
Foreword

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Hippocrates' seemingly straightforward directive to “First, do no harm” is anything but simple in today's medical practice. Nowhere is its complexity more evident, and vexing, than in pain management with controlled substances—particularly with opioids.

Patients in pain who rely on opioids for analgesia and improved function deserve access to safe and effective medication; to deprive them of optimal pain-relief certainly does them harm. Yet these same life-restoring medications carry the potential to do grave harm to patients who may be at risk for addiction and abuse. Significant quantities of prescription opioids are diverted into an illegal black market that puts millions of non-medical “recreational” users at risk of addiction and death—many of them young adults and teenagers. Very few physicians are complicit in this criminal diversion, and there are no proven methods for preventing patients from deceptively acquiring prescriptions—pain, after all, is a subjective symptom for which there are no foolproof diagnostic tests. But the fact that some patients will deceive a physician in order to obtain prescription opioids for non-medical use requires us to be vigilant when prescribing these potent and potentially abusable medications.

Physicians cannot single-handedly eliminate the diversion and abuse of prescription opioids. *But we have a solemn responsibility—to our patients and to society—to be vigilant in reducing these risks.* Too few physicians have educated themselves about the simple steps they can take to become more responsible opioid prescribers.

Sadly, many physicians have sought to reduce the risks of opioid prescribing—including the tangible risk to a physician's own licensure if he or she prescribes outside the standards of medical care—by simply not treating patients in pain, or by not treating them with controlled substances. But as pain treatment becomes increasingly intertwined in the larger medical mission of patient care, it's increasingly important for physicians to become sophisticated about the risks and benefits of opioid therapy—the risks of diversion, abuse, and addiction as well as the benefits in managing acute and chronic pain.

Physicians who prescribe opioids are obliged to comply with both state regulations and the federal Controlled Substances Act. In 2005, there were approximately 720,290 Medical Doctors (MDs) and Doctors of Osteopathic Medicine (DOs) registered with the Drug Enforcement Administration (DEA). All physicians should be familiar with the clinical practices that will help them comply with state and federal statutes.

The Federation of State Medical Boards (FSMB) has commissioned this book and is distributing it to physicians to offer clear and concise guidance in managing the risks of pain management with opioids. Incorporating these strategies into your practice will help you fulfill your dual responsibilities to your patients and to your state and federal licensing authorities.

This book grows out of an initiative launched a decade ago by the FSMB to create its *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*. These consensus guidelines were formulated with input from the major stakeholders on all sides of the issue, including leading pain and addiction specialists, medical societies, state medical boards, and federal law enforcement agencies including the DEA. These guidelines, which were subsequently updated to a *Model Policy* in 2004, have been praised as “well balanced” by such groups as the Pain and Policy Study Group of the University of Wisconsin.* Twenty-eight state medical boards have adopted the Guidelines or *Model Policy* verbatim as their state guidelines, and ten other states have adopted guidelines with similar language.

The FSMB’s *Model Policy* distills safe opioid prescribing into seven concise principles:

1. Evaluation of the Patient
2. Treatment Plan
3. Informed Consent and Agreement for Treatment
4. Periodic Review
5. Consultation
6. Medical Records
7. Compliance With Controlled Substances Laws and Regulations

Although the *Model Policy* represents the most concise consensus guidelines for safe opioid prescribing, until now this document has not been translated into practical terms for clinical practice. Consequently, few physicians are

* For more information see www.medsch.wisc.edu/painpolicy.

familiar with these guidelines, and even fewer utilize them in their practice.

This book answers that unmet physician need by explaining how to incorporate the *Model Policy* into your real-life practice. Its author, Scott M. Fishman, MD, is Past President of the American Academy of Pain Medicine and a true thought leader in academic medicine, clinical practice, and public health policy. Dr. Fishman has worked closely with the FSMB on establishing the current *Model Policy* and has been a champion for safe and effective prescribing for pain management.

After reading this book, you'll understand simple steps you can take to comply with state and federal regulations regarding controlled substance prescribing for pain. FSMB's website (www.fsmb.org/pain) will keep this book updated and offers valuable links to state-by-state regulations and other useful websites to help facilitate pharmacovigilant opioid prescribing in your practice.

The term "pharmacovigilance" is one Hippocrates would surely have grasped. It derives from the Greek *pharmakon*, "drug;" and the Latin *vigilare*, "to keep awake and alert, to keep watch." In modern parlance, it refers to watchfully monitoring and managing the risks of adverse events and side effects of any medication, regardless of the class of drug. Becoming a pharmacovigilant opioid prescriber requires that we understand the risks specific to opioid analgesics and take simple steps to manage them.

Armed with the information in this essential handbook, we can each reaffirm our commitment to "First, do no harm."