Publication of Medical Mutual / Professionals Advocate®

DOCTORS Rx

Volume 20, No. 2 Fall 2012

A Letter from the Chair of the Board

Dear Colleague:

Pain management is a growing and necessary field of medicine, but full of landmines for the practitioner.

This issue of Doctors RX *seeks to sensitize Physicians practicing pain management about warning signs and how to avoid malpractice litigation and Board of Physician investigations.*

George S. Malouf, Jr., M.D.
Chair of the Board
Medical Mutual Liability Insurance Society of Maryland
Professionals Advocate Insurance Company

Pain Management: A Physician Survival Guide

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

Continued on next page

John T. Sly, Esq.
Waranch & Brown, LLC

providing pain management drugs may open them up to disciplinary action or civil liability. This issue of *Doctors RX* seeks to point a way forward for the management of long-term pain management patients from a risk management perspective. As always, good clinical practice and documentation will not only assist in the care and treatment of the patient, it will serve the Physician by helping to avoid legal issues.

Physicians may feel particularly vulnerable in situations where they find themselves caring for patients they did not expect to need long-term pain management. For example, an internist may find himself treating a patient for pain over an extended period of time when it initially appeared the need would only be temporary. In addition, by feeling inadequately trained to address the patient's long-term pain management needs, the general Physician may want to refer the patient to a pain specialist; however, specialists sometimes balk at taking over the management of patients already established on pain management drugs. The general Physician is then faced with either continuing long-term pain management or refusing to provide the care he or she believes the patient needs. Consequently, it may be advantageous to ensure specialty referrals are made early in the care.

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."[1]

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."[1] 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.[2,3] 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."[4]

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.[5] 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 management 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.

(Reproduced from March 1996 BPQA newsletter with permission from the Maryland Board of Physicians.)

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-naive.

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

Instructions for CME Participation

CME Accreditation Statement – MEDICAL MUTUAL Liability Insurance Society of Maryland, which is affiliated with Professionals Advocate® Insurance Company, is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for Physicians.

CME Designation Statement – MEDICAL MUTUAL Liability Insurance Society of Maryland designates this enduring material for a maximum of one (1) *AMA PRA Category 1 Credit*.™ Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Instructions – to receive credit, please follow these steps:

1. Read the articles contained in the newsletter and then answer the test questions.
2. Mail or fax your completed answers for grading:

   Med•Lantic Management Services, Inc.
   225 International Circle
   P.O. Box 8016
   Hunt Valley, Maryland 21030
   Attention: Risk Management Services Dept.

   Fax: 410-785-2631

3. One of our goals is to assess the continuing educational needs of our readers so we may enhance the educational effectiveness of the *Doctors RX*. To achieve this goal, we need your help. You must complete the CME evaluation form to receive credit.
4. Completion Deadline: March 1, 2013
5. Upon completion of the test and evaluation form, a certificate of credit will be mailed to you.

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 Objectives: 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

	Strongly Agree				Strongly Disagree
Part 1. Educational Value:	5	4	3	2	1
I learned something new that was important.	❑	❑	❑	❑	❑
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?

_____

_____

_____

Part 3. Statement of Completion: I attest to having completed the CME activity.

Signature: _____ Date: _____

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

Name: _____ Telephone Number: _____

Address: _____

_____

_____

_____

become addicted or is diverting the medication for money. A habitual prescription drug abuser is prone to frequent mood swings, anxiety and physical discomfort. Commonly, most prescription drug addicts have a past history of drug addiction and/or abuse. To hide their addiction, many prescription drug addicts will visit different Doctors or pharmacies to get more pills. The addiction may take an individual so far as to steal prescription medication from others. Be aware of complaints from family members and people in the community. Also, ensure that the local pharmacies know how to contact you with any concerns regarding your patients taking opioid pain medications.

As noted above, simple pill counts at office visits can help deter diversion and misuse. However, the Physician should consider the use of both urine and blood testing to determine the level, if any, of the prescribed medication in the patient's system, together with any other drugs. If the patient's systemic level is high, they are likely misusing the medication. If it is low or absent, diversion needs to be considered.

A Physician has a duty to properly address legitimate pain complaints by a patient. However, the Physician must also closely monitor the use of narcotic pain medications for the health of their patients and for their own protection. The Maryland BOP has been consistent over time regarding what they want to see out of Physicians practicing pain management and reiterated its support of the 1996 guidelines in a 2007 newsletter article related to the issue of pain management which is available at: http://www.mbp.state.md.us/forms/spring2007.pdf.

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 Professions' Drug Laws for Practitioners. Among other things, providers 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

References

1. *Carollo, Kim, "Many Doctors Fail to Monitor Potential Opioid Abuse Appropriately" http://abcnews.go.com/Health/primary-care-physicians-fail-monitor-patients-opioids-abuse/story?id=13149464 (March 17, 2011).*
2. *"Systematic Review: Treatment Agreements and Urine Drug Testing to Reduce Opioid Misuse in Patients With Chronic Pain" Ann Intern Med June 1, 2010 152:712-720.*
3. *Katz NP, Sherburne S, Beach M, et. al., "Behavioral monitoring and urine toxicology testing in patients receiving long-term opioid therapy" Anesthesia & Analgesia. 2003; 97(4):1097-102.*
4. *Heit, Howard A., et. al., "Tackling the Difficult Problem of Prescription Opioid Misuse" Ann Intern Med June 1, 2010 152:747-748.*
5. *Maryland BPQA Newsletter, Vol. 4, num. 1, pp. 1-3, Mar. 1996 ("Hobelmann Letter").*

Doctors RX

Elizabeth A. Svoysky, J.D., *Editor*
Assistant Vice President - Risk Management

Dr. George S. Malouf, Jr., M.D., *Chair of the Board*
MEDICAL MUTUAL Liability Insurance Society of Maryland
Professionals Advocate® Insurance Company

Numbers you should know!

Home Office Switchboard	410-785-0050
Toll Free	800-492-0193
Incident/Claim/ Lawsuit Reporting	800-492-0193
Risk Management Program Info	ext. 215 or 204
Risk Management Questions	ext. 224 or 169
Main Fax	410-785-2631
Claims Department Fax	410-785-1670
Web Site	mmlis.com proad.com

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!

Publication of Medical Mutual/Professionals Advocate®

DOCTORS Rx

Volume 20, No. 2 Fall 2012

Medical Mutual Liability Insurance Society of Maryland
Professionals Advocate® Insurance Company
Home Office: Box 8016, 225 International Circle
Hunt Valley, MD 21030 • 410-785-0050 • 800-492-0193

PRST STD
U.S. POSTAGE
PAID
PERMIT NO. 5415
BALTIMORE, MD