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CONTINUING EDUCATION

Wyeth
TRENDS IN PHARMACY AND PHARMACEUTICAL CARE

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CREDIT:

This lesson provides two hours of CE credit and requires a passing grade of 70%.*

OBJECTIVES:

Upon completion of this article, the pharmacist should be able to:

- Describe the pharmacist's responsibility to screen controlled-substance prescriptions to prevent drug diversion
- Describe the pharmacist's responsibility to ensure that

legitimate pain patients are not denied access to necessary medications
- List the Drug Enforcement Administration requirements for assurance of appropriate prescribing and dispensing
- Discuss the corresponding responsibility of pharmacists to avoid "knowingly" dispensing purported prescriptions
- Discuss the standards for pain management applicable to prescribers and dispensers
- List the steps pharmacists can take to avoid dispensing a controlled substance to a person who should not receive it

*To receive credit you must complete the evaluation. Upon successful completion, the University of Florida College of Pharmacy will mail Statements of Credit for written quizzes within 10 working days. Participants completing the program on-line may print a Statement of Credit after successfully completing the program.

GOAL:

To review the new molecular entities approved in 2002

Pain management regulation

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Pharmacists have a very special responsibility as the gatekeepers of the nation's drug supply. They must not only use their clinical skills to ensure that prescribed medications are therapeutically appropriate for patients, they must also use their observational skills to ensure that medications are not diverted for inappropriate uses. A controlled-substance medication dispensed to a person whose intent is to use the medication to support an addictive habit—outside government-approved programs that permit the prescribing of methadone, LAAM (levo-alpha-acetyl-methadol), and buprenorphine to addicts—is considered a diverted medication. Pharmacists have a clear responsibility to prevent diversion.

Pharmacists also have a responsibility to ensure that patients in pain receive medication that will relieve suffering. Pharmacy is a caring profession dedicated to meeting the needs of individual patients, as well as the needs of society. Patients in pain have not always received necessary and appropriate medications, because of the barriers that exist to the provision of opioid analgesics. Opioid analgesics are controlled substances, and the regulatory imperative to avoid

controlled-substance diversion has, at times, interfered with the professional imperative to relieve human suffering through care and concern for individuals in pain.

The key to successful pharmacy practice is balance between diversion-prevention activities and patient care activities. Pharmacists must strive to develop practice strategies aimed at ensuring the prevention of controlled-substance diversion while simultaneously making certain that patients in pain do not needlessly suffer. It is a difficult job, but it is a job that can be successfully performed by pharmacists who develop a clear understanding of the field of pain management regulation. Through such an understanding, pharmacists can be encouraged and enabled to provide opioid analgesics when they are appropriate for a patient in pain, secure in the knowledge that regulators will tolerate an occasional good-faith error in dispensing, despite the fact that the error may result in controlled-substance diversion.

Federal regulation of controlled substances

The structure of federal controlled-substance law, administered by the Drug Enforcement Administration (DEA), creates a closed system of drug distribution. The drugs within the closed system are classified into one of five schedules, with schedules II through V being those drugs that have a recognized, legitimate role in medical care. The degree of regulatory oversight declines as the number assigned to the schedule increases, because the propensity for abuse declines as well. Businesses and individuals authorized to control the distribution of these scheduled drugs are required to register with DEA. Very specific rules have been established for storing, shipping, prescribing, and dispensing of the drugs. Record-keeping requirements, from cradle to grave, must be adhered to strictly. The end result is that DEA and other regulatory agencies have the ability to know where a controlled substance is, where it has been, or where it has gone, by conducting an audit of a registrant.

Unfortunately, the closed system is not as closed as everyone in health care and law enforcement would wish. Pharmacists, physicians, and other DEA registrants are frequently seen as easy targets for criminals determined to divert controlled substances from the supposedly closed system. Even the most caring and

competent physicians and pharmacists can be duped into providing access to controlled substances by those who have no business using them. Diversion of this kind is a threat to the public health because it leads to substance abuse and the personal and social tragedies that accompany abusive behaviors. Diversion is also a threat to individual health, because conservative behaviors by physicians and pharmacists, intended to drastically restrict illicit access to controlled substances, have the unintended but foreseeable effect of also decreasing access by patients who suffer acute and chronic pain.

DEA regulations: DEA has consistently said that its goal is to reduce controlled-substance diversion without adversely affecting the quality of pain management. The agency recognizes a complementary role of physicians and pharmacists in the prevention of controlled-substance diversion. This complementary role is recognized in federal regulations, which state:

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

This single paragraph is central to the development of an understanding of the appropriateness of physician and pharmacist conduct in the prescribing and dispensing of controlled substances. There are several interesting aspects of this paragraph.

Legitimate medical purpose: "A controlled substance prescription, to be valid, must be issued for a legitimate medical purpose...." This is a perplexing phrase. For it to have any real meaning, the phrase *nonlegitimate medical purpose* must also have meaning. Yet it is difficult to conceive of a medical purpose that would not be legitimate. Medicine is an inherently legitimate activity. If the prescriber's purpose in ordering the

controlled substance is medical, then it is legitimate. If the reason for the controlled-substance prescription is not medical, then it is not legitimate. The impossibility of conceptualizing a nonlegitimate medical purpose, and the resulting impossibility of conceptualizing a legitimate medical purpose, leads to the conclusion that the words *legitimate* and *medical* are redundant. This means that a pharmacist's responsibility is to distinguish medical prescriptions from those that are not medical. This is the same thing as distinguishing legitimate Rxs from those that are not legitimate. But there is no further responsibility to distinguish between legitimate and nonlegitimate medicine, because that is a meaningless concept. If a prescription is medical, then it is legitimate.

In practice, the redundancy is an important one, because it clarifies that pharmacists are supposed to intercede in prescriber practices that would result in diversion to nonmedical, or nonlegitimate, drug uses. Yet, under the DEA rule, pharmacists are not required, nor are they authorized, to evaluate the quality of a prescriber's practice, if that practice is clearly medical. For example, a pharmacist might believe that a particular opioid analgesic is not the appropriate one for a patient. Or a pharmacist might believe that a dosing frequency is not optimal for a patient. However, if the medication is clearly being prescribed for a medical purpose, the pharmacist has no responsibility or authority under the DEA rule to intercede and refuse to fill the prescription. Professional standards in pharmacy will often require communication with the prescriber and/or the patient under these circumstances, but the refusal to dispense is not required or authorized under DEA regulations.

Usual course of professional practice: Pharmacists must ensure not only that a prescription is for a medical purpose, but also that it has been issued in the "usual course of professional practice." Under DEA rules, this means that the prescriber has conducted as extensive an examination as is warranted by the prescriber's professional standards, that a treatment plan has been developed, and that all medical care has been adequately documented. The usual course of professional practice does not include selling prescriptions to persons who are drug diverters. It also does not include a practice that creates a mere pretense of medical care, establishing an appearance of propriety when the reality is that diversion is either the explicit or implicit purpose.

Course of professional practice should not be confused with *scope* of professional practice. There are certain prescribers who have limited authority to prescribe based on the type of practice license they have been granted. Dentists must limit their practice to the teeth and jaw, podiatrists must limit their practice to the feet and ankles, and veterinarians must limit their practice to animals. These are limitations on the scope of practice. Allopathic physicians (M.D.s) and osteopathic physicians (D.O.s) have virtually unlimited scope of practice. They may choose to limit their practices to a specialty, such as surgery, internal medicine, or dermatology, but these optional specialties do not limit their scope of practice under the law. A practitioner prescribing within the apparent scope of that practitioner's practice may nonetheless be operating outside the course of professional practice and vice versa.

For example, a dentist who prescribes a large dose of opioids for an indication of jaw pain, would seem to be within the scope of practice but would be working outside the usual course of practice if the prescription were sold to a drug dealer. Likewise, a psychiatrist who is prescribing for an indication of jaw pain would be operating within the usual course of professional practice if the patient were depressed as a result of the jaw pain, even though an initial review might lead to the conclusion that jaw pain is outside the scope of practice for a psychiatrist. In determining whether a prescription has been issued within the usual course of professional practice, the focus is on the conduct of the prescriber and not on the credentials of the prescriber.

Applying 'legitimate medical purpose' and 'usual course of professional practice': Consider the following hypothetical situation: A patient seeks assistance from Physician A. The patient is a legitimate pain patient. The patient's primary care physician, who is timid about prescribing high-dose opioids, has not met the patient's need for opioid analgesics. Physician A has developed a sham practice that in reality is not medicine at all. It is a practice of selling prescriptions to people who pay the physician a fee on a scale that escalates with the number of dosage units prescribed. After conducting no exam whatsoever, but creating false documentation of complete care, the physician issues a prescription for the patient. The prescribed opioid analgesics are clearly indicated for this patient, based on every recognized standard of pain management practice. Is this a valid prescription? No, it is not a valid prescription, even though it has been issued for a

legitimate medical purpose, because the prescription has not been issued in the usual course of professional practice.

Consider a second hypothetical situation: A patient seeks assistance from Physician B. The person is actually not a patient at all but a drug diverter. This person has no legitimate need for any pain medication. But this person has learned how to behave like a pain patient, and his good acting skills lead Physician B to believe opioid analgesics are indicated. Physician B conducts a thorough exam, with extensive documentation. All standards of medical practice for pain management are met or exceeded by Physician B. A prescription for opioid analgesics is issued for this person. It is a valid prescription? No, it is not a valid prescription, even though it has been issued in the usual course of professional practice, because the Rx has not been issued for a legitimate medical purpose.

For a controlled-substance prescription to be valid, it must be issued both for a legitimate medical purpose and in the usual course of professional practice. Neither of these two hypothetical prescriptions meets the double-barreled requirement.

The 'knowingly' condition: Despite the fact that both of the above-described hypothetical prescriptions are not prescriptions at all, but purported prescriptions, a pharmacist filling either of them has not necessarily violated federal law. This is because a violation of federal law has occurred only when a pharmacist has "knowingly" filled a purported prescription. The *knowingly* condition is the means through which DEA acknowledges that an occasional misstep by a pharmacist who is trying hard and who is duped into filling a purported prescription, despite making extensive efforts to avoid doing so, is forgiven as the necessary cost of ensuring access to appropriate therapy for patients who need controlled substances. Filling a purported prescription does not violate federal law. *Knowingly* filling a purported prescription is a violation.

When does a pharmacist know that a prescription is not a prescription but is instead a purported prescription? This question represents the most troubling aspect of the "knowingly" condition. Is a mere suspicion of invalidity sufficient to convey knowledge of invalidity? Or, is there sufficient knowledge of invalidity only when the presenter of a prescription confesses to the pharmacist

that the prescription is not valid? The reality lies somewhere in between. Mere suspicion is not enough to support invalidity, but ignoring indicators of invalidity until there is an outright confession is equally unsupportable. A pharmacist *knows* that a prescription is a purported prescription either when the pharmacist actually understands that the Rx has been issued not for a legitimate medical purpose or outside the usual course of professional practice, or when the pharmacist *should* know this based on circumstances.

A pharmacist cannot deliberately close her or his eyes to obvious red flags indicating the possibility of invalidity and then claim ignorance when confronted with the reality of invalidity. On the other hand, a pharmacist is not required to imagine the existence of red flags and interrogate every patient presenting an Rx for an opioid analgesic, based on the possibility that any Rx may be invalid. In the absence of any evidence to the contrary, a pharmacist may assume that a prescription is valid. When factors suggest there may be some question about validity, the pharmacist should address those factors by speaking to the patient and/or the prescriber. Only when there is confirmation that a prescription is invalid should the pharmacist refuse to dispense.

Pain management standards

The ambiguity of pharmacist and physician responsibilities under federal law has led to circumspection by both pharmacists and physicians in their practices. Fear of regulatory action against one's professional license has led to a chilling effect on prescribing by physicians and on dispensing by pharmacists. Pharmacists have become cautious in their screening of controlled-substance prescriptions, including those for opioid analgesics, to eliminate any possibility that they might ever dispense controlled substances pursuant to a purported prescription. The adverse effect this caution has on pain management has led to the adoption of standards of practice applicable to the use of controlled substances to treat pain. The Federation of State Medical Boards first adopted the standards, and the National Association of Boards of Pharmacy has endorsed them. These standards describe the responsibilities of physicians and pharmacists in prescribing and dispensing controlled substances for pain.

Definitions: The pain management standards include

definitions that help clarify frequently misunderstood concepts. These definitions are more than semantic. They help physicians and pharmacists understand how to classify patients and how to respond to patients. The goal is to treat similar patients in a similar way, but to treat different patients in different ways. The key definitions are as follows:

Addiction: Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects; it is characterized by compulsive use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

Note that addiction is a psychological phenomenon. Addiction occurs when there is compulsive use despite harm. This is a characteristic of drug addicts but not of pain patients. Although drug addicts may become pain patients, pain patients do not become drug addicts. Pharmacists need not be concerned that pain patients who have no history of addiction will become addicts simply through the use of opioid analgesics to treat pain. The medical use of an appropriate drug will not lead to compulsive use despite harm.

Physical dependence: Physical dependence on a controlled substance is a physiologic state of neuroadaptation that is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

As opposed to addiction, physical dependence is a physiological rather than a psychological phenomenon. Simply because a patient can be expected to have a withdrawal syndrome upon abrupt discontinuation of prescribed opioid analgesics does not mean that the patient is addicted to opioid analgesics. Physical dependence is normal and expected. It is clearly not the same as addiction under the standards for pain management.

Tolerance: A physiologic state, tolerance results from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is

observed with a constant dose. Pain patients, like patients who use many other types of drugs, sometimes develop a tolerance to opioid analgesics over time. This tolerance manifests as a need to increase the dosage to achieve the same analgesic effect. This is not addiction. A pharmacist should not conclude that a steady increase in the use of opioid analgesic medication means that a patient has become addicted. It is tolerance that the pharmacist is observing. Tolerance is a normal and acceptable occurrence.

Pseudoaddiction: This is a pattern of drug-seeking behavior by pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Some pain patients do not receive adequate analgesia from their primary care physicians, due to the physicians' concerns that the patients may receive too much medication. The old adage "Start low and go slow" has led some physicians to start with a dose so low that there is no analgesic effect and to go so slow that there never will be an analgesic effect. Patients who are receiving care from these physicians must go to other physicians to have their pain management needs met. They may bring Rxs to a pharmacist from several different physicians, all of whom are underdosing the patient's pain. This is the only way the patients can achieve pain relief. These patients are not drug-seeking, they are relief-seeking. Pharmacists should beware of confusing such patients with addicts.

Pain management guidelines: The Federation of State Medical Boards has carved out a "safe harbor" for physicians in their prescribing of controlled substances for the treatment of pain. In the regulatory storm of controlled-substance compliance, the safe place to be is within the parameters of the pain management guidelines. A physician who is conscientious in his or her practice, and who complies with the guidelines, will discover that regulatory authorities are forgiving of the relatively few errors of inappropriate prescribing that "sneak through the cracks" of a busy practice. These guidelines are useful for pharmacists in determining which prescribers are practicing consistent with the norms of their profession and which practitioners are on the fringe of their profession or clearly outside it. The guidelines have seven components. They are primarily intended to be used by regulators in the evaluation of a prescriber's practice, but they may also be of use to pharmacists in their screening of a prescription for

legitimacy.

1. Evaluation of the patient: A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

2. Treatment plan: The written treatment plan should state objectives that will be used to determine treatment success—such as pain relief and improved physical and psychosocial function—and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed consent and agreement for treatment: The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive Rxs from one physician and one pharmacy when possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities, including:

- urine/serum medication levels screening when requested
- number and frequency of all prescription refills
- reasons for which drug therapy may be discontinued (i.e., violation of agreement)

4. Periodic review: At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as improvement in patient's pain intensity and improved physical and/or psychosocial

function (e.g., ability to work, need of healthcare resources, ability to perform activities of daily living, and quality of social life). If treatment goals are not being achieved, despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

5. Consultation: The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

6. Medical records: The physician should keep accurate and complete records to include:

- the medical history and physical examination
- diagnostic, therapeutic, and laboratory results
- evaluations and consultations
- treatment objectives
- discussion of risks and benefits
- treatments
- medications (including date, type, dosage, and quantity prescribed)
- instructions and agreements
- periodic reviews

Records should remain current, be maintained in an accessible manner, and be readily available for review.

7. Compliance with controlled-substance laws and regulations: To prescribe, dispense, or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the *Physicians Manual of the U.S. Drug Enforcement Administration* and any relevant documents issued by the state medical board for specific rules governing controlled substances as well as applicable state regulations.

Pharmacists are responsible for ensuring that the controlled-substance Rxs they honor are legitimate.

Should a pharmacist believe that a prescriber is blatantly selling prescriptions, without even attempting to practice medicine, the pharmacist has every right to request an explanation. However, it is the process that matters most, not the outcome. It is not possible to look at a dose of a medication, or a frequency of use, and decide from that information only that a prescription is invalid. The way in which the prescriber is practicing is the most critical factor, not the result, and the federation guidelines describe the right way to do this.

The VIGIL process

Pharmacists who commit to providing appropriate care, without dispensing inappropriate medications, should develop practice procedures to provide a consistent approach to controlled-substance prescription screening. It is important for irrelevant factors, such as the patient's appearance, to be factored out of screening decisions. For example, drug diverters and drug addicts may use body piercing and tattoos, but legitimate patients also use them. It is impossible to simply look at a person who presents a controlled-substance prescription and discern from that person's appearance whether he or she is a drug addict or a drug diverter.

The VIGIL process (Verification, Identification, Generalization, Interpretation, Legalization) provides a justifiable system through which a pharmacist can review a prescription for an opioid analgesic and decide whether it is valid. The goal of VIGIL is to filter out prescriptions that are too suspicious to warrant filling but let through those that are beyond reasonable suspicion. VIGIL applies only to prescriptions that are potentially of concern to a pharmacist. For those Rxs that are beyond suspicion, because the prescriber is well known to the pharmacist and the patient is well known to the pharmacist, VIGIL would be unnecessary. Prescriptions that are obviously legitimate should be filled without using this process.

For Rxs that are clearly not legitimate, because they have been blatantly altered or because the pharmacist has another means of knowing for certain that the prescription is invalid, VIGIL is equally inappropriate. Obvious purported prescriptions should be refused without using the process. VIGIL is a means of discerning the difference between prescriptions and purported prescriptions, where there is a question about legitimacy that cannot be immediately resolved.

Verification: Any patient who is unknown to a pharmacist, or a well-known patient who presents a prescription for an opioid analgesic for the first time, should expect that the pharmacist would want to verify the Rx with the prescriber. This is not an unreasonable policy for a pharmacist. To insist on verification is in no way a suggestion that an Rx is unlawful or that a patient has engaged in inappropriate behavior. It is a comment on the times we live in and not on the patient, the prescriber, or the prescribed drug. It is a policy that protects the patient as well as the pharmacist, the prescriber, and the community.

Adequate verification of an opioid analgesic prescription requires contact by the dispensing pharmacist with the prescriber or with a person who formally serves as a representative of the prescriber. At certain times of day, this contact may not be possible, and pharmacists may wish to work out ways to obtain timely verification for patients whose schedules do not coincide with normal prescriber office hours. Perhaps on-call physicians will have some means to provide verification, although frequently it is difficult for an on-call physician to vouch for an occurrence within a colleague's practice. Sometimes a fellow pharmacist will be willing to verify that a pain patient is a responsible user of controlled substances, and this verification may be acceptable under some circumstances. Pharmacists may wish to provide a temporary partial supply of a controlled substance if they are unable to supply the full quantity because of the impossibility of verification. DEA has indicated that such an approach would be permissible under federal law, as long as the rules applicable to partial filling are followed.

Legitimate pain patients will usually not object to a pharmacist's insisting on verification of a prescription; drug diverters and drug addicts will, however, become nervous. A patient who becomes upset and angry over a pharmacist's policy of verification may be a patient in pain rather than a drug diverter, but pain patients need to act responsibly by allowing a pharmacist the opportunity to obtain verification. Those who object to a reasonable verification policy and who become so offended that they take their business elsewhere should be viewed as no great loss to a pharmacy practice that insists on ensuring the integrity of the nation's drug supply.

Identification: Pharmacists have a right to know the

identity of the people to whom medications are being given. Many pain patients cannot pick up their own medications, so they send another person to perform this favor for them. Pharmacists should not be reluctant to require photo identification of anyone who picks up an opioid analgesic prescription for a patient. If that person is not the patient, then the pharmacist is obligated to find out who the person is and what relationship that person has with the patient. This may require a telephone call to the patient or to the prescriber to ensure that the person requesting delivery of the medication is authorized to do so.

Pharmacists may wish to photocopy the identification card of the patient or of the person picking up an Rx for the patient. Legitimate pain patients will generally not mind doing this; drug diverters will become very nervous over it. Pharmacists can use their discretion to determine when an exception should be made to the mandatory identification rule, if circumstances suggest that the person is not one who would be expected to routinely carry a photo identification card.

Generalization: Legitimate pain patients will want to know the so-called house rules at a pharmacy. Through a set of explicit standard rules, pharmacists and patients can come to an understanding of their mutual responsibilities and the behaviors that each can reasonably expect of the other. Pain patients will want to comply with those rules to ensure themselves continued access to necessary medications.

House rules may include the steps necessary to resolve an apparent problem with "too early" dispensing. They may include the times of day when new Rxs for opioid analgesics may be presented for filling (designed to coincide with times of day when prescribers are available for verification). New patients with opioid analgesic prescriptions, or familiar patients who are presenting opioid analgesic Rxs for the first time, should be told that any apparent pattern of medication overuse will require contact with the prescriber. A pharmacy may feel comfortable dispensing opioid analgesics only to those patients who receive all their pharmaceutical products and services at the pharmacy. Some patients may prefer to have only their opioid analgesic prescriptions filled at a particular pharmacy and use a different pharmacy for their other pharmaceutical products and services. These patients may be told that they must make a choice of which pharmacy to use and stick with that pharmacy for

all of their pharmaceutical care needs. Drug abusers and drug diverters will likely choose not to accept the rules. Their decision to go elsewhere will not be unwelcome.

Interpretation: After insisting on verification, requiring identification, explaining the "house rules," and listening to patients describe any special needs they may have, a pharmacist must finally decide whether the circumstances warrant the dispensing of opioid analgesics to a patient. This is a decision to make with great care, because a wrong decision can either deny necessary relief to a suffering patient or perpetuate the addictive behavior of a person who has lost the power of self-control.

Regulators understand the difficulties pharmacists face in this screening role. Pharmacists are humans, and humans make mistakes. What is important is not to always get it right, but to always try to get it right. Experienced pharmacists may develop a sense of the circumstances that a particular situation just does not feel good. But care should be taken not to let personal bias affect a subjective feeling. An objective system like VIGIL can help pharmacists make good, defensible interpretations of the circumstances they face when asked to dispense an opioid analgesic prescription.

Legalization: Once the decision to dispense has been made, pharmacists should ensure that all applicable legal requirements have been met. Although the primary focus of controlled-substance regulation is on the prevention of diversion, specific rules have been developed for the handling of controlled substances. A pharmacist who violates these rules may be subject to regulatory action, even if no diversion has occurred. For C-II prescriptions, the special dispensing requirements are extensive.

1. C-II prescriptions must be in writing.

- In case of an emergency situation, oral authorization is permitted

  –Quantity prescribed must be limited to that necessary for the emergency

  –Pharmacist must reduce oral Rx to writing

  –R.Ph. must ensure the prescriber is legitimate

–Within seven days, the prescriber must deliver to pharmacist a written prescription

- A facsimile may serve as the original prescription

–Compounding for parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion

–Patient is resident of long-term care facility

–Patient is enrolled in hospice care

2. C-II prescriptions may not be refilled.

3. Partial filling of C-II prescriptions is permitted.

- If pharmacist is unable to supply full quantity

–Remaining portion must be dispensed with 72 hours or not at all

–Prescriber must be notified if remainder not dispensed

- Some patients may be dispensed partial supply over 60-day period

–Patient is a resident of a long-term care facility

–Medical diagnosis documenting a terminal illness

4. Some information on C-II prescriptions may be changed after pharmacist contacts prescriber.

- Patient's address
- Drug strength
- Drug quantity
- Directions for use

Conclusion

The pharmacist's responsibility to provide appropriate pain medications to those who need them, and to also deny access to controlled substances by those who would abuse them, is not easily met. But it is a core responsibility of the profession. By following the activities described above, pharmacists can achieve necessary balance in their professional practices.

References available upon request

TEST QUESTIONS

Write your answers on the answer form below (photocopies of the answer form are acceptable) or on a separate sheet of paper. Mark the most appropriate answer.

1. With regard to the nation's drug supply, pharmacists' special responsibility is to act as:

a. Clinical practitioners
b. Gatekeepers
c. Midlevel practitioners
d. Law enforcement agents

2. When a controlled substance is dispensed to a person whose intent is to use the medication to support an addictive habit (outside a government-approved program), this medication is called:

a. An unapproved new drug
b. An off-label drug
c. A diverted drug
d. An investigational drug

3. The pharmacy profession is dedicated to meeting the needs of:

a. Neither patients nor society
b. Patients but not society
c. Society but not patients
d. Both patients and society

4. Which of the following statements is key to professional pharmacy practice?

a. Diversion prevention is more important than patient care.
b. Patient care is more important than diversion prevention.
c. Neither diversion prevention nor patient care is important.
d. There should be a balance between diversion prevention and patient care.

5. Of what sort of error will regulators be tolerant?

a. Good-faith
b. Bad-faith

c. No-faith
d. Faithless

6. Into how many schedules have controlled substances been organized under federal law?

a. Three
b. Four
c. Five
d. 10

7. Under federal law, record-keeping requirements for controlled substances cover:

a. Acquisition only
b. Distribution only
c. Dispensing only
d. Cradle to grave

8. Who is responsible for reducing controlled-substance diversion?

a. Neither physicians nor pharmacists
b. Physicians, but not pharmacists
c. Pharmacists, but not physicians
d. Physicians and pharmacists share this responsibility

9. Which of the following distinctions is a pharmacist required to make under DEA regulations?

a. Medicine from nonmedicine and also legitimate medicine from nonlegitimate medicine
b. Medicine from nonmedicine, but not legitimate medicine from nonlegitimate medicine
c. Legitimate medicine from nonlegitimate medicine, but not medicine from nonmedicine

d. Neither medicine from nonmedicine nor legitimate medicine from nonlegitimate medicine

10. Dentists must limit their practice to the teeth and jaw. What sort of limitation is this?

a. Course of practice
b. Course of conduct
c. Course of relationship
d. Scope of practice

11. A physician may not sell prescriptions without any medical need, making only a sham of medical practice. What sort of limitation is this?

a. Course of practice
b. Course of conduct
c. Course of relationship
d. Scope of practice

12. A pharmacist dispenses a controlled substance pursuant to a purported prescription. What aspect of the pharmacist's conduct would lead to a violation of DEA regulations?

a. The pharmacist acted "knowingly."
b. The pharmacist acted "inadvertently."
c. The pharmacist acted "unintentionally."
d. The pharmacist acted "nonvolitionally."

13. Fear of regulatory action has led to what sort of effect on dispensing by pharmacists?

a. A "chilling" effect
b. An "enabling" effect
c. An "enacting" effect
d. A "reasoning" effect

14. A person experiences a neurobehavioral syndrome resulting in the use of controlled substances for his or her psychic effects and is characterized by compulsive use despite harm. This is called:

a. Addiction
b. Physical dependence
c. Tolerance
d. Pseudoaddiction

15. A pain patient experiences a physiologic state of neuroadaptation characterized by the emergence of withdrawal syndrome if drug use is stopped abruptly. This is called:

a. Addiction
b. Physical dependence
c. Tolerance
d. Pseudoaddiction

16. A pain patient experiences a physiologic state resulting from regular drug use in which an increased dosage is needed to produce the same effect. This is called:

a. Addiction
b. Physical dependence
c. Tolerance
d. Pseudoaddiction

17. A pain patient exhibits drug-seeking behavior that results from receiving inadequate pain management. This is called:

a. Addiction
b. Physical dependence
c. Tolerance
d. Pseudoaddiction

18. Following the issuance of an emergency C-II prescription, the prescriber must deliver a written Rx to the pharmacist in:

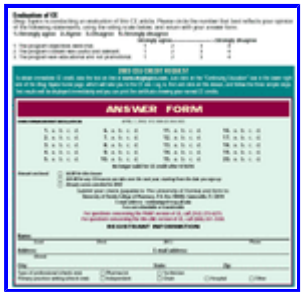
a. Seven days
b. 14 days
c. 21 days
d. 30 days

19. A pharmacist partially fills a C-II Rx because he is unable to supply the full quantity prescribed. The balance must be supplied within:

a. 72 hours
b. Seven days
c. 14 days
d. 60 days

20. Which of the following information may be changed on a C-II prescription by an R.Ph. who has contacted the prescriber and received authority to make the change?

a. Drug prescribed
b. Patient's name
c. Directions for use
d. Identity of the prescriber



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David Brushwood. CE: Pain management regulation. *Drug Topics* 2003;7:67.