



A PHARMACY CONTINUING EDUCATION PROGRAM

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

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**The program ID # for this lesson is 707-000-02-001-H03.
Pharmacists completing this lesson by January 31, 2005 may receive full credit.
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**The objectives of this lesson are such that upon completion the
participant will be able to:**

1. List the current requirements for dispensing controlled substances for pain.
2. Describe the movement toward legal recognition of collaborative drug therapy management between pharmacists and physicians.
3. Discuss the regulatory environment of pain management therapy.
4. Describe the "corresponding responsibility" of the pharmacist in dispensing controlled substances.
5. Discuss the legal implications of "collegial accountability" as a means to protect physicians & pharmacists from regulatory intrusion into their pain management practices.

COLLABORATIVE DRUG THERAPY MANAGEMENT & CONTROLLED SUBSTANCE DISPENSING FOR PAIN

This lesson suggests a policy-in-practice solution to the problem of under treated chronic pain. Through legally authorized collaborative drug therapy management, pharmacists and physicians can work together; not only to assure that patients are appropriately treated, but to also assure that a solid objective foundation exists to withstand an accusation of inappropriate medication use. Collaborative practice is an avenue through which physicians and pharmacists can manage the risk that regulatory authorities will misapply policy-on-paper and criticize the prescribing of high doses of narcotic analgesics as inappropriate and/or illegal. The inter-professional collaborative agreement, with the checks and balances that come from a care plan based on recognized clinical practice guidelines, can provide a safe harbor for physicians who aggressively treat chronic pain. Pharmacists can feel more comfortable dispensing high doses of narcotic analgesics to patients whose drug therapy they understand and for whom they share responsibility. Suffering is relieved and the responsible health care providers can present a unified, evidence-based explanation of high dose narcotic use, if confronted by regulatory authorities. **EDITOR'S NOTE: Reference in this lesson is made to federal DEA law, not individual state idiosyncrasies. Where your state's rules & regulations regarding controlled substances vary from federal DEA law, the more strict option applies.**

PHARMACIST LEGAL RESPONSIBILITIES

The pharmacy profession is reinventing itself. Traditionally viewed as sentries standing guard over the nation's medicinal drug supply, confronting any patient or physician whose activities threaten to compromise the integrity of the drug distribution system, modern pharmacists have begun to assume new responsibilities that extend beyond assuring accuracy and appropriateness in pharmaceutical order processing, to include the promotion of good therapeutic outcomes for patients. This expansion of pharmacy practice is not occurring at the expense of medical practitioners, but in collaboration with them. Pharmacists and physicians are creating drug therapy management teams that benefit from the strengths of each team member. This new approach to practice is specifically authorized by the practice acts or administrative rules in at least 30 states, and in most other states proposals are pending to recognize the authority of pharmacists and physicians to collaborate in the management of drug therapy. Empirical evidence supports this type of collaboration as an effective means to improve therapeutic outcomes, reduce health care costs, and relieve human suffering.

EXPANDING INTO DISEASE STATE MANAGEMENT

The disease states that are most frequently managed by pharmacists in collaboration with physicians are diabetes, asthma, hyperlipidemia, and anticoagulation therapy. Although there are reports of collaborative practices in which pharmacists manage chronic pain therapies, such collaborations are not widespread. The low frequency of pain management collaborative practice stands in contrast with the high level of responsibility that has traditionally been accepted by pharmacists in the control of narcotic analgesics, and the high level of regulatory control over the dispensing by pharmacists of these drugs. Pharmaceuticals that have the highest potential for abuse generally must be prescribed in writing, and usually cannot be refilled. Those drugs that are subject to a lower potential for abuse may be prescribed verbally, but refilling of prescriptions is limited in time and quantity, and record keeping requirements are stringent. It is the pharmacist's legal responsibility to insist on clarification by the prescriber if the formal requisites of a controlled substance prescription have not been met. Thus the nature of the physician-pharmacist interaction with regard to narcotic analgesic medications has traditionally been one of confrontation rather than collaboration.

REGULATION AND PHARMACY PRACTICE

The stringent regulatory controls over controlled substance prescribing and dispensing, and the confrontational practices they produce, have historically been a significant barrier to effective therapeutic use of controlled substances. Pharmacists have at times overemphasized the regulatory imperative to not fill purported prescriptions, at the expense of the therapeutic imperative to fill valid prescriptions. As recently as 1980, instructions to pharmacists in *The Pharmacist's Manual*, an official publication of the federal Drug Enforcement Administration (DEA) stated, "A pharmacist who has any doubts, whatever, concerning the legitimacy of a prescription order presented to him should not dispense it." A pharmacist who heeds this advice may well be able to adopt practice strategies that reduce the number of purported prescriptions filled, but such strategies necessarily will also result in the refusal to fill valid prescriptions. The pharmacist's rapport with physicians and with patients will suffer. The trusting relationship that is essential to effective patient care will not develop.

Fortunately, over the past decade, public policy toward pain management has shifted in the direction of tolerance toward, and enthusiastic support of, practices that may occasionally result in the dispensing of controlled substances pursuant to purported prescriptions. The therapeutic imperative to assure that patients who need pain medications get them has led to a more tolerant view of the occasional error by a pharmacist who has acted in good faith but who has nonetheless been duped into filling a purported prescription. The language cited above from *The Pharmacist's Manual* no longer appears in that publication. Nevertheless, there is empirical evidence to suggest that, just as physicians continue their reluctance to prescribe adequate medications for chronic pain, pharmacists are similarly reluctant to dispense high doses of narcotic analgesics. Changes of policy-on-paper have not necessarily led to changes of policy-in-practice. Even when physicians and pharmacists have been informed, through continuing education programs, that policy-on-paper has changed, a history of threatened regulatory enforcement may cause pharmacists to believe that if the new policy seems too good to be true, then it probably is.

Although changes of policy-on-paper are necessary to relieve the problem of under treated chronic pain, a sufficient solution to the problem of under treated chronic pain will be found only through changes of policy-in-practice.

REQUIREMENTS OF SCHEDULE II DISPENSING

Many of the most effective analgesic medications are opioids that are classified in Schedule II under the DEA classification scheme. As pharmacists well know, these medications are the most highly restricted of those that are available for general usage. But DEA rules have been relaxed in recent years, and there are opportunities within the rules for pharmacists to both assure the availability of necessary pain relief and also prevent diversion. The rules in their entirety are easily accessible on the DEA website:

Three of the most important rules are reproduced below. They are relatively self-explanatory. The cross-referenced rules cited below can be found at the DEA website. The language presented is quoted verbatim from DEA regulations. Bracketed language is editorial, provided by the author of this lesson.

GENERAL C-II PRESCRIPTION REQUIREMENTS

Section 1306.11 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the practitioner, except as provided in paragraph (d) of this section. A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in paragraph (e), (f), or (g) of this section. The original prescription shall be maintained in accordance with Sec. 1304.04(h) of this chapter.

[Note that all C-II prescriptions may be faxed, but only under the circumstances below may the faxed C-II prescription serve as the original.]

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule II in the course of his professional practice without a prescription, subject to Sec. 1306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

[Note the distinction between prescription and order for immediate administration. This section makes it possible for institutionalized patients to receive C-II medications for immediate administration pursuant to either a prescription or an order.]

(d) In the case of an emergency situation, as defined by the Secretary in Sec. 290.10 of this title, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner);

(2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in Sec. 1306.05, except for the signature of the prescribing individual practitioner;

(3) If the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and

(4) Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of Sec. 1306.05, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 7 day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Administration if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

[This section describes the circumstances under which a pharmacist may dispense an emergency C-II prescription pursuant to a verbal order, and the process for such dispensing.]

(e) A prescription prepared in accordance with Sec. 1306.05 written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (e) and it shall be maintained in accordance with Sec. 1304.04(h) of this chapter.

(f) A prescription prepared in accordance with Sec. 1306.05 written for Schedule II substance for a resident of a Long Term Care Facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (f) and it shall be maintained in accordance with Sec. 1304.04(h).

(g) A prescription prepared in accordance with Sec. 1306.05 written for a Schedule II narcotic substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this paragraph (g) and it shall be maintained in accordance with § 1304.04(h) of this chapter.

[These three sections describe the types of patients for whom a faxed C-II prescription may serve as the original.]

REFILLS OF C-II PRESCRIPTIONS

Section 1306.12 Refilling prescriptions.

The refilling of a prescription for a controlled substance listed in Schedule II is prohibited. [The message here is brief; C-II prescriptions simply cannot ever be refilled.]

PARTIAL FILLING OF C-II PRESCRIPTION

Section 1306.13 Partial filling of prescriptions.

(a) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription. [Any C-II prescription may be partially filled over a 72-hour period if the pharmacist is unable to supply the full quantity. Procedures for such partial dispensing are noted.]

(b) A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the Act. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

[Partial filling of prescriptions for LTCF or "terminally ill" patients must adhere to these requirements.]

(c) Information pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if this system has the capability to permit:

(1) Output (display or printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, address of the LTCF or address of the hospital or residence of the patient, identification of medication authorized (to include dosage, form, strength and quantity), listing of the partial fillings that have been dispensed under each prescription and the information required in Sec. 1306.13(b).

(2) Immediate (real time) updating of the prescription record each time a partial filling of the prescription is conducted.

(3) Retrieval of partially filled Schedule II prescription information is the same as required by Sec. 1306.22(b)(4) and (5) for Schedule III and IV prescription refill information.

THE PHARMACIST AND DIVERSION PREVENTION

The overall pattern of controlled substance regulation is reflective of the reality that some drugs of abuse are medically useful. But a controlled substance that is diverted outside the system is in violation of the law, and the diverter is subject to civil and/or criminal penalties.

The challenges pharmacists face in keeping controlled substances within the closed system are many and complex. Drug abusers and drug dealers have at times seen pharmacists as easy marks for access to abusable drugs. Unfortunately, pharmacists find themselves in a game with criminals, who use both sophisticated and dangerous methods of inducing pharmacists to divert controlled substances. Pharmacists are mindful of their gatekeeper position at the end of a long chain of drug distribution, and of their responsibility to not provide drug diverters with easy access to this closed system. Pharmacists are equally mindful of their responsibility to care for patients and to provide drug therapy that is medically indicated, despite concerns of potential diversion. Conscientious pharmacists seek to strike a balance between the error of filling a purported prescription, and the complimentary error of refusing a valid prescription; recognizing that reduction of either error necessarily increases the other.

THE "CORRESPONDING RESPONSIBILITY" RULE

DEA regulations provide guidance to pharmacists in the use of judgment to screen suspicious prescriptions. The relevant DEA regulation states:

"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 violations of the provisions of law relating to controlled substances."

This regulation sets out the basic process to be followed by pharmacists in interpreting the legitimacy of controlled substance prescriptions. Pharmacists are not subject to unrealistic expectations, due to the use of the word "knowingly."

However, pharmacists cannot turn their backs on obvious indicia of invalidity, and later claim ignorance that a purported prescription lacked validity.

The leading case interpreting the "corresponding responsibility" rule is *United States v. Hayes*. The pharmacist defendant in this case argued that a pharmacist cannot possibly have a corresponding responsibility to that of a physician, because a pharmacist cannot examine a patient, as can a physician. The defendant also argued that because it is impossible to determine what is really meant by the phrase "corresponding responsibility," the regulation is ineffectual and constitutionally vague. The court admitted that standing alone the phrase "corresponding responsibility" is not crystal clear. But when read in context, the regulation gives adequate notice of proscribed conduct to pass constitutional muster. The pharmacist defendant had filled huge quantities of purported controlled substance prescriptions for a small number of persons. All of the prescriptions had been written by a single physician, who was moving from one motel to another, and was known by the pharmacist to be under investigation for controlled substance diversion. The pharmacist had always telephoned the physician and received assurance that the prescriptions were valid, and the pharmacist claimed that this telephone verification was the limit of his abilities, despite the existence of additional compelling evidence that the prescriptions were not valid. In affirming the pharmacist's conviction, the court emphasized that the pharmacist is not required to have a corresponding responsibility to practice medicine. What is required is the responsibility to not fill an order that purports to be a prescription but is not a prescription, when the pharmacist knows the practitioner "has issued the prescription outside the scope of medical practice."

This final observation is an important one, because it simplifies the otherwise challenging concept of "**legitimate medical purpose**" included with the regulation. Without this clarification, one might take this three-word phrase to mean that pharmacists have a responsibility under DEA regulations to discern not just the difference between medicine and non-medicine, but also the difference between legitimate medicine and non-legitimate medicine. In other words, pharmacists might be required to refuse to dispense unless they make two separate decisions; first, that a prescription is medical, and second, that it is legitimate. If the regulation were interpreted this way, then it might cause a pharmacist, for example, to refuse to dispense a medication for a narcotic analgesic that specifies an unusually large dose (perhaps incorrectly seen as not legitimate), despite assurance that the medication is intended for a patient with chronic pain (unquestionably medicine). The court reduces the three-word phrase to just two words, "**medical practice**," making it clear that pharmacists are not required by this DEA regulation to make judgments about the quality of medicine. They are required only to distinguish medicine from non-medicine. This is a more realistic expectation of pharmacists. Interpreted this way, the DEA regulation does not support refusal by a pharmacist to dispense a controlled substance medication based on a judgment regarding the appropriateness of the therapy, as long as there is a medical purpose (even a questionable one). A pharmacist who uses the DEA "corresponding responsibility" rule to justify challenging the dose, or route of administration, or length of therapy, for an obviously legitimate patient, has misunderstood the narrow scope of the rule.

OVERLY AGGRESSIVE PHARMACY PRACTICE

Despite the relative safety of the "knowingly" phrase with the DEA "corresponding responsibility" rule, some pharmacists have taken it upon themselves to be overly vigilant in their review of controlled substance prescriptions. Pharmacists may challenge physicians, or confront patients, in an accusatory way that some find offensive. When taken to task for such behavior, pharmacists will often rely on the "corresponding responsibility" rule as justification for their actions.

The leading case on aggressive diversion prevention is *Ryan v. Dan's Food Stores, Inc.* The plaintiff in this case was a pharmacist who had been terminated from his employment with the defendant pharmacy, based on numerous complaints by patients. The pharmacist had apparently confronted, in an accusatory way, many patients who presented controlled substance prescriptions, suggesting that the prescriptions may be invalid. Offsetting the complaints by patients were letters from law enforcement authorities, complimenting the pharmacist on his thoroughness in detecting fraudulent prescriptions. As an employee at will, the pharmacist had only one solid argument on which to base his wrongful discharge claim; that his actions were in vindication of a clear mandate of public policy, and that his discharge was contrary to public policy. The pharmacist pointed to the "corresponding responsibility" rule to support his position.

The court agreed that this rule does contain a clear and substantial public policy, but the court noted that this policy is a narrow one. The rule only prohibits pharmacists from knowingly filling purported prescriptions, and does not mandate or even authorize a pharmacist to question every prescription or to conduct an investigation to determine whether a facially valid prescription has been issued other than in the usual course of the prescriber's practice. A prescription that is irregular in some way requires further inquiry by the pharmacist, but after inquiring and obtaining the verifying information, a pharmacist cannot use the rule as the basis for refusal of the prescription. Summary judgment dismissing the pharmacist's wrongful discharge lawsuit was affirmed.

DIVERSION PREVENTION IN EVERYDAY PRACTICE

Most pharmacists try to cooperate with law enforcement authorities and to also meet the needs of patients. When suspicions are aroused regarding the validity of a prescription, pharmacists generally seek clarification from the prescriber. Administrative actions against pharmacists, for failure to make appropriate inquiry of a physician, usually describe egregious circumstances that should have put any pharmacist on notice as to the suspicious nature of the prescriptions. For example, in one case a pharmacist was disciplined for filling prescriptions that were made out for "Steve Allen," "Jerry Lewis," "Terry Tune,"

"Pearl Harbor," "Wells Fargo," "Pop Warner," and other equally fanciful "patients." Under some circumstances, things are not so clear-cut. The law recognizes that there is room for error in the interpretation by pharmacists of the legitimacy of a prescription. It has been held that the refusal by a pharmacist to fill a prescription, based on the mistaken belief that the prescription is forged, does not support a Civil Rights Act claim against the pharmacist. It has also generally been held that a pharmacist who, in good faith, but erroneously, reports a forgery to law enforcement authorities, will not be held civilly liable for malicious prosecution, false imprisonment, or any similar tort.

REGULATORY AUTHORITY FOR COLLABORATIVE DRUG THERAPY MANAGEMENT

The parameters of pharmacy practice are defined by the laws of each state. Not surprisingly, the traditional descriptions of pharmacy practice in most state pharmacy acts have been limited to dispensing functions. Dispensing has changed in concept over time, from limited definitions that include only order interpretation and fulfillment, to those definitions that more broadly include patient education and therapeutic monitoring. However, most states have not, until recently, authorized pharmacists to enter into agreements with physicians for collaborative practice under which pharmacists can order and interpret laboratory tests, modify drug doses, initiate new drug therapy, or discontinue drug therapy, under a protocol or care plan approved by the patient's physician. Even in states where collaborative drug therapy management (CDTM) has been specifically authorized, practices that include management of chronic pain do not seem to be widespread. The relative infrequency of physician-pharmacist collaborations in the area of pain management may be due to the perceived burdensomeness of restrictions on controlled substance prescribing and dispensing.

There is strength in numbers; and the number two is greater than the number one. These two simple statements; one a basic assumption, the other an irrefutable numerical fact, form the framework for an approach to practice that can best be described as "collegial accountability." The purpose of collegial accountability is to provide an evidence-based safety blanket to facilitate potentially risky prescribing choices by physicians who treat pain. The safety blanket is necessary due to a perception that the likelihood of adverse regulatory activity is increased by the aggressive prescribing of large doses of narcotic analgesics. Despite changes in policy-on-paper, and comprehensive continuing education programs designed to communicate these policy changes to physicians, there is evidence that policy-in-practice continues to be overly cautious, and that pain continues to be under treated. Collegial accountability is about changing old perceptions of regulation, so that contemporary views coincide with the reality of a more tolerant regulatory community.

The mechanics of collegial accountability in pain management are straightforward. Pharmacists who have expertise in pain management offer their services as consultants to physicians who request that evidence-based clinical practice guidelines be applied to a specific patient care situation. The consult may be explicit, or it may be implicit in a protocol or in standing orders. The consult may require a patient interview or another patient assessment activity. The pharmacist consultant then recommends a dose of a medication, in writing, documenting the guideline or other objective authority that justifies the use of medication in the recommended way. Depending on the relationship between the physician and the pharmacist, the recommendation may require prior approval by the physician before it is implemented, or it may be automatically accepted in the absence of an express objection. Changes in medication are made in the same way; when there is a need to add, discontinue, decrease, or increase drug use. If a reviewer later raises questions regarding the appropriateness of a patient's drug therapy, the pharmacist's written consult will serve as an accounting of what has occurred and why.

COLLEGIAL PRACTICE

Pharmacists and physicians have worked well together for hundreds of years. The relationship between them has generally been one in which the physician decides what medication is best for the patient and the pharmacist prepares the medication for the patient. Formalization of this prescriber-dispenser relationship occurred relatively recently. Not until 1951 did federal statutes recognize the distinction between prescription and non-prescription drugs, although that distinction had been made by federal regulation in 1938. Although the need to paternalistically limit drugs to prescription-only status has been questioned, and some drugs have been switched from prescription to nonprescription status, most significant advances in drug therapy continue to be available for patients only if they have been prescribed by a physician and dispensed by a pharmacist. The traditional drug distribution system requires pharmacists and physicians to work together, although their activities differ in character and their practice sites are very separate. Pharmacists and physicians have relied on each other, and usually have been respectful and friendly with each other, but they have not been professional colleagues. Pharmacists practice independently of physicians, but order processing activities are done for the physician, by meticulously following the physician's orders. Order processing is a technically complex activity with no margin for error, but it is not intellectually challenging and it requires little judgment.

In collaborative drug therapy management, pharmacists work *with* physicians rather than *for* them. Drug therapy management by pharmacists closes the quality loop in medication use, so that outcomes of therapy are monitored, and meaningful feedback is provided to physicians. CDTM attempts to solve the mystery of why a patient's drug therapy has been less than fully effective during the months between visits to the physician. It is an advance in practice over the linear process of trial-and-error prescribing. This collaboration of pharmacists and physicians is aimed at improving patient's quality of life. It is a practice that has been empirically validated. A collegial approach to the pharmacist-physician relationship has also been judicially endorsed. For example, in *Riff v. Morgan Pharmacy*, the Superior Court of Pennsylvania recognized the value of

pharmacist collaboration with their physician colleagues:

"Fallibility is a condition of the human existence. Doctors, like other mortals, will from time to time err through ignorance or inadvertence. An error in the practice of medicine can be fatal; and so it is reasonable that the medical community including physician, pharmacists, anesthesiologists, nurses and support staff have established professional standards which require vigilance not only with respect to primary functions, but also regarding the acts and omissions of other professionals and support personnel in the health care team. Each has an affirmative duty to be, to a limited extent, his brother's keeper."

ACCOUNTABLE PRACTICE

Responsible health care professionals must expect that they will be held accountable for their actions. Gone are the days when public trust was so complete that health care professionals were subject only to a limited sphere oversight, accompanied by informal and very private sanctions when things had not gone well. In contemporary health care settings, providers are counted on to provide appropriate care, and they may be called to account for undesirable outcomes. The ability to conduct surveillance of the provider-patient encounter is enhanced through modern electronic data systems, and these data facilitate activities of accountability. Evaluators from professional associations, or licensing boards, or federal regulatory agencies, may examine performance data, and then request a health care provider to give an explanation by way of accounting for care provided to a patient. If the accounting given by the responsible health care professional is deemed unacceptable, then there may be liability for technical violations of the law or for adverse outcomes to patients.

Accountability can be both productive and nonproductive. Productive accountability would compare a health care provider's explanation of care with an objective standard such as consensus-developed clinical practice guidelines. It would be flexible enough to adapt to unique or unusual medical needs of individual patients. It would be values-oriented so as to permit providers to practice consistently with the goals of patients and their families. The process of **productive accountability** would be nonobtrusive and respectful of patient privacy and the provider-patient relationship. **Nonproductive accountability** would focus on punishment rather than on improvement. Lacking specificity or explicit patient-oriented standards, nonproductive accountability would coerce providers into attempted compliance with a moving target, resulting in risk-averse behaviors that alternately overuse or underuse available therapies, depending on the perception of what it takes to "play it safe." Collegial accountability is productive accountability. It is a legitimate approach to the use of interdisciplinary expertise to explain why things were done as they were, when questions of propriety have been raised.

In CDTM, pharmacists are called upon to take the next logical step beyond the expanded responsibility they have so eagerly sought. The prospect of having to justify actions taken may be daunting to some pharmacists who have enjoyed the comfort zone of responsibility without accountability. Yet outcomes for patients cannot improve unless both responsibility and accountability are shared by pharmacists and physicians. Sharing accountability with a physician colleague may be a cost of professional growth for pharmacists, but the cost is more than offset by the value of improved patient care.

COLLEGIAL ACCOUNTABILITY IN PRACTICE

The practice of collegial accountability by pharmacists who work with physicians is very similar to that of the consultant medical specialist, who assists an attending physician in the care of patients, but does not usurp the authority of the attending physician. While a pharmacist is responsible to a patient for the recommendation and/or provision of appropriate care, the ultimate decision as to appropriateness of care is made by the physician. Collegial accountability does not invade physician turf, because it is comprised of activities that are currently not being done by physicians. It is an entirely voluntary activity that is available to those physicians who wish to use it, but it is not required of anyone.

Although not widespread throughout the country, there are currently practices in some states, within which pharmacists and physicians collaborate to manage the treatment of chronic pain. These collaborations are beneficial to patients because the physician-pharmacist relationship reduces concerns about inappropriateness of treatment. Regulators who question the propriety of controlled substance use will certainly understand that when two professional colleagues have agreed as to the appropriateness of medication use, there is a high probability that the use is consistent with applicable standards of care. Specific regulatory authority for physician-pharmacist collaborations increases even further the likelihood that no foul play will be found.

CONCLUSION

Through collegial accountability, physicians and pharmacists can be brought together to meet patient needs in pain management. A history of suspicion and confrontation within the pharmacist-physician relationship, produced in part by a regulatory community that has at times placed the importance of diversion prevention above the importance of patient care, can be replaced by a contemporary practice in which the two professions protect each other from inappropriate accusations of impropriety, as they protect patients from harm that results from the underuse of medications. However, collegial accountability requires adoption of new regulations for pharmacy practice, and these new rules have been adopted in only a slight majority of states. The collaborative drug therapy management practices that have developed in the states that have enabled them by regulation, have not generally included the management of chronic pain. The incentive of increased protection from perceived regulatory oversight could serve as the basis for expanded pain management CDTM practices in the future.

Fill in the information below, answer questions and return **Quiz Only** for certification of participation to:
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NAME _____ I.D.#(1st line on label) _____

STREET ADDRESS _____ CITY _____ STATE _____ ZIP _____

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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. Please rate each of the following from 1 to 7. Circle your choices. (1 is the lowest rating; 7 is the highest).

	Poor			Average		Excellent
1. Relevance of topic to practice.	1	2	3	4	5	6 7
2. Author's ability to communicate.	1	2	3	4	5	6 7
3. Author's knowledge of topic.	1	2	3	4	5	6 7
4. Appropriateness of topic.	1	2	3	4	5	6 7

5. Do you have any further comments about this lesson? _____

Please Select the Most Correct Answer

- | | |
|---|---|
| <p>1. Which of these benefits support physician-Pharmacist collaboration?
 A. Improved outcomes
 B. Reduced health care costs
 C. Relief of human suffering
 D. All of these</p> <p>2. Since 1980, the <i>DEA Pharmacist's Manual</i> no longer instructs pharmacists to simply refuse prescriptions, if they are the least bit questionable.
 A. True B. False</p> <p>3. A physician legally authorizes a pharmacist to dispense an emergency supply of C-II medication pursuant to a verbal order. Within 3 days after such authorization, the physician must cause a written prescription to be delivered to the dispensing pharmacist.
 A. True B. False</p> <p>4. For which of these patients may a faxed C-II prescription serve as the original?
 A. Patient in hospice care
 B. Resident of Long Term Care Facility
 C. Drug to be compounded & administered by parenteral infusion
 D. All of these</p> <p>5. A pharmacist is unable to supply the full quantity of a C-II medication. Within what period of time following partial filling may the pharmacist provide the remaining portion?
 A. 24 hours
 B. 72 hours
 C. 7 days
 D. 21 days</p> | <p>6. With what frequency may C-II prescriptions be refilled?
 A. 5 times in 6 months from date of issuance
 B. .5 times in 6 months from date of 1st filling
 C. 5 times in 6 months from date of 1st refilling
 D. None of these</p> <p>7. Pharmacists have a responsibility to screen prescriptions for validity and to not knowingly fill a purported prescription. Under DEA regulations, by what name is this responsibility known?
 A. Correlative responsibility
 B. Constitutional responsibility
 C. Corresponding responsibility
 D. Collegial responsibility</p> <p>8. According to the <i>Ryan v. Dan's Food Stores</i> case, what action should a pharmacist take when presented with a prescription that is irregular in some way?
 A. Make further inquiry for verification
 B. Call the local police
 C. Refuse the prescription
 D. Explain that the pharmacy is "out" of the medication</p> <p>9. The purpose of "collegial accountability" is to provide evidence-based safety blanket for physicians who treat pain.
 A. True B. False</p> <p>10. When did federal statutes recognize the distinction between prescription and non-prescription drugs?
 A. 1906
 B. 1938
 C. 1951
 D. 1962</p> |
|---|---|

Contributing Author

David B. Brushwood, R.Ph., JD
Professor, Pharmacy Healthcare
Administration
University of Florida, Gainesville, FL

Executive Editor

William J. Feinberg,
BS Pharm, MBA



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