From Confrontation to Collaboration: Collegial Accountability and the Expanding Role of Pharmacists in the Management of Chronic Pain

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Federal and state laws create a tightly controlled system for distribution of those drugs that have recognized value in therapy, but also have the potential for abuse. 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 often find themselves in a game with criminals, who use both sophisticated and dangerous methods of inducing pharmacists to divert controlled substances. The effects of this problem on the health-care system have been judicially noted:

The frequency of these crimes has terrorized the community of dispensing pharmacists. Some pharmacists have ceased to carry drugs that are highly desired on the black market, although this interferes with their patients' ability to obtain necessary medicine. This has a serious potential to impede the delivery of health care in many communities around the nation.1

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. Pharmacists strive to always fill valid prescriptions and to always refuse purported prescriptions, but divining between valid and false prescriptions is not an easy task and some error is inevitable. Conscientious pharmacists try to strike a balance between being too trusting (and thus sometimes filling false prescriptions) and suspecting wrongdoing with every irregularity (and thus at times refusing to fill valid prescriptions).

In light of the complex decision-making that is demanded of it, 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 threatened 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 the processing of pharmaceutical orders — namely, to assume 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 twenty-seven states; in most of the other states, proposals are pending to recognize the authority of pharmacists and physicians to collaborate in the management of drug therapy.2 Empirical evidence supports this type of collaboration as an effective means to improve therapeutic outcomes, reduce health-care costs, and relieve human suffering.3

The types of disease that are most frequently managed by pharmacists in collaboration with physicians are diabetes, asthma, hyperlipidemia, and anticoagulation therapy.4 Most expanded pharmacy practices are situated in the institutional setting, but they are increasingly being developed for the local drug store. Although there are reports of collaborative practices in which pharmacists manage chronic pain therapies, such collaborations are not widespread. The low frequency of collaborative pain management practice...
stands in contrast with the high level of responsibility that has traditionally been accepted by pharmacists in the control of opioid analgesics and the high level of regulatory control over pharmacists’ dispensing of these drugs. For example, pharmaceuticals that have the highest potential for abuse generally must be prescribed in writing and their prescriptions cannot be refilled. Those drugs that are subject to a lower potential for abuse may be prescribed verbally, but their refilling is limited in time and quantity and the 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 opioid analgesics has traditionally been one of confrontation rather than collaboration.

Requiring confrontation

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 continue to be similarly reluctant to dispense high doses of opioid analgesics.

Policy-on-paper versus policy-in-practice

Reacting to widely publicized examples of overzealous prosecution or disciplinary action of health-care providers for “overuse of narcotics,” state legislatures have enacted provisions that establish a policy of tolerance, even encouragement, of high-dose opioid use for severe pain. These new policies-on-paper are understandably rewarding for pain advocates who regularly review state statutes, administrative regulations, and published standards of practice. Continuing education programs have been mandated to “get the word out” about the newly published pain management policies; because the point of these policies is not to make pain advocates feel better, but to make patients feel better. The problem is that changes in policy-on-paper have not necessarily led to changes in policy-in-practice. Even when physicians and pharmacists have been informed that the policy-on-paper has changed — through continuing education programs or the like — a history of threatened regulatory enforcement may be causing them to believe that if the new policy seems too good to be true, then it probably is.

Although changes in policy-on-paper are necessary to relieve the problem of undertreated chronic pain, a sufficient solution to the problem will be found only through changes in policy-in-practice. Changing behaviors is more than a function of changing laws or mission statements; there must be a concerted effort to change attitudes. Pharmacists and physicians have a tendency to simplify difficult decisions by adopting their own policy-in-practice shortcuts, e.g., “My policy is to not prescribe Schedule II narcotics over the telephone,” or “We don’t carry Schedule II narcotics.” Although neither of these informal policies-in-practice is supported by official policy-on-paper, they (and others like them) persist as barriers to effective pain management.

A solution to changing policy-in-practice

This article suggests a solution to effecting a change in policy-in-practice. Through collaborative drug therapy management, pharmacists and physicians can work together — not only to assure that patients are appropriately treated, but to 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 the policy-on-paper and criticize the prescribing of high doses of opioid analgesics as inappropriate and/or illegal. The interprofessional 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. In turn, pharmacists will feel more comfortable dispensing high doses of opioid 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 opioid use if confronted by regulatory authorities.

This article begins with a description of the pharmacist’s traditional dilemma as a health-care provider who has been unwillingly conscripted into the nation’s “war on drugs.” As “drug police,” pharmacists have been required to challenge prescribers who order large doses of opioid analgesics, and they have been administratively disciplined for activities that may result in the diversion of controlled substances from medical to nonmedical purposes.

The article then turns to a description of the pharmacist’s role in the monitoring of drug therapy. Administrative rules — primarily those promulgated under the authority of the Omnibus Budget Reconciliation Act of 1990 (OBRA) — and emerging standards of practice recognized in civil malpractice litigation have begun to require that pharmacists assure that prescribed medications are appropriate for the patient. No longer is it acceptable for a pharmacist to merely follow a prescriber’s orders if those orders place the patient at an unreasonable risk of harm.

Finally, this article describes the philosophy of practice known as “pharmaceutical care,” in which pharmacists work with patients as well as with physicians and other health-care providers, to promote drug therapy for the purpose of achieving definite outcomes that are intended to improve a patient’s quality of life. The article reviews the movement toward incorporation of pharmaceutical care into a pharmacist’s practice through authorization of physician-pharmacist collaboration. Pain management is described as an area of therapy that is particularly appropriate for collaborative practice.

The Pharmacist and Diversion Prevention
The overall pattern of controlled substance regulation reflects the reality that some drugs of abuse are medically useful. Even the DEA admits that to overregulate these drugs would interfere with effective therapy and do more harm than good.

Controlled substances are placed in one of five “schedules”: Schedule I for those abusable drugs that have no currently accepted medical use and Schedules II through V for those abusable drugs that do have a currently accepted medical use.

The regulatory goal is to construct a closed system of distribution for controlled substances in Schedules II through V. The system requires registration of those who may legally possess controlled substances, and it imposes stringent record-keeping requirements so that auditors have the ability to track any drug within the system from manufacture to ingestion. 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 “corresponding responsibility” rule
DEA regulations instruct pharmacists on the judgment they should be exercising in screening suspicious prescriptions and preventing their diversion outside this closed system. 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 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, dubbed the “corresponding responsibility” rule, sets out the basic process to be followed by pharmacists in interpreting the legitimacy of controlled-substance prescriptions. Due to the use of the word “knowingly,” pharmacists are not subject to strict liability under this regulation. 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, from the Fifth Circuit Court of Appeals. The defendant in this case had filled huge quantities of purported prescriptions for a small number of persons. All of the controlled substance 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.

The pharmacist claimed that this telephone verification was the limit of his legal responsibility, despite the existence of additional compelling evidence that the prescriptions were not valid. He further argued that a pharmacist cannot possibly have a corresponding responsibility to that of a physician because the pharmacist cannot examine a patient as the physician can. Thirdly, the pharmacist argued that because it is impossible to determine what is really meant by the phrase “corresponding responsibility,” the regulation is ineffectual and unconstitutionally vague.

The court admitted that the phrase “corresponding responsibility,” standing alone, is not crystal clear. But when
read in context, the regulation gives adequate notice of pro-
scribed conduct in order to pass constitutional muster. 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 not to fill an order that purports to be a pre-
scription — but is in fact not a prescription — when the
pharmacist knows the practitioner “has issued the prescrip-
tion outside the scope of medical practice.”

The court observed that the regulation requiring phar-
macists to fill only prescriptions issued for a “legitimate
medical purpose” is in reality a requirement that they fill
only prescriptions issued in the “scope of medical prac-
tice.” This observation is an important one because it sim-
pifies the otherwise challenging concept of “legitimate
medical purpose.” Without this clarification, one might
take this three-word phrase to mean that pharmacists have
a responsibility under the DEA regulation to discern not
just the difference between medical and nonmedical, but
also the difference between legitimate medicine and non-
legitimate medicine.

In other words, pharmacists are not required to refuse
to dispense unless they make two separate decisions — first,
that a prescription is medical, and second, that it is legiti-
mate. If the regulation were interpreted this way, then it might,
for example, cause a pharmacist to refuse to dispense a medici-
ation for an opioid analgesic that specifies an unusually
large dose (perhaps incorrectly seen as not legitimate), de-
spite assurances that the medication is intended for a patient
with chronic pain (unquestionably a medical purpose). In
reducing the three-word phrase to just two words, “medical
practice,” the court made it clear that pharmacists are not
required by this DEA regulation to make judgments about
the quality of medicine. They are required only to distin-
guish medical from nonmedical.

And this is a more realistic expectation of pharmacists.
Interpreted this way, the DEA regulation does not support a
pharmacist’s refusal to dispense a controlled-substance medici-
ation if he or she believes the therapy is inappropriate as
long as there is a medical purpose (even a questionable one).

A pharmacist who uses the 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 corresponding responsibility rule, some pharmacists have
taken it upon themselves to be overly vigilant in their review
of controlled-substance prescriptions. Pharmacists may chal-
lenge physicians, or confront patients, in an accusatory way
that some find offensive. When taken to task for such behav-
ior, pharmacists will often rely on the corresponding respon-
sibility rule as a justification for their actions.

The leading case on aggressive diversion prevention is
Ryan v. Dan’s Food Stores, Inc.,18 from the Supreme Court of
Utah. 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 prescrip-
tions, suggesting that the prescriptions may be invalid. Off-
setting the complaints by patients were letters from law en-
forcement authorities, complimenting the pharmacist on his
thoroughness in detecting fraudulent prescriptions. As an
employee at will, the pharmacist had only one solid argu-
ment on which to base his wrongful discharge claim — that
his actions were in compliance with the law and that his
discharge as a result of this compliance was contrary to pub-
lic policy. The pharmacist pointed to the corresponding re-
ponsibility rule to support his position.

The court agreed that the corresponding responsibility
rule does contain a clear and substantial public policy, but
that this policy is a narrow one. The rule only prohibits
pharmacists from knowingly filling purported prescriptions.
It does not mandate or even authorize a pharmacist to ques-
tion every prescription or to conduct an investigation to de-
termine 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 a basis for refusing to fill the prescription. The court af-
irmed the lower court’s order of summary judgment dis-
missing the pharmacist’s wrongful discharge lawsuit.

Diversion prevention in everyday practice

Most pharmacists try to cooperate with law enforce-
ment authorities as well as meet their patients’ needs. When suspi-
cions are aroused regarding the validity of a prescription,
pharmacists generally seek clarification from the prescriber.
Administrative actions against pharmacists for failure to make
an appropriate inquiry of a physician usually involve ege-
rous 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 fill-
ing prescriptions that were made out for “Steve Allen,” “Jerry
Lewis,” “Terry Tune,” “Pearl Harbor,” “Wells Fargo,” “Pop
Warner,” and other equally fanciful patients.19 Claims by
pharmacists that they simply could not have recognized the
invalidity of such orders fall on deaf ears when the surround-
ing circumstances are examined.

But the question of validity or invalidity is not always
clear cut. Modern pharmacies are busy places to work, with
constant distractions and frequent problems to solve. Phar-
macists take no risks with ambiguous prescriptions that may
result in an overdose or an incorrect drug for a patient. Pharmacists are similarly serious in their efforts to accurately distinguish valid prescriptions from purported ones. But grayer areas do not elicit the same zealousness, and mistakes sometimes occur.

The law recognizes this likelihood and provides pharmacists with room for good-faith error in their interpretation of the legitimacy of a prescription. This “room for error” applies not only to filling invalid prescriptions (under the right circumstances), but also to refusing to fill valid ones. For instance, 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 of 1964 claim against the pharmacist.\(^{21}\) 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.\(^{21}\)

This room for error — and fear of disciplinary action — has, unfortunately, created too much confusion about what the law really requires. Empirical evidence suggests that the pharmacy profession is conflicted over the appropriate way to comply with the legal requirements of controlled substances on a day-to-day basis.\(^{22}\)

For example, data reported in 1999 by Gilson and colleagues indicate that slightly less than half of pharmacists strongly agree with the statement that they would be willing to dispense a Schedule II opioid analgesic on the basis of a telephone order in an emergency.\(^{23}\) Ten percent of pharmacists strongly disagreed with a willingness to dispense under such circumstances, despite there being absolutely no regulatory basis for refusing to fill such an order. Nonetheless, 80 percent of the respondents agreed with the statement that pharmacists’ knowledge of controlled-substance regulations is generally adequate.

Furthermore, over two-thirds of the pharmacists in this study indicated that they were aware of situations in which patients with inadequately treated pain had been suspected of being “drug seekers,” due to their requests for additional pain medications. It is clear that pharmacists are confusing relief-seeking behavior with drug-seeking behavior. Other studies have confirmed that some pharmacists are unnecessarily suspicious of prescriptions for opioid analgesics written for cancer patients. The results of these studies suggest that policy-in-practice still may not accurately reflect the trend of policy-on-paper.

One recommendation for assisting patients in their relief of pain while this gap exists involves hospital-based clinical pharmacist pain management specialists. Not only do these specialists have an important role in their collaboration with physicians and other health-care professionals within the institution where they practice, but they also can serve as an interface with community pharmacy practitioners. When a patient is discharged from the hospital with a prescription for suspiciously large quantities of an opioid analgesic, a hospital pharmacist can notify the community pharmacist that the patient is on the way and that the prescription is legitimate. Intraprofessional communications of this type can improve general understanding of pain management principles among pharmacists, and they can reduce the incidence of interprofessional conflict over refused prescriptions.

The Pharmacist and Patient Safety

The possibility of conflict between pharmacists and physicians over controlled-substance prescriptions is not limited to pharmacists questioning physicians regarding the threshold issue of prescription legality. Pharmacists are also charged with a legal responsibility to verify the therapeutic appropriateness of medications legitimately prescribed for patients, and this responsibility may lead to antagonism within the physician-pharmacist relationship. When a potential problem is evident to the pharmacist once he or she sees the prescription, the pharmacist must balance the need to meet responsibilities to the patient with the need to avoid offending the physician. No matter how friendly an inquiry from a pharmacist may be, questions concerning the appropriateness of drugs that a physician has prescribed necessarily appear evaluative and critical. But a pharmacist must make the inquiry nonetheless. Standards of practice require that pharmacists clarify potential therapeutic problems prior to dispensing a medication. This responsibility has evolved through case law over the past decade, despite concerns that it could increase confrontation between pharmacists and physicians to the detriment of patient care.

The newly recognized patient safety responsibility of pharmacists is the result of several correlated factors, all of which have occurred (at least in part) due to the increasing complexity of pharmacotherapy. Pharmacists are better educated now than they have been in the past, due to the uniform adoption of the clinically oriented Doctor of Pharmacy (Pharm.D.) degree. The need for patient-safety oversight by pharmacists is evident from recent data that show significant problems with drug therapy and the positive effect of pharmacist participation in the resolution of these problems.\(^{24}\) Finally, the economic costs of drug-related morbidity are thought to be so great that there may actually be more money spent in the American health-care system treating the adverse effects of drugs, than there is spent on the drugs themselves.\(^{25}\) For these and other reasons, patient safety is now recognized as a standard of pharmacy practice under common law in many states, and it is mandated under Medicaid conditions of participation.\(^{26}\)

Expanding responsibilities under common law

In one of the earliest cases to consider the expanded responsibilities of pharmacists for drug therapy review, Jones v. K-
Mart Corporation, a federal district court judge in 1985 speculated that Illinois common law would not support a malpractice claim against a pharmacist who had accurately dispensed medications as ordered by the patient’s physician. In a conclusion that should send chills down the spine of anyone who appreciates the importance of team work in health care, the judge stated, “the court holds that a pharmacist has no duty to warn the customer or notify the physician that the drug is being prescribed in dangerous amounts, that the customer is being over medicated, or that the various drugs in their prescribed quantities could cause adverse reactions.” Apparently concerned about pharmacist-physician relations, the court justified its holding by explaining that placing these duties on a pharmacist “would only serve to compel the pharmacist to second guess every prescription a doctor orders.”

Four years later, the Supreme Court of Washington cited the Jones opinion with approval in its own opinion, McKee v. American Home Products Corporation. Concluding that a pharmacist’s responsibilities were limited, the court noted that “[r]equiring the pharmacist to warn of potential risks associated with a drug would interject the pharmacist into the physician-patient relationship and interfere with ongoing treatment.”

The trend of judicial reasoning took a significant shift in the opposite direction in 1994, when the Supreme Court of Indiana issued its opinion in Hooks SuperX, Inc. v. McLoughlin. The plaintiff in the Hooks SuperX case was a chronic pain patient who had been prescribed an opioid analgesic. The defendants, two pharmacists and their pharmacy, were alleged to have refilled the patient’s prescriptions more frequently than was appropriate, resulting in adverse effects that led to a suicide attempt. The Indiana Court of Appeals ruled that to impose a duty on the defendants to protect the patient from this adverse outcome would be contrary to sound public policy, because it would require pharmacists to second guess physicians and would undermine the physician-patient relationship.

The Supreme Court of Indiana reversed, recognizing an expanded duty by pharmacists to promote patient safety. The court based its ruling on three factors: (1) the relationship between pharmacists and patients, (2) the foreseeability of harm to patients when an overuse of opioid analgesics occurs, and (3) public policy considerations.

While noting the ultimate responsibility of physicians to properly prescribe medications, the court reasoned that prevention of medication misuse by pharmacists is “paramount to policy concerns about interfering with the physician-patient relationship.” On this issue, the court concluded that “recognition of a legal duty will encourage pharmacists and physicians to work together in considering the best interests of their customers and patients.”

Legal scholars have generally approved of this shift in thinking. With this decision, pharmacists have been recognized as a positive influence in drug therapy — protecting patients without threatening physicians.

The OBRA 1990 mandate

The trend toward expanding legal responsibilities for pharmacists was given a significant boost by a brief section of the Omnibus Budget Reconciliation Act of 1990, in which prospective drug use review was mandated as a condition of participation in the federally funded, but state administered, Medicaid program. Prospective drug use review requires that the Medicaid state plan establish a point-of-sale review of each prescription prior to its being dispensed. Potential problems, such as therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse, should be discovered through this prospective review. Most states have implemented this standard by imposing the prospective drug use review requirement on pharmacists and specifying that, once potential problems are detected, they must be resolved, perhaps by contacting the prescribing physician.

Prospective drug use review, as defined by OBRA 1990, was judicially recognized as the standard of pharmacy practice for the first time in 1999 by the Court of Appeals of Missouri in the case of Horner v. Spalitto. In Horner, the patient had been prescribed two controlled substances concurrently, one of them in an unusually high dose. The patient died, and an autopsy stated that the death was caused by “adverse effects of multiple medications.” The lawsuit filed against the pharmacist claimed that the pharmacist had negligently failed to protect the patient from an unreasonable risk of harm. Reversing summary judgment for the pharmacist, the appellate court held:

[while] the physician still is responsible for assessing what medication is appropriate for a patient’s condition, ... the pharmacist may be in the best position to determine how the medication should be taken to maximize the therapeutic benefit to that patient, to communicate that information to the customer or his physician, and to answer any of the customer’s questions regarding consumption of the medication.

Regarding the potential for interprofessional conflict that could arise from patient-oriented activities by pharmacists, the court plainly said:

We disagree that a pharmacist’s consulting with a physician about an unusual prescription would
result in antagonism exceeding the potential public benefit. Pharmacists are trained to recognize proper doses and contraindications of prescriptions, and physicians and patients should welcome their insights to help make the dangers of drug therapy safer. 40

Meeting the patient-safety challenge

While pharmacist responsibilities have changed, pharmacy practice sites have remained essentially the same. With an increasing volume of prescription orders to process, pharmacists struggle to meet both their product-oriented and patient-oriented responsibilities. Empirical data indicate that the relatively new patient-safety responsibilities are not being consistently met by pharmacists. 41 In the area of pain management, the study by Gilson and colleagues suggests that some pharmacists may not be fully informed of how medications are appropriately used, thus they may not consistently provide service that is in the patient’s best interest. 41 For example, almost 40 percent of respondents in that study indicated that a dose of opioid analgesic that is greater than the manufacturer’s recommended dose is “probably excessive” and is “a cause for concern.” Slightly more than 10 percent of respondents indicated a reluctance to contact the prescriber with questions about an opioid analgesic regimen prescribed for a specific patient. It is not clear from the study whether this reluctance is due to a failure to recognize the value of such contact or due to a frustration with the inaccessibility of physicians.

The limitations of the traditional pharmacy practice environment, and the obvious need for new approaches to patient care by pharmacists, have led to the development of nontraditional practices that emphasize outcomes-oriented pharmacy care. These practices enable pharmacists to cooperate with physicians and to communicate with patients. Although not widespread at present, community pharmacy practices that emphasize collaborative drug therapy management are growing rapidly. They are a positive addition to the health-care system, enabling improvement in practice for both pharmacists and physicians.

Pharmacist management of anticoagulation therapy and of aminoglycoside therapy have become a standard of practice in many hospitals, where attending physicians’ orders for “anticoagulation per pharmacy” or “gentamicin per pharmacy” are commonly seen. Success in these areas of practice — and a general tendency to attempt in the community practice what has previously been done in the hospital practice — has led to the establishment of a small number of community-based collaborative drug therapy management practices. As hospital pharmacy practice continues to evolve, and as the order “pain management per pharmacy” becomes more widespread, it is not unreasonable to expect that this hospital-based standard will similarly be copied in the community pharmacy setting. There are no guarantees that a successful transition from hospital practice to community practice will occur, but the avenue for the shift exists and it has already happened (although in limited circumstances) for other therapeutic specialties. 42

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. 41 Dispensing has changed in concept over time — from limited definitions that include only interpreting and fulfilling orders 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 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. However, pain management is an area of specialization that is ripe for pharmacist-physician collaboration. Any physicians who specialize in pain management find that their practices emphasize invasive procedures, such as patient-controlled infusion pumps or intraspinal administration, because compensation is readily available for medical procedures. Payment for opioid management is more difficult to obtain, thus this activity is more likely to be willingly shared with a collaborating pharmacist.

To evaluate the scope and character of existing authority for collaborative drug therapy management, executive officers from the boards of pharmacy of each state and the District of Columbia were surveyed. The questions used on the survey instrument are reproduced in Appendix I. Forty-one responses were received. Of those responses, thirty-three were complete responses, five were partial responses, and three indicated that the board was unable to complete the questionnaire. An attempt was made to contact the eight non-responding states. Of these states, five indicated lack of time and three indicated inability to speculate on hypothetical questions as the reason for not responding.

Table I summarizes the responses to the survey questions concerning collaborative practice between physicians and pharmacists. The purpose of asking Questions 5 and 6
Table 1. Regulatory Authority for Pharmacist-Physician Collaboration

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<th>Legal Only in Organized Health-Care Setting</th>
<th>Legal in Any Community Pharmacy</th>
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<tbody>
<tr>
<td>Anticoagulation</td>
<td>20 states</td>
<td>4 states</td>
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<td>Pain Management</td>
<td>22 states</td>
<td>2 states</td>
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(see Appendix I) was to measure any difference in authority to conduct anticoagulation collaborative practice (a relatively common activity) and pain management collaborative practice (a relatively less common activity). The responses failed to show any difference. Thus, one could conclude from the data that there is no regulatory impediment to pain management collaborative practice in the states that authorize collaborative practice.

Of the states that indicated no authority for physician-pharmacist collaboration, six states indicated in open comments that while statutory authority existed for this practice, administrative rules had not yet been adopted to authorize the practice. Respondents in several other states indicated that although collaborative practice was authorized in their state, the way in which the survey question was written suggested that perhaps there could be a technical violation of the statutory requirements — thus indicating that the practice was not lawful.

Statutes or regulations in twenty-five states authorizing collaborative drug therapy management were obtained and examined. Copies of “model” collaborative drug therapy management agreements were requested, and seventeen such agreements were received from five states. Four of the model agreements were directed at pain management. Analysis of the regulatory authority and model agreements for collaborative drug therapy management discloses that collaborative practice in pain management is permitted in the sense that in no state is it forbidden under the newly adopted statutes and regulations.

A review of the model agreements received is provided below. Suffice to say at this point that collaborative drug therapy management is a recognized practice in a majority of states. This practice can enable pharmacists and physicians to improve the quality of pain management through an approach in which pharmacists and physicians function as colleagues, and through which they support each other when called to account for actions taken in the provision of medications to treat chronic pain.

The survey also queried board of pharmacy executive officers regarding the potential for state disciplinary action (e.g., restrictions on practice). Table 2 summarizes the responses to questions about the potential violation of technical requirements for controlled-substance dispensing (Questions 1 and 2 on the survey instrument). Almost every respondent indicated that the simple fact of having developed a reputation for dispensing large doses of methadone to pain patients would likely not subject a pharmacist to any disciplinary action. However, the dispensing of methadone pursuant to a photocopy of a purported prescription would subject the pharmacist to minor discipline in a majority of the states responding. Taken together, these responses suggest an enlightened view of the need to avoid legal impediments to appropriate pain management, along with a continued concern that pharmacists be aware of the problem of controlled-substance diversion.

Table 3 describes responses to questions directed toward meeting the needs of patients (Questions 3 and 4 on the survey instrument). The law permits emergency dispensing of Schedule II controlled substances pursuant to a verbal order, but requires that prescribers issue a written prescription to “cover” the verbal order within seven days, and requires further that pharmacists report to the DEA any prescriber who fails to provide such a written prescription. The responses to these questions indicate that few states are willing to discipline pharmacists who make a conscientious effort to obtain the written order, but nonetheless fail to contact the DEA when their efforts are unsuccessful. This is a minor violation that seems insignificant to the boards of pharmacy. Pharmacists who refuse to fill emergency Schedule II verbal prescriptions due to past experience with prescribers who fail to subsequently provide written orders as required should expect minor disciplinary action in some states. Of the twenty-five states that indicated no likelihood of disciplinary action, many respondents provided commentary criticizing the conduct of the pharmacist who refused legal emergency verbal orders, calling the conduct unethical but not illegal.

**Collegial Accountability in Principle**

There is strength in numbers; and two is greater than 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 account-
The mechanics of collegial accountability in pain management are straightforward. Clinical 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. This activity is most likely to occur in the institutional setting, where the Joint Commission on Accreditation of Healthcare Organizations recently changed the conditions of participation to mandate pain management teams. However, team work in health care can occur outside the institutional setting when health-care providers are motivated to work together.

The pharmacist pain management consult may be ordered explicitly by an attending physician, or it may be implicit in an approved 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 — when there is a need to add, discontinue, decrease, or increase drug use — are made in the same way. 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 occurred and why.

### Colleagial 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. The need to paternalistically limit drugs to prescription-only status has been questioned — and some drugs have been switched from prescription to non-prescription status — yet 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. While pharmacists practice independently of physicians, the processing of orders is done on their behalf by meticulously following the physicians’ orders. Order processing is a technically complex activity with no margin for error, but it is not intellectu-
ally 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. Collaborative drug therapy management 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 the 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 physicians:

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 physicians, 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.

Although the image of a viable collaborative practice amidst the hustle and bustle of a traditional retail pharmacy may seem farfetched to some, the pharmacy industry is currently experimenting with various creative approaches that would transfer lessons learned in the hospital to selected ambulatory care facilities. It is not impossible to imagine that in the future the processing of pharmaceutical orders will be assigned primarily to offsite locations that are linked via the Internet to local pharmacies. Pharmacies might then become primarily providers of services and not products. The documented problems that can occur with unsupervised medication use, and the costs known to be associated with drug-related morbidity, suggest that someone will have to provide drug therapy monitoring. Community pharmacists are well-positioned to provide this service, although it is by no means certain that they will eventually be chosen as the ones to provide it. The implementation of pharmaceutical care activities in community pharmacies could result in expanded access to health care and reduced costs. If this is the case, then there is a distinct possibility that community-based collaborative practice could succeed. It may well be that community-based collaborative drug therapy management is the best solution to the well-documented current problems with drug therapy in ambulatory care.

**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 of oversight, accompanied by informal and very private sanctions when things had not gone well. Today, health-care 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 the care provided to patients. 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 unproductive. 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 value-oriented so as to permit health-care providers to practice consistently with the goals of patients and their families. The process of productive accountability would be unobtrusive and respectful of patient privacy and the provider-patient relationship. Unproductive accountability, by way of contrast, would focus on punishment rather than improvement. Lacking specificity or explicit patient-oriented standards, unproductive accountability would coerce health-care 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 impropriety have been raised.

In collaborative drug therapy management, 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**

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 the physician’s 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 them or anyone. The practice of collegial accountability by pharmacists would be very similar to that of the consultant medical specialist, who assists an attending physician in the care of patients, but does not usurp his or her authority.

**Regulatory authority for collaboration**

The statutes and regulations that authorize collaborative drug therapy management all tend to follow a single pattern. The regulation from the Texas Board of Pharmacy is typical of these rules, and it is reproduced in Appendix II.

The formula used by the Texas Board of Pharmacy to enable physician-pharmacist collaboration focuses on the documentation that the collaboration would produce. The rule specifies the formalities of the relationship between the physician and the pharmacist, and it imposes specific requirements for patient care within that relationship. The rule also requires a report by the pharmacist to the physician concerning the results of drug therapy management. Thus, the rule includes components related to structure, process, and outcomes of care — unlike traditional pharmacy regulations that are oriented almost exclusively to matters of structure.53

Physicians can be confident of the competence of the pharmacists with whom they collaborate because the rule stipulates that only pharmacists who have been specially trained, or who have documented experience, may engage in this activity. The activities that may be performed by a pharmacist in collaborative drug therapy management are broad, but they can be limited by a specific agreement. The process that must be followed by a pharmacist who manages drug therapy is complex, perhaps establishing a standard against which drug therapy management by some physicians might not compare favorably. Frequent communication between pharmacist and physician is required, and documentation created by the pharmacist is subject to strict rules of both confidentiality and privilege.

**The character of collaborative agreements**

An examination of the collaborative drug therapy management agreements provided by the board of pharmacy executive officers discloses several important elements of a sufficient pharmacist-physician arrangement to share responsibility for drug therapy. Although the depth and breadth of the relationship between a pharmacist and a physician may be difficult to capture in a relatively brief document, the framework of that relationship can be described in two or three pages.

The first element of a sufficient collaborative drug therapy management agreement is clarity. The agreement must clearly state the role of the pharmacist within the context of the health-care team, which includes the physician and other health-care personnel. The agreement must state the responsibilities of both the physician and the pharmacist so that there is little room for disagreement over each other’s roles. The agreement should also state those duties which the pharmacist will be expected to independently perform — that is, without consulting the physician — as well as those duties which the pharmacist can perform only when individually requested to do so by the physician. The agreement may stipulate that certain duties are outside the role of the pharmacist.

An appropriate collaborative drug therapy management agreement also provides consistency. The agreement should describe the role of the pharmacist in such a way as to be applicable to various circumstances and patient needs. Less formal arrangements that have developed over time between pharmacists and physicians may have worked well as long as only a particular pharmacist and a particular physician were working together. But when other individuals become involved in collaborative activities, the unique understanding of roles within specific patient-care contexts may not necessarily transfer to new and different situations. Practice guidelines, as opposed to clinical guidelines, can show how duties are met regardless of the patient-care context. Incorporation of process-oriented practice guidelines into these agreements provides a roadmap for consistent practice.

Flexibility is a third characteristic of a sufficient collaborative drug therapy management agreement. It is important for the agreement to incorporate evidence-based clinical guidelines with therapeutic information that gives an objective foundation for care provided under the agreement. However, within a sufficient agreement, guidelines should be incorporated in a way that provides several options, recognizing that individualized clinical judgment is permissible — in fact necessary — to reflect unique patient factors. Pharmacists do not mechanically follow a physician’s orders; rather, they apply what they know about patient care within the framework of the agreement they have with the particular patient’s physician, and they adapt the drug therapy to the patient’s distinctive needs.

Collaborative agreements must also be usable in the sense that they must facilitate pharmacist-physician collaboration by describing the appropriate etiquette of the arrangement.
There would be no purpose in having an excellent agreement that nobody would use due to feelings of discomfort with it and an unfamiliarity with how to use it. A usable agreement is one that not only describes the behaviors of the pharmacist and the physician, but also the relationship between them. To be usable, the agreement must state who is responsible for what and when. It must prescribe communication lines between pharmacist, physician, and patient, and provide assurance that patient care is a shared responsibility, with the physician ultimately retaining the authority for decisions about care.

Finally, a sufficient agreement must be defensible. It must be easily understood by an outside evaluator so that he or she can readily discern what expectations were established for a pharmacist or physician under the agreement and how those expectations were to be met. The agreement must facilitate peer review activities done for quality improvement, perhaps by requiring the creation of documents that show what care was provided and the outcomes that were produced by the care. The collaborative agreement is evidence of the applicable standard of care in the therapeutic area that it addresses, and to be a defensible agreement, it must be recognized as valid by an interdisciplinary consensus group.

**Collegial Accountability in Pain Management**

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 the likelihood that no foul play will be found.

Physician-pharmacist collaboration in pain management faces several procedural obstacles that are not problematic in other therapeutic areas. Most of the medications used in the management of pain are controlled substances, and many of them are highly regulated Schedule II controlled substances. Until several years ago, it would have been very difficult to create a system in which a physician could delegate any pain management authority to a pharmacist. This was due to the high level of documentation required to show direct physician participation in decisions about Schedule II medication use. The rules continue to require significant physician participation, which is, of course, not a bad thing, but some record-keeping requirements have been relaxed so as to permit advanced practices that can improve outcomes for patients. For example, partial fillings of Schedule II prescriptions were at one time restricted to a seventy-two hour period. Thus, a pharmacist could not legally accept a physician’s authority to dispense a supply of Schedule II controlled substances over a period of time extending beyond seventy-two hours. The rule was recently changed for patients who are either residents of a long-term care facility or who have a medical diagnosis documenting a terminal illness. For these patients, a pharmacist may partially fill a Schedule II prescription for up to sixty days. A separate rule has also been changed recently to allow facsimile transmission of Schedule II prescriptions for opioid analgesics if the patient is a hospice patient.

Of the collaborative pain management programs currently in place, the stated purpose is generally said to be the efficient provision of quality care to chronic pain patients. The ultimate objective of the programs is to provide a safe and standardized approach to symptom management. In furtherance of that stated goal, the programs have been developed to streamline the collaborations of the pharmacist, nurse, and physician by assuring communication and facilitating decision-making. Appendix III describes the process of collaborative pain management practice at one hospital.

The process of care customarily begins with the development of a treatment algorithm and then approval of the algorithm by the medical staff of an institution or by an individual physician. A patient is enrolled in the collaborative drug therapy management program by a signed order from a physician. A nurse then assesses the patient. A plan of care is developed by an interdisciplinary team, and is then signed by the patient’s physician. The plan of care may include therapies that fall outside the pain management treatment algorithm. The treatment algorithm is then instituted, and a pharmacist dispenses needed medication as per the algorithm. Appendix IV contains the treatment algorithm for a collaborative practice at one hospital.

As the provision of care progresses through the algorithm, assessments are performed periodically by a nurse and changes in drug therapy are made as necessary by a pharmacist based on the nurse’s assessment. Within twenty-four hours of any change under the algorithm, the pharmacist faxes a copy of the algorithm progress notes, summarizing the assessment and the change to both the physician and the nurse. If all steps in the algorithm are completed and the symptoms are not relieved, then the attending physician is contacted by the pharmacist. Progress notes are created for patient care and quality improvement review. Appendix V contains a sample pain management collaborative practice progress note.

Authority for pharmacists to start, stop, or change drug therapy under the algorithm is granted through a signature sheet naming all pharmacists to whom drug therapy management authority is granted. The sheet is signed by all physicians granting such authority or by the medical director of a practice group in which drug therapy management authority
is extended to pharmacists. A standard form for algorithm progress notes is generally adopted; it is typically in a form that can easily be transmitted by facsimile. Outcomes of care are usually monitored in a systematic way, and changes are made to the algorithm as needed.

**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 and, in turn, protect patients from the harm of over- or undertreatment. 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 been developed by regulation have generally not included the management of chronic pain. The incentive of increased protection from perceived regulatory oversight could serve as the basis for expanded collaborative pain management practices in the future.

**REFERENCES**

2. See L.A. Ferro et al., “Collaborative Practice Agreements Between Pharmacists and Physicians: Some forward-thinking pharmacists are taking what may be the next logical step in the evolution of pharmaceutical care,” Journal of the American Pharmaceutical Association, 38 (1998): 655–666 (noting the lack of a clear consensus on what is permitted under collaborative practice agreements, but suggesting that, as a general rule, collaborative practice agreements between pharmacists and physicians permit the pharmacist to make specific types of changes in the drug therapy of a specific patient or group of patients, following a written protocol approved by the pharmacist and the physician). Arizona and Georgia recently became the 26th and 27th states to authorize collaborative practice under protocol by pharmacists. See “More States Join Movement to Pharmacist Participation in Drug Therapy Management,” American Journal of Health-System Pharmacy, 57 (2000): 1116–1117. The other states in which drug therapy management by pharmacists is currently authorized are Arkansas, California, Hawaii, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, South Dakota, Tennessee, Texas, Vermont, Virginia, and Washington.
4. See Ferro et al., supra note 2. The therapies listed as being most frequently the subject of collaborative agreements between pharmacists and physicians are those that can be monitored by a pharmacist through a test of drug efficacy (i.e., blood glucose for diabetes, peak flow meter for asthma, blood lipids for hyperlipidemia, and the INR [International Normalized Ratio] for anticoagulation therapy). The efficacy of drug treatment for pain can also be monitored by a pharmacist through patient interviews regarding the level of comfort and pain sensation. See A.E. Bonomi, R. Shiklar, and M.W. Legro, “Quality-of-Life Assessment in Acute, Chronic, and Cancer Pain: A Pharmacist’s Guide,” Journal of the American Pharmaceutical Association, 40 (2000): 402–415 (describing the instruments currently available to pharmacists, and other health-care providers, through which an assessment can be made of the impact of pain on quality of life).

12. Florida law now provides that health-care professionals may substitute continuing education on "end-of-life care and palliative health care" for the mandatory continuing education on AIDS/HIV, as long as the licensee has completed an approved AIDS/HIV course in the immediately preceding relicensure period. Fla. Stat. 455.604 (1999).

13. The problem of informal policies-in-practice is compounded when regulators themselves either do not know the policies-on-paper or they fail to communicate them well to the regulated industry. This problem can, at least partially, be addressed through educational programs geared for regulators. See D.E. Joranson and A.M. Gilson, "Improving Pain Management Through Policy Making and Education for Medical Regulators," Journal of Law, Medicine & Ethics, 24 (1996): 344–47.

14. See G.R. Haislip, "Impact of Drug Abuse on Legitimate Drug Use," Advances in Pain Research and Therapy, 11 (1989): 205–211 (concluding that the law is not a problem in providing an adequate supply of drugs, particularly narcotics, to patients for the treatment of intractable pain). DEA regulations formally acknowledge this perspective in a section that addresses availability of pain management medications: "This section is not intended to impose any limitations on a physician or authorized hospital staff ... to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts." 21 C.F.R. § 1306.07(c) (1999).


17. 555 F.2d 258 (5th Cir. 1979).

18. 972 F.2d 395 (Utah 1998).

19. 555 F.2d 258 (5th Cir. 1979).


26. See H. Huang, infra notes 35–36 and accompanying text.


29. See id. at 1051.

30. See id. at 1053.

31. 642 N.E.2d 514 (Ind. 1994).

32. See id. at 519.


36. See id. at 434–444.

37. 1 S.W.3d 519 (Mo. Ct. App. 1999).

38. See Grainger-Rousseau et al., supra note 3.


40. See id. at 524.

41. See id. at 523, n.5.

42. See id. at 524.

43. See Doucette et al., supra note 22.

44. See id. at 523, n.5.

45. See id. at 524.

46. See id. at 523, n.5.

47. 1 S.W.3d 519 (Mo. Ct. App. 1999).


50. See id. at 271–272.
A pharmacist in your state begins to receive a large number of prescriptions for methadone from a group of physicians who specialize in pain management. There is no question that these prescriptions are for pain, and that the patients for whom the prescriptions are dispensed are actually suffering chronic pain. The pharmacist is concerned that the large volume of prescriptions she fills for methadone will raise a "red flag" with regulators regarding the legitimacy of her dispensing. Nevertheless, she believes she has a professional responsibility to dispense these medications. The volume of her methadone dispensing increases dramatically as word gets around to patients that this pharmacist will fill methadone prescriptions without accusing them of being drug addicts. Other pharmacists become concerned about rumors they have heard that the pharmacist is dispensing large volumes of methadone. One of the other pharmacists files a complaint with the state board of pharmacy. What outcome do you believe is most likely for this pharmacist based solely on the facts as given?

Clarifying Comments:

Question 2: Assume the same facts as those in question #1. However, assume further that the pharmacist has filled a photocopy of a methadone prescription, presented by the niece of a patient who had a legitimate need for the drug. Five other pharmacies in the area also filled a photocopy of this prescription. Thirteen pharmacies refused to fill this photocopy. An investigation discloses that the pharmacist filled 85 prescriptions for methadone during the week in which the photocopy was filled, and 84 of these prescriptions were perfectly valid. A complaint is filed with the board of pharmacy over the filling of the one photocopy of a prescription for methadone. What outcome do you believe is most likely for this pharmacist based solely on the facts as given?

Clarifying Comments:

Question 3: A pharmacist in your state fills a written prescription for Demerol 50 mg on Thursday afternoon. The prescription is written by an orthopedic surgeon and is for a two-day supply of the drug to treat back pain of a patient who regularly has pharmaceutical products and services provided by this pharmacist. Two days later, on Saturday afternoon, the pharmacist is contacted by the patient and is requested to dispense a refill, which the pharmacist declines to do, citing federal law. The patient is unable to locate the orthopedic surgeon that afternoon, but the patient's regular physician is willing to telephone in an emergency authorization to dispense a supply of Demerol 50 mg sufficient to cover the patient's needs until Monday when the patient can visit the orthopedic surgeon. The pharmacist fills the order, but seven days later the prescriber has still not sent a written prescription to the pharmacist to cover the emergency dispensing. The pharmacist contacts the prescriber's office five times to request that this be done. Each time the pharmacist receives assurance that the prescription will be sent, but the prescription never arrives. The pharmacist thoroughly docu-
ments each of the five attempts to contact the prescriber, and attaches this documentation to the authorization for emergency dispensing. There is no question that the drugs have not been diverted, this is simply a matter of incomplete recordkeeping. An inspector notes that the written prescription has not been received, and disciplinary action is initiated against this pharmacist based on this circumstance.

_____ This pharmacist will likely not be disciplined by the board of pharmacy.
_____ This pharmacist will likely receive a minor disciplinary action by the board of pharmacy.
_____ This pharmacist will likely receive a major disciplinary action by the board of pharmacy.

Clarifying Comments:

**Question 4:** Assume the same facts as in question #3. However, the pharmacist has not been subject to any discipline by the board. But the pharmacist has become utterly disgusted with the failure of physicians to deliver hard copies of Schedule II prescriptions subsequent to their verbal orders for emergency dispensing of Schedule II drugs. The pharmacist adopts a policy of not filling any emergency orders for Schedule II controlled substances, despite the needs of patients, because he does not want to be placed in the position of possibly not receiving the written orders later. Two patients, who are regular patients of the pharmacy, are denied narcotic analgesics under emergency circumstances by this pharmacist, despite the assurances of their physicians that a written prescription would be sent. The pharmacist states that he has simply had enough of this nonsense and will not fill emergency Schedule II prescriptions no matter what the prescriber promises. The patients file a complaint with the board of pharmacy for failure to provide complete pharmaceutical services.

_____ This pharmacist will likely not be disciplined by the board of pharmacy.
_____ This pharmacist will likely receive a minor disciplinary action by the board of pharmacy.
_____ This pharmacist will likely receive a major disciplinary action by the board of pharmacy.

Clarifying Comments:

**Question 5:** A pharmacist and a physician in your state come to know and trust each other very well. Together the pharmacist and physician develop a collaborative practice agreement, in which the pharmacist and physician specify how a patient’s anticoagulation therapy is to be managed by the pharmacist. The agreement contains very specific decision assistance algorithms that guide the pharmacist in managing the patient’s anticoagulation. The algorithm contains instructions for changing the dose of prescribed drugs, initiating new drugs, and discontinuing prescribed drugs. According to the agreement, the pharmacist need not contact the prescriber prior to making changes that are authorized under the algorithm, but the pharmacist must immediately notify the prescriber following any change. Both the pharmacist and physician have signed this collaborative practice agreement. The physician begins to send to the pharmacist patients who require anticoagulation monitoring. Can this collaborative practice be done in your state?

_____ No, this collaborative practice may not be done legally.
_____ Yes, this collaborative practice may be done legally, but only within an organized health care system such as a hospital, a nursing home or a health maintenance organization.
_____ Yes, this collaborative practice may be done legally, in any community pharmacy.

Clarifying Comments:

**Question 6:** Assume essentially the same facts as in question 5. The pharmacist and physician in your state have come to know and trust each other very well. Together the pharmacist and physician develop a collaborative practice agreement, in which the pharmacist and physician specify how a patient’s narcotic analgesic pain therapy is to be managed by the pharmacist. The agreement contains very specific decision assistance algorithms that guide the pharmacist in monitoring the patient’s pain. The algorithm contains instructions for changing the dose of prescribed drugs, initiating new drugs, and discontinuing prescribed drugs. According to the agreement, the pharmacist need not contact the prescriber prior to making changes that are authorized under the algorithm, but the pharmacist must immediately notify the prescriber following any change. Both the pharmacist and physician have signed this collaborative practice agreement. The physician begins to send to the pharmacist patients who require pain management. Can this collaborative practice be done in your state?

_____ No, this collaborative practice may not be done legally.
_____ Yes, this collaborative practice may be done legally, but only within an organized health care system such as a hospital, a nursing home or a health maintenance organization.
_____ Yes, this collaborative practice may be done legally, in any community pharmacy.

Clarifying Comments:
APPENDIX II
Texas Board of Pharmacy Rule for
Drug Therapy Management by a Pharmacist

RULE § 295.13: Drug Therapy Management by a Pharmacist under Written Protocol of a Physician

(a) Purpose. The purpose of this section is to provide standards for the maintenance of records of a pharmacist engaged in the provision of drug therapy management as authorized in § 3.061 of the Medical Practice Act and § 17(x) of the Act.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act — The Texas Pharmacy Act, Texas Civil Statutes, Article 4542a-1, as amended.
(2) Board — The Texas State Board of Pharmacy.
(3) Confidential record — Any health-related record maintained by a pharmacy or pharmacist, such as a patient medication record, prescription drug order, or medication order.
(4) Drug therapy management — The performance of specific acts by pharmacists as authorized by a physician through written protocol. Drug therapy management does not include the selection of drug products not prescribed by the physician, unless the drug product is named in the physician initiated protocol or the physician initiated record of deviation from a standing protocol. Drug therapy management may include the following:
   (A) collecting and reviewing patient drug use histories;
   (B) ordering or performing routine drug therapy related patient assessment procedures including temperature, pulse, and respiration;
   (C) ordering drug therapy related laboratory tests;
   (D) implementing or modifying drug therapy following diagnosis, initial patient assessment, and ordering of drug therapy by a physician as detailed in the protocol; or
   (E) any other drug therapy related act delegated by a physician.
(5) Medical Practice Act — The Texas Medical Practice Act, Texas Civil Statutes, Article 4495b, as amended.
(6) Written protocol — A physician’s order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Texas State Board of Medical Examiners under the Medical Practice Act.

(i) a statement identifying the individual physician authorized to prescribe drugs and responsible for the delegation of drug therapy management;
(ii) a statement identifying the individual pharmacist authorized to dispense drugs and to engage in drug therapy management as delegated by the physician;
(iii) a statement identifying the types of drug therapy management decisions that the pharmacist is authorized to make which shall include:
   (I) a statement of the ailments or diseases involved, drugs, and types of drug therapy management authorized; and
   (II) a specific statement of the procedures, decision criteria, or plan the pharmacist shall follow when exercising drug therapy management authority;
(iv) a statement of the activities the pharmacist shall follow in the course of exercising drug therapy management authority, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made. Documentation shall be recorded within a reasonable time of each intervention and may be performed on the patient medication record, patient medical chart, or in a separate log book; and
   (v) a statement that describes appropriate mechanisms and time schedule for the pharmacist to report to the physician monitoring the pharmacist’s exercise of delegated drug therapy management and the results of the drug therapy management.

(B) A standard protocol may be used or the attending physician may develop a drug therapy management protocol for the individual patient. If a standard protocol is used, the physician shall record what deviations, if any, from the standard protocol are ordered for that patient.

(c) Notification.

(1) Initial notification. Prior to initially engaging in drug therapy management, a pharmacist shall provide the board with:
   (A) the name, license number, and address of the
supervising physician;
(B) the address where the records of such drug
therapy management are maintained; and
(C) a statement attesting to the fact that the
pharmacist has within the last year:
(i) completed at least six hours of
continuing education related to drug
therapy offered by a provider approved
by the American Council on
Pharmaceutical Education (ACPE); or
(ii) engaged in drug therapy management as
allowed under previous laws or rules. A
statement from the physician supervising
the acts shall be sufficient
documentation.

(2) Continuing requirements. A pharmacist engaged
in drug therapy management shall:
(A) annually complete six hours of continuing
education related to drug therapy offered by a
provider approved by the American Council
on Pharmaceutical Education (ACPE). (These
hours may be applied towards the hours
required for renewal of a license to practice
pharmacy.)
(B) notify the board of any change in supervising
physician or change in the address where the
records of drug therapy management are
maintained.

(d) Supervision. Physician supervision shall be as specified
in the Medical Practice Act, § 3.061 and shall be
considered adequate if the delegating physician:
(1) is responsible for the formulation or approval of
the written protocol and any patient-specific
deviations from the protocol and review of the
written protocol and any patient-specific
deviations from the protocol at least annually and
the services provided to a patient under the
protocol on a schedule defined in the written
protocol;
(2) has established and maintains a physician-patient
relationship with each patient provided drug
therapy management by a delegated pharmacist
and informs the patient that drug therapy will be
managed by a pharmacist under written protocol;
(3) is geographically located so as to be able to be
physically present daily to provide medical care
and supervision;
(4) receives, on a schedule defined in the written
protocol, a periodic status report on the patient,
including any problem or complication
encountered;
(5) is available through direct telecommunication for
consultation, assistance, and direction; and
(6) determines that the pharmacist to whom the
physician is delegating drug therapy management
establishes and maintains a pharmacist-patient
relationship with the patient.

(e) Records.
(1) Maintenance of records.
(A) Every record required to be kept under this
section shall be kept by the pharmacist and
be available, for at least two years from the
date of such record, for inspecting and
copying by the board or its representative and
to other authorized local, state, or federal law
enforcement or regulatory agencies.
(B) Records may be maintained in an alternative
data retention system, such as a data
processing system or direct imaging system
provided:
(i) the records maintained in the alternative
system contain all of the information
required on the manual record; and
(ii) the data processing system is capable of
producing a hard copy of the record
upon the request of the board, its
representative, or other authorized local,
state, or federal law enforcement or
regulatory agencies.

(2) Written protocol.
(A) A copy of the written protocol and any
patient-specific deviations from the protocol
shall be maintained by the pharmacist.
(B) A pharmacist shall document all interventions
undertaken under the written protocol within
a reasonable time of each intervention.
Documentation may be maintained in the
patient medication record, patient medical
chart, or in a separate log.
(C) A standard protocol may be used or the
attending physician may develop a drug
therapy management protocol for the
individual patient. If a standard protocol is
used, the physician shall record what
deviations, if any, from the standard protocol
are ordered for that patient. A pharmacist
shall maintain a copy of any deviations from
the standard protocol ordered by the
physician.
(D) Written protocols, including standard
protocols, any patient-specific deviations
from a standard protocol, and any individual
patient protocol, shall be reviewed by the
physician and pharmacist at least annually
and revised if necessary. Such review shall be
documented in the pharmacist’s records.
Documentation of all services provided to the
patient by the pharmacist shall be reviewed
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by the physician on the schedule established in the protocol.

(f) Confidentiality.

1. A pharmacist shall provide adequate security to prevent indiscriminate or unauthorized access to confidential records. If confidential health information is not transmitted directly between a pharmacy and a physician, but is transmitted through a data communication device, the confidential health information may not be accessed or maintained by the operator of the data communication device unless specifically authorized to obtain the confidential information by this subsection.

2. Confidential records are privileged and may be released only to:
   (A) the patient or the patient's agent;
   (B) practitioners and other pharmacists when, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well-being;
   (C) other persons, the board, or other state or federal agencies authorized by law to receive such information;
   (D) a law enforcement agency engaged in investigation of suspected violations of the Controlled Substances Act or the Dangerous Drug Act;
   (E) a person employed by any state agency which licenses a practitioner as defined in the Act if such person is engaged in the performance of the person's official duties; or
   (F) an insurance carrier or other third party payer authorized by a patient to receive such information.

3. This section shall not affect or alter the provisions relating to the confidentiality of the physician-patient communication as specified in the Medical Practice Act, § 5.08.

(g) Construction and Interpretation.

1. As specified in the Medical Practice Act, § 3.061(e), this section does not restrict the use of a pre-established health care program or restrict a physician from authorizing the provision of patient care by use of a pre-established health care program if the patient is institutionalized and the care is to be delivered in a licensed hospital with an organized medical staff that has authorized standing delegation orders, standing medical orders, or protocols.

2. As specified in the Medical Practice Act, § 3.061(d), this section may not be construed to limit, expand, or change any provision of law concerning or relating to therapeutic drug substitution or administration of medication, including the Act, § 17(a)(5).
APPENDIX III

Central Washington Hospital

POLICY: HOME CARE SERVICES-HOSPICE/PHARMACY

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STANDARD: CONTINUUM OF CARE/CARE OF PATIENTS

- Effective Date: 10/97
- Revised Date: 06/16/00

SUBJECT: HOSPICE PRESCRIPTIVE AUTHORITY

SYMPTOMS MANAGEMENT ALGORITHMS

- Approved:
  - Director Home Care Services
  - Director of Pharmacy

POLICY: It is the policy of Central Washington Hospital Hospice Services to efficiently provide quality care to Hospice patients, and:

A. To provide quality symptom management for patients suffering distressing symptoms resulting from a terminal disease process.

B. To provide a safe and standardized approach to symptom management.

C. To improve on the timely delivery of needed interventions for symptom management (i.e. prescriptions for needed drugs obtained quickly).

D. To streamline the collaborations of the Pharmacist, Nurse and Physician by assuring communication and facilitating decision making.

E. To be cost effective while improving overall quality of care.

GENERAL:

The nurse is responsible for the initial and ongoing assessment of the patient’s condition and presenting symptoms. He/she will collaborate with the Pharmacist according to the algorithm.

The credentialed Pharmacist, with Washington State Board of Pharmacy Prescriptive Authority, will prescribe medications for Hospice patients in accordance with algorithms approved by a physician. The Pharmacist may continue, modify or initiate the drugs according to the process.

The Pharmacist or Hospice Nurse will consult with the physician according to the algorithm and at any time deemed necessary.

A. Algorithm Process Procedure:

1. Patient admitted to the Hospice program. A signed prescription from the attending physician, or indication on a signed Hospice Plan of Care, will be obtained to initiate the algorithms. An authorization letter from the attending physician for their patients may be used in lieu of a signed prescription.

2. A medication profile will be completed and a copy sent to the Pharmacy within 24 hours.

3. A Plan of Care will be developed by the Hospice Interdisciplinary Team and a copy sent to the Pharmacy.

4. A Plan of Care will be completed and signed by the attending physician.

5. Current medications will be continued as long as they are effective in controlling symptoms. A list of current medications will be kept by Pharmacy on a Medication Tracking Sheet. When a change occurs on a non-
algorithm medication, Hospice nurse will immediately notify Pharmacy (nurse will call if medication change accompanies algorithm change, otherwise a copy of the change will be sent to Pharmacy). The Pharmacist will use this information to update the patients profile in the Hospice Workbook.

6. When a symptom is observed and an algorithm is being considered for implementation, the Hospice nurse will consult with the Pharmacist as defined by the algorithm. The assessment data will be reviewed and a plan of action determined. The Pharmacist will prescribe per the algorithm and dispense the needed medication.

7. Within twenty-four (24) hours of an algorithm change, the Pharmacist will fax a copy of the algorithm Progress Notes summarizing the consultation process to the attending physician and Hospice nurse.

8. The Hospice nurse will perform an ongoing assessment of the patient’s condition.

9. If the current step in the algorithm is not working (i.e. not effective in relieving the patient’s distressing symptom), the Hospice Nurse will follow protocol and consult with the Pharmacist. Follow-up assessments may be performed within twenty-four (24) hours of therapeutic change, or as indicated in the specific algorithms or per clinician judgment. The Pharmacist will determine if any change in current drug therapy is needed based on the nursing assessment and prescribed according to the algorithm.

10. Once all of the steps in an algorithm are completed and symptom is unrelieved the Hospice nurse and Pharmacist will consult. The Pharmacist or Hospice Nurse will contact the attending physician.

11. For medications that fall outside of the algorithm the Pharmacist will write the new orders and dispense the medication upon a verbal order from the attending physician. This will be documented by the Pharmacist on a Algorithm Progress Note with a copy sent to the Hospice nurse and physician. The Hospice nurse may also write new orders upon a verbal order from the attending physician. The Pharmacist will dispense the medication upon a telephone order from the hospice nurse or a faxed order from the physician.

12. If the patient is admitted to the hospital, algorithms will be suspended while patient is in-house and resumed upon discharge.

B. Pharmacy Procedure:
   The Pharmacist will:
   1. Prescribe the identical drug, strength, route, and instructions as outlined in the algorithm.
   2. Use the DEA number of Central Washington Hospital Professional Pharmacy when prescribing scheduled drugs.
   3. Review relevant patient information, before enacting any portion of the algorithm. Verify nurse assessment is complete. (Telephone consultation.)
   4. Consider for appropriate therapy, but not be limited to: accepted doses, allergy, weight, sex, age and known disease processes.
   5. Include monitoring parameters, such as adverse reaction, possible drug interactions, individual pharmacokinetics, as well as patient response in algorithm decisions.
HOSPICE ALGORITHM PROCESS

PATIENT ADMITTED TO HOSPICE

FAX, WRITTEN, ORAL APPROVAL GIVEN TO BEGIN ALGORITHMS

ASSESSMENT/INFORMATION GATHERING

PLAN OF CARE DEVELOPED

COMMUNICATION WITH PHYSICIAN

ALGORITHMS INSTITUTED

ONGOING ASSESSMENT AND EVALUATION

- CURRENT ALGORITHM STEP NOT WORKING
  - START NEXT STEP

  PHARMACIST

  - CONSULTS PHYSICIAN AS NEEDED

  - Protocol completed.

  Pharmacist/hospice nurse coordinates further care plans.

  Pharmacist/hospice nurse calls physician for further drug orders and communicates information to hospice nurse/pharmacist.
APPENDIX IV

Pain Treatment Algorithm

STEP I
Mild Pain

- APAP 500 mg po/pr q4h ATC (MDD 4000 mg)
- OR
- Ibuprofen 200 mg po q 4-6h ATC (MDD 2400 mg)
- OR
- Choline magnesium trisalicylate 1000 mg po bid
* Consider adjuvant for pain syndromes

Partial or No relief

Pharmacist assess:
- Patient compliant with ATC dosing?
- Need to increase dose?
- Need to change drug?

Pharmacist-Nurse consultation to advance to Step IV

Relief

Continue medication & reassess at regular intervals

No relief

Always dispense maximum end of dosing range/frequency
Dispense 2 week supply unless otherwise instructed by R.N.

Pain Treatment Algorithm

STEP II
Moderate Pain

- Vicodin I-II po q4-6h ATC (MDD 8 tabs)
- OR
- Percocet I-II po q 4-6h ATC (MDD 12 tabs)
- OR
- Oxycodone 5 mg I-II po q4-6h ATC
If sustained release is needed:
- Oxycetin 10 mg SR po bid
- MS Contin 15 mg po bid
(may use Vicodin, Percocet, or Oxycodone above for breakthrough pain)
* Initiate bowel program when starting narcotic
* Consider adjuvant for pain syndromes
* If using Vicodin/Percocet, d/c Tylenol from Step I

Partial or No relief

Pharmacist assess:
- Patient compliant with ATC dosing?
- Need to increase dose?
- Need to change drug?

Pharmacist-Nurse consultation to advance to Step IV

Relief

Continue medication & reassess at regular intervals

Always dispense maximum end of dosing range/frequency
Dispense 2 week supply unless otherwise instructed by R.N.
Generic substitution permitted on all prescriptions
**Pain Treatment Algorithm**

**STEP III**

**Severe Pain**

- Oxycontin po bid
- MS Contin po bid or Duragesic patch q3d
- *Starting dose should be equianalgesic to previous narcotic agent (see equianalgesic chart). Upward titrations of 25-100%.*

For breakthrough pain (25% of daily opioid use):
- Morphine sublingual tabs (10,15,30 mg) po, sl q3o pm
- OR
- Dilaudid po q3o pm
- OR
- Roxanol liquid po q3o pm
- *Initiate bowel program when starting narcotic
- *Consider adjuvant for pain syndromes

- continue medication & reassess at regular intervals
- Relief

**Partially or no relief**

- Pharmacist assess:
  - Patient compliant with ATC dosing?
  - Need to increase dose?
  - Need to change drug?

- Pharmacist-Nurse consultation to advance to Step IV
- No relief

**Pain Treatment Algorithm**

**STEP IV**

- Consider morphine CADD PCA
  - (If patient allergic to morphine, RPh will consult MD for other options)
- Criteria for instituting CADD PCA
  - (RPh & RN to determine)
  - patient no longer able to swallow
  - patient has questionable GI absorption of meds
  - patient not well controlled with oral meds even after multiple upward titrations
- Route of administration
  - vascular access (Groshong, PICC, or Port) for IV route is preferred. On rare occasions a subcutaneous route may be used if IV is unattainable and subcutaneous route is clinically inappropriate.
- Determining starting dose
  - Starting dose of morphine should be equianalgesic to current oral dose of opioid (see conversion formula and equianalgesic chart)
  - Usual concentration of morphine is 10mg/mL. More concentrated solutions are used when hourly rate exceeds 10mg/hr. Concentration is calculated according to hourly rate.

**NOTE:** Subcutaneous infusion should not exceed 2mL/hr.

- Titration Parameters
  - calculate the past 24 hours total opioid usage (RN to provide information, RPh to calculate)
  - if needed, convert to equivalent dose of morphine (see equianalgesic dose chart)
  - divide total daily dose by 24 - this gives hourly rate. Drip rate may be increased (by 25-50%) Q4-6 hours if poor symptom control
  - bolus doses for breakthrough pain = 100% of hourly rate. Breakthrough dose is given every 10-15 minutes.
- Assessment
  - Relief: Continue to assess & titrate up or down pm to maintain optimal pain control.
  - No Relief: If pain rating is consistently ≥ 5 on scale of 1-10 for greater than 24 hours, in spite of repeated upward titrations, Pharmacist will consult with Physician. Consider switching to another opioid or epidural infusion. Reconsider adjuvant for pain syndromes.
APPENDIX V

HOSPICE/PHARMACY
ALGORITHM PROGRESS NOTES

Patient: ________________________________

Conference with ______________________ RN Algorithm: ____________________________

Date: ________________ Time ________________ Physician: ____________________________

Nursing Assessment Completed per Protocol □ Yes □ No (Explain)

Summary ________________________________________________________________

Plan

□ Continue Present Drug regimen with no change

□ Discontinue ________________________________ (Drug/Dose)

New Rx(s)

<table>
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<tr>
<th>Drug</th>
<th>Amount Dispensed</th>
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□ Refill Current Drug Therapy ________________________________________________

Medication to be: □ Picked up by: □ Family □ RN □ Other _______________________

Faxed to: ________________________________

Physician

Hospice Nurse

Review ________________________________________________________________

Review Date ________________________________

Comments: ______________________________________________________________

Pharmacist: ________________________________

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