription drugs is not subject to disciplinary actions under the following circumstances:

- ? When treating pain for a patient with a terminal condition;
- ? When treating pain associated with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition;
- ? When treatment involves utilizing only drugs that do not exert their effects at the central nervous system; and
- ? When treatment involves utilizing only drugs that are not controlled substances and are classified as antidepressants.

In treating terminal illness it would be unreasonable and unethical to subject the physician to rules that might make the care of the patient more difficult. It is assumed that the physician will use good and counseled judgment in making decisions in caring for a terminally ill patient, and that such decisions will be discussed with the patient and family.

4731-21-06 goes on to state that a practitioner who treats intractable pain by utilizing prescription drugs is not subject to disciplinary action by the board solely because the practitioner treated the intractable drugs with prescription drugs. He or she will only be subject to disciplinary action if the use of prescription drugs is not in accordance with the law, which in this case is 4731.052 presented earlier.

Rule 4731-21-01 **Definitions**

As used in Chapter 4731-21 of the Administrative Code:

(A) "Addiction" means a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, despite adverse social, psychological and/or physical consequences, the continued use of which results in a decreased quality of life. Physical dependence alone is not evidence of addiction.

(B) "Believes" or "has reason to believe" does not require absolute certainty or complete unquestioning acceptance; but only an opinion based on reasonable information that a patient is suffering from addiction or drug abuse or engaging in diversion of drugs.

(C) "Board" means the state medical board of Ohio.

(D) "Diversion" means the conveyance of a prescription drug to a person other than the person for whom the drug was prescribed or dispensed by a practitioner.

(E) "Drug abuse" means a maladaptive or inappropriate use or overuse of a medication.

(F) "Emergency" means an unforeseen combination of circumstances or the resulting state that calls for immediate action.

(G) "Intractable pain" means a state of pain that is determined, after reasonable medical efforts have been made to relieve the pain or cure its cause, to have a cause for which no treatment or cure is possible or for which none has been found. "Intractable pain" does not include pain experienced by a patient with a terminal condition. "Intractable pain" does not include the treatment of pain associated with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.

(H) "Pain" means an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.

(I) "Physical dependence" means a physiologic state of adaptation to a specific drug or medication characterized by the development of a withdrawal syndrome following abrupt cessation of a drug or on administration of an antagonist.

(J) "Practitioner" means an individual holding a certificate under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatry and practicing within his or her scope of practice as defined by section 4731.51 of the Revised Code.

(K) "Prescription drug" means a drug which under state or federal law may be administered or dispensed only by or upon the order of a practitioner and includes the term "dangerous drug" as defined by section 4729.02 of the Revised Code.

(L) "Podiatrist" means an individual holding a certificate under Chapter 4731. of the Revised Code to practice podiatry and practicing within his or her scope of practice as defined by section 4731.51 of the Revised Code.

(M) "Protracted basis" means for a period in excess of twelve (12) continuous weeks.

(N) "Terminal condition" means an irreversible, incurable, and untreatable condition caused by disease, illness, or injury from which, to a reasonable degree of medical certainty as determined in accordance with reasonable medical standards by a patient's attending medical doctor or doctor of osteopathic medicine and one other individual holding a certificate under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery who has examined the patient, both of the following apply:

(1) There can be no recovery;

(2) Death is likely to occur within a relatively short time if life -sustaining treatment is not administered.

(O) "Tolerance" means decreasing response to the same dosage of a prescription drug overtime as a result of physiologic adaptation to that drug.

(P) "Utilizing prescription drugs" means prescribing, administering, dispensing, supplying, selling or giving a prescription drug.

References:

1. Joranson D, Federal and State Regulation of Opioids. J Pain Management, 1990; 5 (1):512-23.
2. Joranson D, Gilson AM. Controlled substances, medical practice and the law. IN: Schwartz H. Psychiatric practice under fire: The influence of Government, the media and special interests on somatic therapies. American Psychiatric Press, 1994: 173-194.

TREATING INTRACTABLE PAIN AND OHIO LAW

There is one best answer for the following question:

1. The Medical Board of Ohio position paper was formulated in 1996 for all the following reasons except:
 - a. Realized physicians may be reluctant to prescribe certain drugs to treat chronic benign pain.
 - b. Because some physicians feel that law enforcement agencies may prosecute them if it is perceived that their prescribing is out of the ordinary.
 - c. To assure that pharmacists would not object to filling prescriptions for chronic benign pain just as they were written by the physician.
 - d. To provide diagnostic criteria for chronic benign pain.
2. The reason for Rule 4731-21-01 is explicitly stated to provide physicians with reasonable guidelines to treat patients who otherwise might not receive effective treatment.
 - a. True
 - b. False
3. All the following except _____ may be a likely cause of chronic benign pain.
 - a. Diabetic neuropathy
 - b. Amenorrhea
 - c. Psoriatic arthritis
 - d. Scoliosis
4. An initial evaluation of the patient treated for intractable pain should include _____.
 - a. Determination of possible substance abuse.
 - b. A psychological evaluation.
 - c. A review of previous therapies.
 - d. All the above
5. A patient must be informed of the benefits and risks of receiving prescription drug therapy, and only the patient can give consent for such treatment.
 - a. True
 - b. False
6. If there are no medical records of valid recent evaluation and treatment, the physician treating a patient for intractable pain must have the patient evaluated by at least one physician who would be qualified by special training to otherwise treat the patient.
 - a. True
 - b. False
7. An individualized treatment plan should be developed after the initial evaluation but does not necessarily have to be documented in the patient's record.
 - a. True
 - b. False

8. A reasonable period of time for the use of prior evaluation and treatment information is not defined in Rule 4731-21-01 but would likely be _____.
- a. One month
 - b. Three months
 - c. Six months
 - d. Up to twelve months
9. At appropriate periodic intervals the physician must, according to Rule 4731-21-02, assess all the following except _____.
- a. The efficacy of treatment.
 - b. That prescription drug treatment remains indicated.
 - c. That the treatment is affordable to the patient.
 - d. For possible untoward drug effects.
10. The physician can demand that a patient have a drug screen while he or she is being treated for intractable pain and the patient must comply if treatment is to continue.
- a. True
 - b. False
11. Under no circumstances can the same drug therapy be continued if it is shown that a patient being treated for intractable pain has become addicted.
- a. True
 - b. False
12. The physician can rely on the subjective reports of the patient or the caregiver in assessing possible drug- seeking behavior provided the physician's perception is that the patient has not exhibited drug-seeking behavior in the past.
- a. True
 - b. False

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