



A PHARMACY CONTINUING EDUCATION PROGRAM

W-F Professional Associates, Inc. 400 Lake Cook Rd., Suite 207 Deerfield, IL 60015 847-945-8050

January 2007 "Assuring Legitimacy of Controlled Substance Rxs for Pain" 707-000-07-001-H03



THIS MONTH
"Pharmacy Law
2007"

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HAVE YOU RECENTLY MOVED? PLEASE NOTIFY US

Legitimate use of narcotic analgesics for chronic pain is often a misunderstood therapeutic rationale. As pharmacy practitioners, we must realize the significance of this viable option. This lesson provides 3.0 hours (0.3 CEUs) of credit, and is intended for pharmacists in all practice settings.

The program ID # for this lesson is 707-000-07-001-H03.

Pharmacists completing this lesson by January 31, 2010 may receive full credit.

To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required), and return the quiz. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.

If you have any comments, suggestions or questions, contact us at the above address, or call toll free 1-800-323-4305. (In Alaska and Hawaii phone 1-847-945-8050). Please write your ID Number (the number that is on the top of the mailing label) in the indicated space on the quiz page (for continuous participants only).

The objectives of this lesson are such that upon completion the participant will be able to:

1. Describe the balance that must be sought in the treatment of pain & the prevention of drug diversion.
2. Discuss regulatory policy in the prescribing & dispensing of opioid analgesics.
3. List the factors that correlate with regulatory problems for health care providers who use opioids in the treatment of chronic pain.
4. Describe the strategies that professionals face in order to avoid regulatory problems in the provision of opioids to legitimate chronic pain patients.

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BACKGROUND

The pain management movement over the past ten years has led chronic pain patients to increased expectations that their suffering will be relieved. No longer resigned to silently live and die in pain, the approximately 50 million Americans who experience severe pain at least once every month have heard the renewed commitment from health care providers to do what can be done to improve patients' quality of life. Chronic pain sufferers have become insistent that they receive necessary medications when there is no medical reason to deny them. Among the most effective therapies are the opioid analgesics. These drugs have relatively few adverse effects, and they have avoided the controversies that have plagued other analgesics such as the NSAIDs.

Unfortunately, the opioid analgesics are subject to abuse, and some people who suffer the disease of addiction use diverted pharmaceuticals as a preferable alternative to street drugs such as heroin, methamphetamine, or crack cocaine. Because of the illicit market for diverted prescription opioids, pharmacies are sometimes seen as a target for drug diverters. The failure by a pharmacy to do what is necessary to prevent drug diversion will attract the attention of regulators whose job is to prevent diversion. Regulators may confuse a successful pharmacy that is treating chronic pain with a pharmacy that is being careless and is being victimized by drug diverters, because both deal with high volumes of controlled substances, and they are easily confused with each other when observed casually. This is a problem that physicians also face, and it is a problem that must be successfully addressed to assure that regulators resist interfering with rational pharmacy practice, while at the same time they step in when necessary to stop diversion at a careless pharmacy.

DIVERSION PREVENTION AND THE LAW

Controlled substance laws have been enacted to create what is known as a "closed system" of controlled substance distribution. To create this closed system, the law places the drugs that are subject to control into one of five schedules, numbered from I to V, with the least regulated schedule having the highest number, and the most regulated having the lowest number. The potential for abuse, and the recognition of medical use are the criteria that cause drugs to be placed in a particular schedule. The pharmaceutical drugs that have a potential for abuse are placed into one of the schedules other than Schedule I, which is reserved for the non-pharmaceutical controlled substances. The closed system also requires DEA registration of the businesses and individuals who have the authority to control scheduled drugs within the system. Individuals who work for registered businesses (as do most pharmacists) need not register with the DEA. The system imposes requirements for distribution and control of the regulated drugs. These requirements specify how prescriptions are to be issued, by whom, and how drugs may be stored and dispensed. Finally, the closed system requires record keeping from cradle to grave. The cradle is the synthesis of a molecule of a controlled substance, and the grave is dispensing to a patient. Any controlled substance that exists outside this closed system is said to have been "diverted," and the person responsible for the diversion has violated the law.

The high degree of security applicable to controlled substances leads regulators to assert that the system of distribution is a closed one, and that because the system is closed, access is denied to anyone other than those who have legal authority to possess pharmaceutical controlled substances. The reality of pharmaceu-

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tical controlled substance availability for nonmedical purposes belies this assertion and leads even the most casual observer to query whether there really is a closed system of controlled substance distribution. Medications intended for use in the relief of suffering are diverted to illicit purposes. The closed system is not really "closed" at all. The diversion of controlled substances leads to abuse and addiction that create human suffering. For this reason, drug regulators have emphasized the need to reduce drug diversion and resulting abuse. This emphasis on diversion prevention begs two questions. First, through what leaks in the supposedly closed (but obviously wide open) system does diversion occur? Second, who is responsible for controlled substance diversion?

There are no definitive answers to those questions. And they are important questions to ask. If the majority of controlled substance diversions are from non-medical sources, then the majority of enforcements should be in those areas. Non-medical diversion, through robbery, hijacking, burglary, employee theft, patient leakage, importation and the Internet, may be contributing the largest share of pharmaceutical controlled substances to the illicit market. If this is the case, then efforts to more tightly control prescribing and dispensing of controlled substances will be unsuccessful, because these activities are not the most common sources of diversion. Recent research suggests that the non-medical sources of diversion may predominate over the medical sources of diversion.

ACHIEVING BALANCE: THE PRACTITIONER'S DILEMMA

Pharmacists uniformly support the position that medications, including opioid analgesics, should always be provided to patients who need them. Untreated or under treated pain is an epidemic in America. Approximately 50 million Americans suffer chronic pain, and in only 25% of these cases is this pain treated effectively. Pharmacists are the custodians of the nation's drug supply. If patients cannot get medications from their pharmacists, then they cannot get them at all. The principles of pharmaceutical care recognize that people who need help should receive it from their pharmacists. Chronic pain patients deserve competent, caring and confidential pharmaceutical services. They deserve to be treated with respect. In return for the competent care they receive from pharmacists, chronic pain patients can expect that they will be required to behave responsibly while using opioid analgesics. The dispensing to a patient of a controlled substance brings with it a set of duties for the patient, because these controlled substances can be abused if diverted from the possession of the patient.

Pharmacists also uniformly support the proposition that a person who has no legitimate need for controlled substances should not receive them. The people who pretend to be pain patients and who behave in ways that dupe pharmacists into dispensing to them, should be screened out of the general population of patients and unceremoniously told to leave and never return. The pushers should be pushed out of the pharmacy. This is a non-controversial position.

In pharmacy, although there is general agreement that legitimate patients should receive medication, and that would-be diverters should be denied them, there is little agreement about how to achieve these dual goals. Pharmacists run the risk that overly aggressive practices toward pain patients will result in the denial of medica-

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tions to a person who legitimately needs them. Practices that are overly relaxed about diversion prevention run the complimentary risk of allowing diverters to obtain medications they should not receive. Both of these results are problematic, because in each case there is human suffering. Emphasis on the prevention of one problem will increase the occurrence of the other. The key to effective practice in pain management is balance. When balance is the focus of practice, occasionally some pain patients will be denied medications they deserve, and occasionally drug diverters will receive medications they do not deserve. But in a balanced pharmacy practice, the vast majority of pain patients will receive their medication, and the vast majority of drug diverters will be denied. The key to success is in finding the balance.

PAIN MANAGEMENT AND THE LAW

Because the legal responsibilities of health care providers in the treatment of pain have not been well understood in the past, the Federation of State Medical Boards has adopted Model Policies for the Use of Controlled Substances in the Treatment of Pain. These Model Policies have been endorsed by the National Association of Boards of Pharmacy. In approximately half of the states, the Model Policies have been adopted, in one form or another, by the boards of medicine. In several states, the boards of pharmacy have adopted the content of the Model Policies, and have made this content either mandatory or suggested for pharmacists. Regardless of the formalities with which the state has adopted the Model Guidelines, they serve as the best description of the legal responsibilities of health care providers who take care of patients in pain.

Among the many principles expressed in the Model Policies is the directive that the treatment of a pain patient shall not be judged solely based on the quantity and duration of the prescribed medication. Factors other than the volume of opioids prescribed and the length of time they have been used must enter into the evaluation of a chronic pain patient's treatment.

A key component of the Model Policy is a list of definitions that are relevant to pain management practice. The key definitions are as follows:

Addiction: Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestation. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Physical Dependence: Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction: The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse: Substance abuse is the use of any substance for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance: Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

These definitions help with an understanding of the responsibilities of pharmacists in the care of pain patients, and in the methods to use in screening prescriptions to distinguish legitimate patients from drug diverters. For example, a patient who reduces her dose of opioid medication and begins to experience withdrawal symptoms cannot be considered an addict. These symptoms result from physical dependence, and not from addiction. Likewise, a patient who must gradually increase his dose of opioid medication is not an addict, but has instead experienced tolerance. A person uses several different physicians to obtain an adequate supply of medication, because each physician under doses the prescribed medications, is showing signs of relief-seeking behaviors known as pseudoaddiction, and not the drug-seeking behaviors that characterize addiction. These conclusions are not based on beliefs or personal opinions. They are based on the

laws enacted under the Model Policy of the Federation of State Medical Boards.

Health care providers and regulators do not always see eye-to-eye in their interpretation of facts in a pharmacy practice, and in their application of the law to the facts. There are certain problematic “red flags” that are recognized by regulators based on the conduct of health care providers who see these same factors as the signs of success in practice. For example, the fact that “patients come from miles away” to have their prescriptions filled, and their drug therapy monitored, at a particular pharmacy, is sometimes seen by regulators as a red flag signaling diversion. But pharmacists understand that if there is a specialty pain management practice with a commitment to meeting the needs of chronic pain patients, those patients will come from miles away to the pharmacy. What may appear malevolent may in reality be benevolent. The same is true when multiple symptoms are being treated. Regulators are sometimes critical of a pharmacist for dispensing a long-acting opioid, a short-acting opioid, an antidepressant, a hypnotic and a skeletal muscle depressant to chronic pain patients. This looks like polypharmacy, which is a “red flag” for diversion. But the explanation may very well be that chronic pain patients need all of these drugs to treat their condition in a holistic way. High doses are another “red flag” for regulators, but health care providers realize that there is no ceiling dose of opioids, and that the common practice is to titrate opioids as high as is necessary to achieve an analgesic dose without adverse effects. The diversity in perspectives on the facts that form the basis of regulatory “red flags” can lead to conflicts between regulators and health care providers.

THE FEDERAL STANDARD

Under federal law, pharmacists share with prescribers the responsibility to prevent the diversion of controlled substances. The specific language of the federal law is as follows:

“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. 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. 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 violation of the law.”

The language of this important law contains many words and phrases that warrant consideration. First and foremost is the word “knowingly.” Pharmacists are given assurance that, although they may fill a purported prescription (the rule makes a distinction between prescriptions and purported prescriptions), they will not be in violation unless they knowingly fill a purported prescription. So there are two ways to comply with the law. One way is to fill only prescriptions, as opposed to purported prescriptions, and the other way is to fill purported prescriptions, but do so without knowing that the orders are not prescriptions. Either way the pharmacist is in the clear. The law recognizes that the best a pharmacist can do is to act in good faith, and that a pharmacist may at times inadvertently fill a purported prescription without knowing that this is occurring. The law accepts this occasional good faith dispensing of a purported prescription as the necessary cost of practicing pharmacy in a way that focuses on providing patients with medications that they need to relieve suffering. Perfection is not required, just good faith efforts.

The concepts of “legitimate medical purpose” and “usual course of professional practice” are what determine whether an order is a prescription as opposed to a purported prescription. The concept of “legitimate medical purpose” is confusing, because it is difficult to tell what the word “legitimate” means as a modifier of the word “medical.” It is hard to conceptualize a medical purpose that would not be legitimate, thus it is hard also to conceptualize a medical purpose that is legitimate. Does the word “legitimate” mean that medical purposes must be evidence-based or approved by consensus, or does the word mean simply that medical purposes for controlled substances must be related to the treatment of a disease or symptom, even if there is no evidence or consensus to support the prescribing of the drug for that disease or symptom? Analysis of the phrase, within the context of litigated cases, suggests that the words “legitimate” and “medical” are redundant, and that a “legitimate purpose” and a “medical purpose” mean the same thing, when evaluating the prescribing of controlled substances. Therefore, the pharmacist’s responsibility is to recognize that an order has been

issued for a medical purpose, even though there may be no evidence or consensus to support the order. An order that is outside the norm of medical practice is a prescription nonetheless, because it has been issued for a legitimate medical purpose in the sense that it is intended to treat or prevent a disease, rather than to support behaviors related to abuse and/or addiction.

The reference in the rule of "course of practice" is different from what is normally referred to as "scope of practice." Whereas the former refers to the activities of the prescriber in issuing the order, the latter refers to the credentials of the prescriber. The prescribing of hydrocodone/acetaminophen may be within the scope of a dentist's practice when ordered for tooth pain, but nonetheless outside the course of the dentist's practice if no examination is made of the patient, no assessment is done of the patient's pain, and no recordkeeping is maintained by the dentist of the order. Even though such an order may be intended for a legitimate medical purpose, it will not be a prescription if it is issued outside the usual course of professional practice (i.e., in the absence of a prescriber-patient relationship), and the pharmacist who fills the order with knowledge that it is outside the usual course of professional practice has knowingly filled a purported prescription.

VIGIL: A REAL WORLD APPLICATION OF ABSTRACT LEGAL PRINCIPLES

The legal rules for the dispensing and prescribing of controlled substances are difficult to interpret. The complexity of them invites efforts to develop approaches to practice that make sense in the real world of health care, and that meet the legal requirements for prescribing and dispensing of controlled substances. One such approach is known as VIGIL. The VIGIL approach includes five steps: (1) Verification, (2) Identification, (3) Generalization, (4) Interpretation, and (5) Legalization. The VIGIL approach is not necessary for prescribing situations that are clearly legitimate. Usually, when a controlled substance is prescribed for a 7 day supply or less, and at a low dose, there are few questions about legitimacy, and the steps of VIGIL need not be followed. Likewise, with a patient who has obvious problems using controlled substances responsibly, VIGIL will not suddenly instill a sense of responsibility. Thus, a patient who has a history of forging prescriptions, or of using diverted medications purchased from non-medical sources, requires treatment and monitoring by addiction medicine specialists. The VIGIL process will not help address the problems of this patient, and it should not be relied on for them.

The purpose of VIGIL is to restore a policy of balance in a pharmacy that has faced problems in controlling inappropriate controlled substance use by patients, and/or that has been victimized as a source of drugs for diverters. By using VIGIL, pharmacists and physicians can collaborate to assure that legitimate chronic pain patients continue to receive necessary medications, and that the diversion of controlled substances is curtailed. There are three specific goals of the VIGIL process. The first goal is to screen out non-patients who are faking pain and who will divert controlled substances they acquire. These folks need to be sent packing from the pharmacy. The second goal is to impress upon legitimate patients that they have responsibilities in the use of opioids for pain, and that in exchange for meeting those responsibilities, their prescriber and pharmacist will continue to compassionately and caringly provide the services and products they need. The third goal is to show good faith in prescribing and dispensing, so that any regulator who is concerned about a pharmacist or a prescriber will have those concerns alleviated when it becomes clear that the VIGIL process was used. There is no way to be perfect in any area of pharmacy practice, including controlled substance dispensing, but the VIGIL process is useful evidence to show that the greatest care was taken to prevent controlled substance diversion.

Since the VIGIL process works best when prescribers and pharmacists are collaborating with each other for the benefit of the patient, it is important for pharmacists to know how prescribers should behave within the process. Pharmacists can teach the VIGIL process to prescribers, if prescribers are reluctant to provide access to opioids without a program to protect them from participating in the diversion of controlled substances.

VERIFICATION

The first step in the VIGIL process answers the question, "is this patient a responsible opioid user?" The responsibilities of prescribers for verification are as follows:

- Talk with the patient openly about prior drug use and ask specifically whether the patient has experienced problems using opioids as prescribed.

- Do not prescribe high dose opioids as an initial treatment for pain without verifying that the patient has previously used these drugs responsibly. Verification can come from another health care provider who knows the patient. In the absence of this verification, start with non-opioid analgesics and work up to the opioids as long as the patient behaves responsibly.
- Define success with therapy. Make sure the patient knows that pain management therapy can reduce pain but not eliminate it.
- Be open to verification requests by a pharmacist.

The pharmacist’s responsibility under the verification step is:

- Call the prescriber for verification the first time a patient presents a prescription for an opioid analgesic that the patient has not previously used. If the prescriber cannot be contacted immediately, then provide a partial supply on prescriptions that appear to be non-problematic (under federal law, there is a 72 hour period for partial filling of C-II’s). Let chronic pain patients know of this policy so they will bring prescriptions for new drugs during their prescriber’s office hours to facilitate verification.
- When contacting the prescriber’s office, ask the contact person what the purpose is for the medication. Do not ask for the diagnosis, because this is too threatening a question. There may be no firm diagnosis yet, and the treatment of pain during the differential diagnosis is within the standard of care. Document what the contact person says about the purpose (headache, back pain, neuropathic pain, for example). This will provide evidence that the dispensing was for a legitimate medical purpose.
- As time passes, there may be the need to re-verify a prescription if a patient’s behaviors are suspicious. Always contact the prescriber when there is any concern about a patient’s drug therapy. Do not call the police. This is a medical matter.

IDENTIFICATION

The identification step is quite straightforward. Any person who receives a prescription or medication must provide government-issued photo identification. This rule applies to any friend or family member who appears at the clinic or at the pharmacy to pick up a document or medication for the patient. Anyone who cannot produce a photo ID should be asked to return later with the photo ID, or to have someone else perform the pickup service. On rare occasions, an exception can be made to this rule if circumstances seem to warrant.

The photo ID should be photocopied, or information from it should be written down. Keep the photocopy or written information stapled to the prescription.

GENERALIZATION

During the third step of the VIGIL process, patients need to be told the responsibilities they must meet, in return for which they can expect to be provided services and products in a caring and compassionate manner. Patients have a responsibility to meet the general standards that are applied to them, but they also have a right to know in advance what those standards are. Each prescriber and each pharmacist must decide what rules work well within their practices. There is no one-size-fits-all set of standards that will meet the needs of every health care provider. Among the rules that prescribers and pharmacists may wish to establish are the following:

- Keep all controlled substances under lock and key as you would your money or your jewelry. It is your responsibility to limit access to your medications.
- No sharing these drugs with anyone.
- If you are more than 20% too early for a C-III refill, call the prescriber before contacting the pharmacist.
- There will be no emergency “refills” (verbal authorizations for a C-II) when there is no true emergency. It is your responsibility to plan ahead so you do not run out of your medication.
- You must use only one prescriber and only one pharmacy to obtain opioid analgesics. It is your choice whom to use. If you must obtain opioids elsewhere in an emergency, you must inform your regular prescriber and pharmacist that this special circumstance has occurred.

Sometimes it is useful to commit these, or other, rules to writing and have the patient, prescriber and pharmacy all agree to be parties to a formal agreement. Such an agreement should never be referred to as a “contract” because it lacks the requisites of a contract and may obligate parties to perform inflexibly according

to explicit terms of the agreement. Many prescribers and pharmacists will prefer to avoid the cumbersomeness of a written document, and this is perfectly fine. The point is not so much to "get it in writing" as it is to assure there is a clear understanding, and this can be done verbally.

Pharmacists who are made parties to pain management agreements must assure that when they become aware of a violation of the agreement, the prescriber is notified. This is not a law enforcement function, and it should not be done punitively. It is a collaborative function and should be done in the spirit of problem identification on the way to finding a workable solution.

INTERPRETATION

By the time the first three VIGIL steps have been completed, most drug diverters will have been scared off, taking their business elsewhere to practitioners who do not involve themselves in patient care to the degree the VIGIL process does. Chronic pain patients will not object to the requirements of VIGIL, because they understand, from long term use of opioids, that access to these medications brings responsibilities. As long as in return they receive services and products with respect and concern, the investment of their time will be seen as worthwhile. Chronic pain patients want to be validated through verification, they want to provide identification to become known and familiar in a clinic or pharmacy. They also want to know the rules of a practice so they can comply with them. Chances are good that after the first three steps, drug diverters are gone, and legitimate patients understand their responsibilities. However, there may be occasions when a health care provider needs additional reassurance that a person should be allowed access to controlled substances. When this occurs, the Interpretation step is useful.

The purpose of this fourth step is to address any lingering concerns about the appropriateness of prescribing or dispensing. This can be done in several ways:

- Call a trusted colleague and describe the situation (always omitting any information that would identify the patient), and ask for an informal "professional practice and procedures consult."
- Use a brief questionnaire to determine whether a patient is likely to abuse medications prescribed to treat pain. There are several of these that are available and can be accessed through an Internet search.
 - The Drug Abuse Screening Test (DAST).
 - The Opioid Risk Tool (ORT).
 - The Screener and Opioid Assessment for Patients in Pain (SOAPP).
- Require patients to maintain a diary with extensive descriptions of their functioning between exams, or ask them to have a friend or relative accompany them to describe their functionality.

Frequent consultation between prescriber and pharmacist is another way to assure that an appropriate comfort level is found, and that patients receive medications they need while access is denied to diverters.

LEGALIZATION

The final step in the VIGIL process is legalization. It goes without saying that the chronic pain patient is not one with whom legal corners should be cut. Sometimes in medical and pharmacy practice it becomes obvious that the law is getting in the way of effective patient care, and a technical violation of the law occurs to better meet the patient's needs. This is a reality of practice that is routinely forgiven. But not when the patient is being prescribed drugs that are subject to abuse, as are the opioid analgesics. The only viable approach to prescribing and dispensing these drugs is to stay "squeaky clean" from a legal perspective.

Prescribers need to make sure they perform some sort of physical assessment of the patient prior to prescribing, and to document thoroughly what they do in caring for the patient. Pharmacists need to make sure they follow up on DUR edits and counsel patients (not just make an offer) about the appropriate use of their medications.

THE "DO NOT FILL UNTIL" CONTROVERSY

One of the most problematic legal technicalities of the past two years has been the practice of issuing multiple same-day C-II prescriptions, dating them all on the day of issuance, but directing that the pharmacist

dispense the ordered quantity sequentially over time, by instructing "Do Not Fill Until [date]" on the prescription. The issuance of "DNF" prescriptions is a practice that has been common for at least a decade. The Drug Enforcement Administration (DEA) advised health care providers to do exactly this for years prior to 2004, when they suddenly decided it should not be done, although they now have changed their perspective again.

The DNF controversy arose as a result of the adoption of a Prescription Pain Medication Frequently Asked Questions (FAQ) document in late August, 2004. This document had been negotiated between a small number of pain management advocates and clinicians, and a small number of regulators. The result was a document that purported to describe a "safe harbor" in which prescribers and pharmacists could take care of their patients without worrying about regulatory oversight. Among other things, the FAQ recognized and endorsed the previously approved DNF practice that had never been illegal. The FAQ document was posted to the DEA website with great fanfare, accompanied by press releases and press conferences. The DEA boasted that they were an agency that could work well with health care providers and avoid misunderstandings that get in the way of patient care. Within six weeks the FAQ document was withdrawn due to unspecified "misstatements." One month later three misstatements were identified.

The DEA explained that one misstatement in the FAQ was the language saying: "The number of patients in a practice who receive opioids, the number of tablets prescribed for each patient, and the duration of therapy with these drugs do not, by themselves, indicate a problem, and they should not be used as the sole basis for an investigation by regulators or law enforcement." The DEA objected to this statement because it could lead health care providers to believe that the factors described are of no concern whatsoever to regulators, when in fact they are of some concern. Since there is little disagreement with the DEA on this point, this first clarification caused no alarm among health care providers.

The second FAQ misstatement referenced by the DEA said: "Family and friends, or health care providers who are not directly involved in therapy, may express concerns about the use of opioids. These concerns may result from a poor understanding of the role of this therapy in pain management or from an unfounded fear of addiction; they may be exacerbated by widespread, sometimes inaccurate media coverage about abuse of opioid pain medications." In labeling this assertion a misstatement, the DEA noted the statement could be interpreted to mean that concerns by family and friends should be given no credence, when in fact these concerns should be seriously considered by health care providers. This was another clarification with which there was no serious disagreement by health care professionals.

The third FAQ misstatement identified in late 2004 by the DEA caused a great deal of angst among health care providers. The FAQ had said "A physician may prepare multiple prescriptions on the same day with instructions to fill on different dates." This statement acknowledged a longstanding practice in medicine and pharmacy of permitting physicians to write multiple C-II prescriptions on the same day, date them all on the date of issuance, and write "do not dispense until [date]" on all prescriptions, but the prescription intended for immediate dispensing. It is a practice that avoids requiring stabilized patients to return to their physician more often than is necessary. Prior to the issuance and withdrawal of the FAQ, this practice was officially endorsed by the DEA as the right way to provide continuing access to C-II medications over time, when expensive and inconvenient physician visits were not medically necessary. The practice reduces health care costs, it accommodates patients (many of whom are ill and cannot travel without exacerbating their condition), and it obviates the necessity of prescribing a huge supply of drugs at one time and thus making these drugs subject to diversion.

In labeling this sentence a "misstatement," the DEA, for the first time ever, indicated that multiple same day C-II prescriptions was essentially the same as authorizing refills of C-II prescriptions, which is impermissible under the Controlled Substance Act. This single action produced a firestorm of reaction from health care providers, patient advocates, and state regulators. Over the next two years there were inconsistent interpretations by the DEA of its policy on multiple same-day prescriptions, accompanied by threats of prosecution against those who violated the policy, but no actual enforcement of the reinterpreted law against anyone who chose to continue the practice.

In the fall of 2006, the DEA issued a "notice of proposed rulemaking," in which it retracted its earlier position that multiple same-day C-II prescriptions with "do not fill until" instructions are illegal. A new DEA regulation has been proposed, in which this common practice will now explicitly be allowed. The exact word-

ing of that regulation has not yet been determined, but it is clear that the DEA has backed away from its earlier ill-advised opinion that ran contrary to what they themselves had traditionally espoused as the appropriate way to prescribe continuing access to C-II medications.

CONCLUSION

The challenges for pharmacists in the monitoring of controlled substance prescriptions are daunting, but it is possible to meet regulatory requirements and still provide necessary medications to patients who suffer. Collaboration between prescriber, pharmacist and patient is the key to determining whether controlled substances are being used for medical reasons, or instead, are being diverted to non-medical reasons. Within this triangle relationship, patients must understand that their responsibilities are as significant as are those of the prescriber and the pharmacist. Compassionate and caring professional practice, combined with tough love toward the patient, can help prevent drug diversion without denying access to medications by anyone for whom they are therapeutically appropriate.

Fill in the information below, answer questions and return **Quiz Only** for certification of participation to:
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LESSON EVALUATION

Please fill-out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1. Does the program meet the learning objectives?

Describe the balance that must be sought in treating pain & drug diversion	Yes	No
Discuss regulatory policy in prescribing & dispensing of opioid analgesics	Yes	No
List factors that correlate with regulatory problems relevant to opioids used for chronic pain	Yes	No
Describe strategies to avoid regulatory problems with legitimate pain patients	Yes	No

2. Was the program independent & non-commercial?

	Poor		Average		Excellent	
	1	2	3	4	5	6

3. Relevance of topic to your practice

4. What did you like most about this lesson? _____

5. What did you like least about this lesson? _____

(WATCH OUR WEBSITE FOR RESULTS OF PARTICIPANT EVALUATIONS)

Quiz—Please Select the Most Correct Answer

- | | |
|---|---|
| <ol style="list-style-type: none"> 1. Approximately how many Americans experience pain at least once every month <ol style="list-style-type: none"> A. 5,000 B. 50,000 C. 500,000 D. 5,000,000 2. Non-pharmaceutical controlled substances are in which schedule? <ol style="list-style-type: none"> A. I B. II C. IV D. V 3. A new patient presents a prescription for 120 oxycodone 80 mg tablets. According to VIGIL, you would: <ol style="list-style-type: none"> A. Refuse to fill B. Verify validity with prescriber C. Call police D. Dispense ½ to prevent diversion 4. The key to effective practice in pain management is: <ol style="list-style-type: none"> A. Aggressive policing B. Suspicion & distrust C. Balance D. An open door policy 5. The Model Policies for the Use of Controlled Substances in the Treatment of Pain have been endorsed by: <ol style="list-style-type: none"> A. FDA B. CMS C. NABP D. HCFA | <ol style="list-style-type: none"> 6. A pain patient engages in relief seeking behaviors that resolve upon institution of effective analgesic therapy. According to FSMB, this is called: <ol style="list-style-type: none"> A. Addiction B. Physical dependence C. Tolerance D. Pseudoaddiction 7. A pain patient experiences a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect. This is called: <ol style="list-style-type: none"> A. Addiction B. Physical dependence C. Tolerance D. Pseudoaddiction 8. What is the meaning of the phrase "legitimate medical purpose?" <ol style="list-style-type: none"> A. The best medicine B. Normal medicine C. Intent to treat or prevent a disease D. Consensus medicine 9. Non-medical sources of diversion may predominate over medical sources. <ol style="list-style-type: none"> A. True B. False 10. Which of these is useful in determining whether a patient is likely to abuse medications prescribed to treat pain? <ol style="list-style-type: none"> A. DAST B. ORT C. SOAPP D. All of these |
|---|---|

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