The Drug Enforcement Administration and Proposed Model Guidelines for the Use of Controlled Substances in Pain Management

Speech by Patricia M. Good before the Federation of State Medical Boards Symposium on Pain Management and State Regulatory Policy
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INTRODUCTION

Good morning ladies and gentlemen. My name is Pat Good and I am Chief of the Liaison and Policy Section of the Drug Enforcement Administration's Office of Diversion Control. I appreciate the opportunity to have reviewed, and to be able to comment upon, the Federation of State Medical Boards' Proposed Model Guidelines for the Use of Controlled Substances in the Treatment of Pain. Perhaps some of you have heard my predecessor, Tom Gitchel, speak about DEA's recognition of the need for pain management guidelines, and its support of the development of pain management guidelines such as the ones you propose. Today I am going to re-emphasize a number of comments he made in the past.

THE FEDERAL LAW ENFORCEMENT ROLE

DEA carries out the mandates of the Controlled Substances Act (CSA) to prevent, detect and investigate the diversion of controlled substances by legitimate handlers. The provisions of the CSA related to prescription drugs exist so that controlled substances are available for legitimate purposes, while maintaining reasonable controls to prevent their diversion. DEA has consistently emphasized and supported the prescriptive authority of a physician under the CSA to prescribe, dispense or administer controlled substances for the treatment of pain within acceptable medical standards.

THE CSA / APPROPRIATE USE

The CSA specifically recognizes the essential medial purpose of the controlled substances, declaring that "the drugs...have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." (21 U.S.C. § 801(1)) The requirement under the CSA regarding a controlled substances prescription is that it must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. (21 C.F.R. § 1306.04(a))

DEA has consistently emphasized and stated that a physician should not hesitate to prescribe, administer or dispense controlled substances when they are indicated for a legitimate purpose. (Drug Enforcement Administration, Physician's Manual, Rev. Mar. 1990, 21.) However, the CSA by design does not define "legitimate medical purpose" nor does it set forth standards of medical practice. These issues can only be defined by the medical community and its internal review processes.

The CSA does not address medical treatment issues such as selection or quantity of the drug prescribed. Such medical decisions arise from the prescribing physician's medical judgment. DEA concurs that a physician's medical judgment is the first step in determining the appropriate course of action in the treatment of pain. This judgment must be based upon professional training, medical specialty and practice guidelines. That judgment, in concert with the establishment of a bona fide physician-patient relationship which includes thorough examination of the patient, a review of the patient's medical history, and proper follow-up and monitoring, combine to constitute legitimate medical practice. The physician has a continuing responsibility to monitor the patient receiving controlled substances and to re-evaluate their original judgment on an on-going basis. The proposed guidelines serve to institutionalize this philosophy.

Professional conferences and peer-reviewed research also greatly assist in providing a physician with clarification as to what constitutes acceptable medical practice for the management of pain with controlled substances. Since the proposed model guidelines reflect the latest currently acceptable standards, they will prove invaluable in helping a physician form his medical judgment in making pain management decisions, in providing the elements necessary for legitimate pain treatment, and in allaying any fear of adverse consequences from licensing boards or investigative agencies when none is justified. In short, the guidelines assist everyone concerned in better defining the elements of legitimate pain treatment, thereby providing the courts and licensing boards a sound and definitive basis to judge instances which clearly fall outside acceptable norms.

Although the proposed model guidelines under consideration do not intend to define the complete or best medical practice, they do communicate what state medial boards consider to be within the boundaries of professional practice and eliminate some currently existing "gray areas."

THE NEED FOR REGULATORY AND LAW ENFORCEMENT SCRUTINY

Drugs used in pain management are addictive, abused and trafficked. Unfortunately, there are dishonest physicians and other health professionals who willingly abuse the public trust conveyed by their license and knowingly sell these drugs to abusers or traffickers. There are physicians prescribing large quantities of controlled substances for the illicit market, and their actions will, on occasion, cast suspicion on other legitimate large prescribers until the facts are known. There are other physicians, negligent though well-meaning, who either feel that they are alleviating the pain and suffering of patients who are misusing or selling the medications or who readily prescribe without due diligence.

Engaging in pain treatment does not give a physician’s license to ignore the fact that abusers may attempt to take advantage of the doctor. Some abusers or criminal "rings," referred to as "doctor-shoppers," specifically target physicians specializing in pain treatment. While we recognize that the[sic] these physicians are practicing within accepted medical standards, their "doctor shopping" patients generate law enforcement and regulatory scrutiny. Physicians engaging in pain treatment must maintain certain levels of responsibility to minimize the risk of inappropriate prescribing and diversion.

Although the element of motivation varies between the dishonest and negligent physicians, the activities of each can result in the diversion of controlled substances. Better education of all health care professionals in the field of pain management is essential and should include training about patient scams, diversion and abuse. Likewise, the proposed model guidelines serve to educate both health care professionals and regulators as to the propriety of pain management treatment elements. From a law enforcement standpoint, the guidelines will help pierce the veil of pain management legitimacy that some unscrupulous physicians hide behind to divert drugs for non-medical uses.

DEA INVESTIGATIONS

When DEA receives complaints or first encounters unusual prescribing patterns or illegal sales of the prescribed drugs by patients, DEA and its state counterparts pursue information to first determine whether it appears that the prescribing activity is legitimate. State medical boards, empowered by their state legislatures and comprised of physicians, are generally the first line monitoring the medical professional and in disciplining physicians who prescribe controlled substances, including narcotics, in a manner which constitutes questionable practice. The medical boards review practices against standards of acceptable medical practice. The proposed model guidelines, in setting out the required elements of legitimate pain practice, minimize the importance of historically suspicious factors such as prescribing

quantity and frequency, and place them in the proper context of other factors present in legitimate treatment.

DEA generally refers more questionable practices to the appropriate medical board for determination of whether the practitioner complied with the standard of acceptable medical practice. DEA will actively pursue action when a physician's activities are clearly outside the scope of legitimate medical practice and pursues prosecution or licensing action. Even then, enforcement authorities and other courts rely upon testimony of medical experts to distinguish acceptable medical treatment from criminal, unethical or negligent activities. But a physician need not fear DEA action of prescribing controlled substances in good faith for a legitimate medical purpose within the acceptable scope of professional practice, with appropriate documentation. The proposed model guidelines help clarify whether a physician's controlled substance handling falls within or without acceptable standards of medical practice.

CONCLUSION

In conclusion, there is no Federal law or regulation inhibiting a physician from treating a patient with controlled substances other than the requirement that the treatment occur in accordance with acceptable medical standards and within the usual course of professional practice. DEA advocates appropriate medical prescribing of controlled substances for bona fide patients. DEA investigates and takes actions against registrants when the controlled substance prescribing is clearly outside "the usual course of professional practice." "Gray areas," of practice are generally referred to the appropriate state medical board for determination of the standard. The proposed guidelines help eliminate "gray areas" of practice.

DEA has long encouraged the developing education programs and practice guidelines in this area to better inform practitioners of both the proper treatment of pain and appropriate prescribing practices, as well as of the safeguards to prevent patient diversion and abuse. A delicate balance exists between efforts to control drug diversion and abuse and the legitimate practice of medicine and the availability of controlled substances for patients in need. The proposed model guidelines will go far in helping to preserve this delicate balance. The guidelines will help physicians comply with acceptable pain management standards and will help DEA and other regulators determine whether such treatment is appropriate under the circumstances. Perhaps most importantly, the guidelines will help ensure patient access to needed controlled substances for pain management.