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Legal Aspects of Opioid Management

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WHAT IS THE PROBLEM?

Why the Concern?

- In 2010, New Jersey saw 7,238 admissions to State-licensed or certified substance abuse treatment programs as a result of prescription painkiller abuse. That number represents a dramatic increase of nearly 2,000 from the previous year's admissions, and an increase of more than 5,000 from 2005, according to statewide statistics.
- In the United States, every day 2,500 youths take a prescription pain reliever for the purpose of getting high for the very first time, according to the Office of National Drug Control Policy.
- The number of American teenagers and adults who abuse prescription drugs is greater than those who use cocaine, hallucinogens, and heroin combined, according to the 2009 National Survey on Drug Use and Health, compiled by the US Department of Health and Human Services.
- In 2010, drug overdose deaths outnumbered motor vehicle traffic deaths in 31 states.
- Top 20% of prescribers account for 72% of prescriptions and 63% of overdose deaths.

Nevertheless ..

It is well recognized that narcotics are valuable agents in reducing the suffering of many patients who otherwise would experience a greatly diminished quality of life.

Balance

- Government has an obligation to establish a system of controls to prevent abuse trafficking and diversion of narcotic drugs while at the same time ensuring their medical availability. (available at http://www.painpolicy.wisc.edu).
- Physicians, therefore, are also tasked with considering both the needs of the individual patient and the public's health and safety.

Risks of Wrongdoing When Prescribing Narcotics

- Criminal Conviction
- Administrative Action (e.g., loss of medical license, loss of CDS or DEA registration)
- Medical Malpractice Actions

LEGAL STANDARDS

Legal Standards - Generally

Even though there are different legal standards for imposing criminal, administrative and medical malpractice penalties (e.g., criminal prosecution is based upon activities that fall outside the usual course of professional practice vs. medical malpractice actions that are based on substandard care), the relevant standard of care is typically a consideration in such legal proceedings.

Criminal/Administrative Legal Standards – Federal and New Jersey

"A prescription for a controlled substance to be effective must be issued for a *legitimate medical purpose* by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . . An order purporting to be a prescription issued not in the *usual course* of professional treatment . . . is not a prescription within the meaning and intent of [the Controlled Substances Act] 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." *21 CFR 1306.04*

New Jersey regulation (*NJAC 13:45H-7.4*) reiterates this Federal regulation.

Criminal/Administrative Legal Standards – Supreme Court

In US v. Moore (1975), the Supreme court held that registered physicians may be prosecuted for violation of the Controlled Substances Act when their activities fall outside the usual course of professional practice.

Practically

In order to be found in violation of the law, a physician must:

- Distribute (e.g., prescribe) or dispense a controlled substance;
- Act knowingly;
- Act in a manner that was not for legitimate medical purposes in the usual course of his professional medical practice or is outside of the bounds of medical practice.

Good Faith – Standard of Care

- In US v. Hurwitz, the US Court of Appeals (4th Circuit) determined that the an objective standard should be applied when determining if a physician has acted in "good faith" (for purposes of determining "legitimate medical purposes")
- Further, Hurwitz notes "[g]ood faith is not merely a doctor's sincere intention towards the people who come to see him, but, rather, it involves his sincerity in attempting to conduct himself in accordance with a standard of medical practice generally recognized and accepted in the country." (quoting US v. Hayes (9th Cir. 1986))

Standard of Care

Note: Even though criminal liability does not extend to physicians who are merely practicing below the standard of care, evidence that a physician has practiced within the standard of care is an effective defense to criminal charge (as well as medical malpractice claims).

PROTECTING AGAINST ALLEGATIONS OF WRONGDOING

Demonstrating Good Faith

Physicians need to establish that they made a good faith attempt to comply with recognized standards of care when prescribing narcotics.

Strategies

- Strategies to establish good faith include:
  - Screening instruments
  - Consideration of clinical guidelines
  - Narcotic therapy agreements
  - Ongoing monitoring
  - Prescription monitoring program reports

Screening instruments

- According to the standard of practice in medical literature, screening tools should allow for physician to identify risks, stratify patients into categories of risks and provide levels of care that reflect the identified risk.
- Validated screening tools should be used.

Screening instruments

Turning a blind eye on high risk behaviors or traits has been a common characteristic of physicians who have been convicted for violating State and Federal controlled substances laws.

Screening Tools

Screening assessments must be well documented in order to be effective.

Example: In February 2010, the DEA published its opinion in the matter of Jerri Hassman, MD (Notice of Denial Application). In that case, expert testimony established that appropriateness of prescribing controlled substances depends on the level of documentation, and without adequate documentation, it is inappropriate to prescribe. From that opinion it is clear that physician must document completely their rationale for prescribing else they risk loss of their DEA registration.

Clinical Guidelines

- Clinical practice guidelines can be controversial (depending on the information used to establish the guidelines); nevertheless, they may provide protection from legal liability for allegedly inappropriate care.
- Adherence to such guidelines tends to be persuasive evidence of conformance with a recognized standard of practice.

Narcotic Therapy Agreement

- Although the effectiveness of Narcotic Therapy Agreements is still debated, they provide a framework for establishing a clear set of rules governing the relationship between physician and patient.
- Narcotic Therapy Agreements do not replace, and should be used in conjunction with, an informed consent process that clearly outlines the risk of abuse and addiction.

Narcotic Therapy Agreement

A well drafted Narcotic Therapy Agreement includes:

- A discussion of the risks of narcotics
- A description of the physician's policies regarding refills, urine screening, keeping appointments, etc.
- An outline the patient's responsibility (taking medication at dose and frequency prescribed, storage, disclosure of other medications, no forum shopping, etc.)
- A clear statement that the physician may stop prescribing the narcotic if there is a violation of the agreement

Ongoing Monitoring of Compliance

- Screening instruments and narcotic therapy agreements are ineffective if there is not documentation of ongoing monitoring of compliance with prescription regimens.
- Physicians need to be aware of the signs of misuse.
- Typically ongoing monitoring involves random urine testing. Other monitoring (e.g., review of appointment cancellations, other types of testing, review of prescription monitoring databases) should be considered when warranted.

New Jersey Prescription Monitoring Program ("NJPMP")

- NJPMP is a Statewide database that collects prescription data on Controlled Dangerous Substances and Human Growth Hormone dispensed in outpatient settings in NJ (*NJSA 45:1-45 et seq*)
- Access is available to prescribers and pharmacists who are licensed in NJ and who are in good standing with their respective licensing boards.

NJPMP Requirements

- A new law requires practitioners to access the NJPMP database prior to prescribing Schedule II controlled dangerous substances:
  - To **NEW** patients for acute or chronic pain; and
  - On a quarterly basis for **ALL** patients during the period of time the patient continues to receive such Schedule II controlled dangerous substances.
- Unless, an exception is met . . .

Exceptions

- A practitioner does **not** need to access the NJPMP database in certain circumstances such as:
  - When prescribing no more than a five-day supply of a controlled dangerous substance in the emergency department of a general hospital;
  - When administering a controlled dangerous substance directly to a patient;
  - When prescribing a controlled dangerous substance to be dispensed by an institutional pharmacy; or
  - When prescribing less than a 30-day supply of a controlled dangerous substance to a patient immediately after the patient has undergone an operation, procedure, or treatment for acute trauma.
- Practice Tip: If possible, check the NJPMP database prior to prescribing to avoid questions and ambiguities

NJPMP

- Problem: Patients may obtain medications from other states.
- Many (but not all) states, including New York, currently participate in the NABP PMP Interconnect, which facilitates the transfer of prescription monitoring program ("PMP") data across state lines.
- Pennsylvania does not currently share their PMP data; however, Pennsylvania is in the process of becoming a PMP Interconnect participant.

OPTIONS IN ADDRESSING A DIFFICULT PATIENT

Addressing the Difficult Patient

If misuse is identified or suspected, steps need to be taken to protect the patient and the physician.

Options In Addressing A Difficult Patient

Physicians can discharge a patient for any reason provided the physician gives the patient thirty-days notice in writing and provides care during those thirty-days.

Note: consideration still needs to be given to the impact of withdrawal.

Addressing the Difficult Patient

Alternatively, patients can be referred to pain management specialists for appropriate monitoring and follow-up.

Addressing the Difficult Patient

Consideration can also be given to other clinical options such as abuse-deterrent opioids.

Addressing the Difficult Patient

Regardless of the approach that is taken, once a physician is aware that a patient is abusing or selling narcotic medications, the physician can be held liable (under criminal laws, medical malpractice and by administrative agencies) if he or she continues to prescribe the narcotics.

Note: as of now, the law is rather ambiguous as to the physician's responsibility for the wrongdoing of patients and most case law favors the physician. Nevertheless, the courts tend to have little tolerance for physicians who ignore problem patients.

2013 NEW JERSEY OVERDOSE PREVENTION ACT

- As of February 5, 2015, health care practitioners can prescribe (and pharmacists can dispense) through a standing order, an opioid antidote *(i.e.,* naloxone hydrochloride aka "Narcan") to a person that is deemed capable by the health care practitioner of administering the antidotes to overdose victims (e.g., law enforcement, first responders and family members).
- Practitioners who prescribe (and pharmacists who dispense) Narcan in good faith will not be subject to criminal or civil liability or subject to any professional disciplinary action.
- The New Jersey State Board of Medical Examiners (the "BME") has issued a certificate of waiver allowing physicians and other prescribers to write a prescription for Narcan in the name of the person receiving the prescription, rather than the end user who will be administered the agent.
- In addition, the BME has waived the requirements for a physical examination before or follow up appointment after the issuance of the prescription for the antidote.

FINAL NOTE

PROTECT PRESCRIPTION PADS

PROTECT PRESCRIPTION PADS

- Keep an index of your prescription pads.
- Store prescription pads under lock and key.
- Immediately report missing prescription pads.

PROTECT PRESCRIPTION PADS

A licensed practitioner practicing in this State must maintain a record of the receipt of New Jersey Prescription Blanks. *NJSA 45:14-55*

REPORT LOST PRESCRIPTION PADS

The practitioner must notify the NJ Office of Drug Control in the Division of Consumer Affairs as soon as possible but no later than 72 hours of being made aware that any New Jersey Prescription Blank in the practitioner's possession has been stolen. Upon receipt of notification, the Office of Drug Control shall take appropriate action, including notification to the Department of Human Services and the Attorney General.

Summary

- Standard of Care
- Document, Document, Document
- Be Awake

Questions

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