Can treating pain be painful? In a recent claim against a Doctor, a patient undergoing treatment for chronic back pain was found deceased at home in bed. An autopsy revealed methadone toxicity as the cause. The decedent's estate filed a medical malpractice action against the Physician and the practice alleging that the group: 1) provided a starting dose that was excessive for an opiate-naive individual; 2) failed to consider other medications the patient was taking and their potential additive effects; and 3) failed to appropriately monitor the patient for side effects and possible toxicity.

Unfortunately, the types of complaints outlined in this suit are becoming more commonplace as a growing number of Physician practices are faced with the dilemma of treating patients with complex pain issues.

Almost five decades ago, governments around the world adopted the 1961 Single Convention on Narcotic Drugs. In addition to addressing the control of illicit narcotics, it obligated countries to work towards universal access to narcotic drugs deemed necessary to alleviate pain and suffering. However, Physicians attempting to care for their long-term pain patients often feel torn between their obligation to appropriately treat pain and their concern that
providing pain management drugs may open them up to disciplinary action or civil liability. This issue of providing pain management drugs may open them up to surrounding prescription drug addictions that have led to musicians and TV personalities had well-publicized issues the past few years, after a number of famous athletes, Doctors routinely provide pain management drugs to patients – especially opioid medications – with proper monitoring and control. The issue of misuse and abuse of opioid pain medications entered popular discussion during the past few years, after a number of famous athletes, musicians and TV personalities had well-publicized issues surrounding prescription drug addictions that have led to criminal activity and accidental overdoses.

This dilemma faces Physicians while the American public is being deluged by high profile stories alleging that Doctors routinely provide pain management drugs to patients – especially opioid medications – without proper monitoring and control. The issue of misuse and abuse of opioid pain medications entered popular discussion during the past few years, after a number of famous athletes, musicians and TV personalities had well-publicized issues surrounding prescription drug addictions that have led to criminal activity and accidental overdoses.

A poignant example of the media’s attention to this issue was a recent story by ABC News titled, “Many Doctors Fail to Monitor Potential Opioid Abuse Appropriately.” The program focused on studies that demonstrated a rise in the abuse of prescription painkillers over the past two decades. Even more unsettling was the coverage of a recent study that suggested “primary care Physicians may not be diligently monitoring patients who are taking opioid painkillers such as OxyContin, even those who are at risk for becoming dependent on them.”

The study, conducted by Dr. Joanna Starrels, assistant professor of medicine at the Albert Einstein College of Medicine and Montefiore Medical Center in the Bronx, N.Y., reviewed “more than 1,600 primary care patients prescribed long-term opioids and looked at how frequently they received three strategies for reducing the risk of misuse.” The three risk-reduction strategies identified by the study were urine tests, face-to-face office visits at least every six months and within a month of changing an opioid prescription, and limiting the number of early refills. Data showed that only eight percent of the patients in the study had any urine drug testing, less than half had regular office visits and nearly 25 percent received multiple early refills. The American College of Physicians, in editorializing on the issue of patient compliance in the pain management context and the findings of the Starrels study noted, “A substantial problem in evaluating compliance with and efficacy of treatment agreements and urine drug testing, with respect to managing the risk for opioid misuse, is a lack of consistency both in content and utilization of these tools and the definition of aberrant behavior.”

The Maryland Board of Physicians (BOP) has long been interested in ensuring that prescription pain medications, in particular, are closely watched by Physicians. Given the recent spate of news in this field, the BOP appears to be particularly aggressive in investigating and disciplining Physicians regarding abuse of opioid pain medications. There are many examples of actions taken against Physicians regarding the use of opioid medications. One should be aware that the BOP has been issuing “summary suspension” orders which are effective immediately. A Physician usually has only a short period of time after which such an order is entered to address the allegations in an attempt to reinstate his or her license to practice medicine. While the BOP has aggressively disciplined Physicians in relation to the provision of pain management drugs, it has also stated that it wishes to ensure patients are receiving appropriate pain control. The BOP has done a major favor for practitioners by outlining what it sees to be evidence of good clinical practice. In particular, in a 1996 letter signed by Charles F. Hobelmann, Jr., M.D., the BOP made clear that it does not want legitimate pain to go untreated due to fears of disciplinary action.

To assist practitioners, the BOP outlined six factors that it looks to in determining whether a Physician has acted appropriately in prescribing and monitoring pain management drugs. These factors continue to be the benchmark against which the BOP judges the propriety of a Physician’s action in the area of prescribing controlled drugs. They can also assist a Physician in appropriately assessing a patient’s need for long-term pain management drugs and whether the patient is appropriately using those drugs. The factors identified by the BOP are:

History and Physical – Generally speaking, it is improper to prescribe any medication for any patient without first taking the steps essential to evaluation. This is particularly true of the chronic pain patients because other treatment modalities may be beneficial and because it is important to recognize the addict who may complain of pain as a means to maintain a habit. Prescribing narcotics without a documented evaluation always represents substandard care.

Treatment Plan – Just as treatment for diabetes or hypertension has a specific objective, so should treatment for chronic pain. Frequently, the pain cannot be completely relieved but the use of analgesic drugs may lead to an improved sense of well-being, better sleep or even a return to work. The goal of analgesic therapy should be documented and the patient’s progress measured against this goal.

Informed Consent – Since long-term narcotic use will usually result in habituation and tolerance, these risks should be discussed with the patient. Alternatives should be offered if they exist and the clinical record should refer to the discussion.

Periodic Review – The course of treatment and the meeting of therapeutic goals should be periodically reviewed as is the case with any patient suffering from chronic disease. Modification of treatment or its discontinuation should be considered depending upon how well goals are being met. New information about the etiology of the pain or its treatment should be evaluated.

Consultation – The complexity of chronic pain frequently requires evaluation by consultants who may suggest alternatives or additions to therapy. This may be particularly true of the patient who is at risk for drug misuse. The patient with a history of substance abuse requires special care in documentation, evaluation and consultation before long-term opiate treatment can be safely prescribed. Some pain management specialists recommend a written agreement with these and other patients before such therapy.

Records – Adequate documentation is the key to manage- ment of these difficult patients and is the key to protecting the Physician from legal or Board action. Documentation of the steps noted above should be recorded in a fashion that would allow another practitioner to understand and follow through with treatment.

The concepts articulated in the Hobelmann letter serve as guidelines which provide the basis for the following practice suggestions:

1. A history and physical in a chronic pain patient should include a holistic evaluation. It should consider the specific etiology of pain (e.g., trauma), prior treatment to address the underlying cause of pain, radiology studies and any barriers to properly addressing pain such as depression or a patient’s financial concerns.

2. A patient’s experience with opioid medications should be clearly documented as certain pain management options such as Fentanyl patches depend on whether or not the patient is opioid-naïve.

3. It is critical that follow-up assessments be done by the Physician to determine how well the treatment plan is working. Also, regular evaluations of whether new or different modalities can be implemented to address the underlying cause of pain should be completed and included in the progress notes.

4. While not specifically addressed in the Hobelmann letter, it is strongly recommended that in addition to basic informed consent, a
patient embarking on chronic pain management drugs should execute a “pain contract” that explicitly states that opioid medications may be prescribed and that random drug testing and pill counts may be instituted.

5. It is critical that a patient understand that opioids can be addictive and are not to be abused or diverted. This will assist the practitioner in monitoring patient drug usage and will make clear to the patient that opioid medications, while useful, do have negative aspects to them. This will help the patient make a more considered decision. For example, for a patient with long-standing back pain, a practitioner may wish to consider new surgical options or block techniques. This will permit the patient to benefit from developing medical technology and may serve to eliminate or reduce the need for opioid medications.

6. It is strongly recommended that chronic pain sufferers be evaluated on a regular basis for whether referral to another specialist might be beneficial. As examples, would the patient benefit from a follow-up orthopedic evaluation or from physical therapy? Has any new radiological technology been developed that might help identify the cause of pain so that treatment of the underlying condition can occur? Does part of the patient’s pain profile include a psychological component that may be amenable to mental health therapy?

7. All of this should be documented and evaluation for other consultations should occur on a yearly basis, whether such consultation recommendations are made or not. For example, a consulting orthopedist should be able to rely on the pain management Doctor’s records in determining the history of the patient’s problems, what modalities have already been used and what options the patient has considered. It is not sufficient that boilerplate language is used. Considered and detailed records are necessary. All of this will assist in developing a good plan of care for the patient.

In addition to addressing clinical appropriateness of prescribing long-term pain management medications, a Physician must also be alert to potential indications of misuse and diversion. From the practitioner’s standpoint, diversion or other misuse of opioid pain medications can both inhibit a patient’s ability to actively participate in life activities because he or she is not properly using the pain medications and can pose serious legal concerns. If you have already had the patient execute a pain contract, the patient should be aware that opioid medications can be addictive and that you reserve the right to complete pill counts, urine testing and blood testing to ensure proper use of such medications. The key is to adequately address the patient’s pain issues while ensuring safe use of the opioid medications.

In addition to properly evaluating a chronic pain patient and developing a coherent plan of care, a practitioner should be aware of some of the “red flags” of potential abuse and diversion of prescription pain medications. It is strongly recommended that you document if a patient claims he has lost his pain medication, for example. Inquire into the circumstances and determine whether the explanation is legitimate. Also, has the patient repeatedly claimed a loss of medication? If so, there may be an issue of misuse or diversion.

Prescription drug abusers may complain about either vague or acute symptoms in order to obtain more medication and may show a lack of interest in treatment options other than medication. So, if the discussion of reconsidering or modifying his prescription elicits an angry and defensive response from the patient, the Physician should inquire further and consider whether the patient has

CME Test Questions

1. The risk reduction strategies outlined in Dr. Starrel’s study include all BUT:
   A. Urine testing
   B. Face-to-face office visits every six months
   C. Limiting the number of early refills
   D. Background checks

2. Use of boilerplate language is the most effective documentation tool to protect Physicians from allegations of inappropriate prescribing.
   A. True  B. False

3. Which of the following practices are consistent with risk reduction and good patient care?
   A. Executing a pain contract
   B. Instituting pill counts
   C. Random drug screens
   D. All of the above

4. Methods to control diversion include all of the following EXCEPT:
   A. Pill counts
   B. Random blood and urine testing
   C. Questioning the patient’s family members
   D. Inquiring about lost prescriptions

5. Which of the following are red flags that may signal diversion and misuse?
   A. Frequent requests for early refills
   B. Lack of interest in alternative treatment
   C. Vague symptoms
   D. All of the above

6. Dr. Starrel’s study identified which of the following problems with managing the risk of opioid misuse:
   A. Unclear definition of opioid abuse
   B. Lack of standards for the frequency of urine testing
   C. Lack of consistency and utilization of these tools and the definition of aberrant behavior
   D. B and C

7. The Maryland BOP has the authority to issue summary suspension orders in connection with an investigation of Physician prescribing practices.
   A. True  B. False

8. The BOP’s suggested practices concerning prescribing and monitoring of pain management drugs include all EXCEPT:
   A. History and physical
   B. Treatment plan
   C. Informed consent
   D. Criminal background check

9. Patients with a history of substance abuse warrant special care in evaluation, consultation and documentation.
   A. True  B. False

10. Chronic pain sufferers should be evaluated for specialty referral on a regular basis, at minimum once per year.
    A. True  B. False
CME Evaluation Form

Statement of Educational Purpose

Doctors RX is a newsletter sent twice each year to the insured Physicians of MEDICAL MUTUAL/Professionals Advocate.®

Its mission and educational purpose is to identify current health care related risk management issues and provide Physicians with educational information that will enable them to reduce their malpractice liability risk.

Readers of the newsletter should be able to obtain the following educational objectives:
1) Gain information on topics of particular importance to them as Physicians,
2) Assess the newsletter’s value to them as practicing Physicians, and
3) Assess how this information may influence their own practices.

CME Objectives for “Pain Management: A Physician Survival Guide”

Educational Objective: Upon completion of this enduring material, participants will be better able to:
1) Recognize the critical importance of complete work-ups of their patients
2) Identify warning signs of misuse of pain medication
3) Understand the issues that raise concern with the Board of Physicians when managing chronic pain

Part 1. Educational Value:

I learned something new that was important.

Strongly Agree Strongly Disagree
5 4 3 2 1

I verified some important information.

☐ ☐ ☐ ☐ ☐

I plan to seek more information on this topic.

☐ ☐ ☐ ☐ ☐

This information is likely to have an impact on my practice.

☐ ☐ ☐ ☐ ☐

Part 2. Commitment to Change: What change(s) (if any) do you plan to make in your practice as a result of reading this newsletter?

____________________________________________________________________________________________________________________________________________________________________________________________________________________________________________________________________________________


Signature: ____________________________ Date: ____________________________

Part 4. Identifying Information: Please PRINT legibly or type the following:

Name: __________________________________________ Telephone Number: ____________________________

Address: __________________________________________

Virginia Physicians

Like Maryland, the Virginia Board of Medicine appears aggressive in investigating and disciplining Physicians for the abuse of opioid pain medications and in relation to the provision of pain management drugs. Virginia providers should be familiar with Virginia law, including the Board of Medicine’s regulations governing the practice of Medicine and the Department of Health Professionals’ Drug Laws for Practitioners. Among other things, provi-
derers should use pain contracts, pain scales/activity logs, regularly query the Prescription Monitoring Program and avoid refilling prescriptions early. The Board of Medicine has a Guidance Document and information available on its web site: www.dhp.virginia.gov/medicine

Doctors RX

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HIPAA Reminder: Data Encryption – Do It Now!

The HITECH Act of 2009 made a number of changes to the HIPAA Security Rule – the most important being the requirement for HIPAA-covered entities and their business associates to provide notification in the event of a breach of “unsecured protected health information.” This means that if a hacker were able to gain access to a Physician practice’s computer system that contained protected health information (PHI), the Physician practice would have to inform all patients and the Department of Health and Human Services (HHS) of the breach. In certain situations, the practice is required by law to notify the local media.

Many Physicians and Physician practices believe that utilizing passwords is a sufficiently secure means of protecting electronic PHI. This is not the case, as hackers could remove the hard drive from devices, such as laptops, and access private information (including patient data) through another system. The one and only exception to this new requirement is encryption technology. Encryption is a technique that transforms information in such a way as to make it unreadable. Therefore, if electronic PHI is stored and transmitted in encrypted form, then you do not need to notify patients, even if a security breach occurs. For peace of mind and the security of your patients and the practice – encrypt!