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Legal Aspects of Opioid Management

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Agenda

- The Opioid Issue
- Legal Standards
- Protecting Against Allegations of Wrongdoing
- Options in Addressing a Difficult Patient
- Protecting Prescription Pads
- Questions

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.
- 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).

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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.

Note: Not following the law applicable to dispensing opioids will challenge the defense of good faith

Strategies

- Strategies to establish good faith include:
  - Screening instruments
  - Consideration of clinical guidelines
  - Pain management 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 physicians must document completely their rationale for prescribing else they risk loss of their DEA registration.

Clinical Guidelines

- Clinical practice guidelines can differ (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.

Pain Management Agreement

A written contract or agreement that is executed between a practitioner and a patient prior to the commencement of treatment for chronic pain using a Schedule II controlled dangerous substance or any other opioid drug which is a prescription drug.

Pain Management Agreement

The new prescribing law in New Jersey provides that the pain management agreement is intended to cover the following concerns:

- Prevent the possible development of physical or psychological dependence on the patient;
- Document the understanding of both the practitioner and the patient regarding the patient's pain management plan;
- Establish the patient's rights in association with treatment and the patient's obligations in relation to the responsible use, discontinuation of use, and storage of Schedule II controlled dangerous substances, including any restrictions on the refill of prescriptions or the acceptance of Schedule II prescriptions from practitioners

Pain Management Agreement

- Identify the **specific medications and other modes of treatment**, including physical therapy or exercise, relaxation, or psychological counseling, that are included as a part of the pain management plan;
- Specify the measures the practitioner may employ to **monitor the patient's compliance**, including but not limited to random specimen screens and pill counts; and
- Delineate the process for **terminating the agreement**, including the consequences if the practitioner has reason to believe that the patient is not complying with the terms of the agreement

Ongoing Monitoring of Compliance

- Screening instruments and pain management 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, and by out-of-state pharmacies (*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

- Practitioners are required 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 . . .

- Note: Again, failure to check the NJPMP – besides being a violation of the law – will challenge a "good faith" defense

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, always check the NJPMP database prior to prescribing to avoid questions and ambiguities and conflicts with the new prescribing law

NABP PMP Interconnect

- Problem: Patients may obtain medications from other states.
- Many (but not all) states currently participate in the NABP PMP Interconnect, which facilitates the transfer of prescription monitoring program ("PMP") data across state lines.
- The 10 States that do not currently share their PMP data are: Washington, Oregon, California, Wyoming, Nebraska, Missouri, Florida, North Carolina, Pennsylvania and Hawaii.
- However, Pennsylvania, North Carolina, and Wyoming are in the process of becoming PMP Interconnect Participants.

New Prescribing Law for Treatment of Acute and Chronic Pain

- On February 15, 2017, Governor Christie signed a bill into law that sets a 5-day limit on initial prescriptions for pain-killing opioids for acute pain
- The law went into effect on **May 16, 2017**.
- Applies to physicians, dentists, optometrists, podiatrists, physician assistants, certified nurse midwives and advance practice nurses authorized to prescribe controlled substances

Prior to Issuing an Initial Prescription for Acute or Chronic Pain

- Prior to issuing an initial prescription* for acute **or** chronic pain the practitioner must:
  - Take and document the results of a thorough medical history, including the patient's experience with non-opioid medication and non-pharmacological pain management approaches and substance abuse history;
  - Conduct, as appropriate, and document the results of a physical examination;
  - Develop a treatment plan, with particular attention focused on determining the cause of the patient's pain; and
  - Access relevant prescription monitoring information under the Prescription Monitoring Program

*An "initial prescription" means that the patient has not had a prescription for that medication (or pharmaceutical equivalent) in the **last year**. Talking to the patient, looking at their medical record and checking the Prescription Monitoring Program is necessary to determine whether your prescription would be the patient's "initial" prescription.

Issuing an Initial Prescription for Acute Pain

- No practitioner may issue an initial prescription for a Schedule II controlled dangerous substance or any opioid drug, which is a prescription drug, in a quantity exceeding a *five day supply for treatment of* ***acute pain***.
- Any prescription for **acute pain** must be the *lowest effective dose of immediate-releasing opioid drug*.
- "Acute pain" means pain, whether relating from disease, accidental or intentional trauma, or other cause, that the practitioner reasonably expects to last only a short period of time.

Issuing Subsequent Prescriptions for Acute Pain

- **No less than 4 days** after issuing the initial 5-day prescription, the practitioner may issue a subsequent prescription in any quantity that complies with State and federal laws provided that:
  - The subsequent prescription would not be deemed an initial prescription under the law;
  - The practitioner deems the Rx is necessary and appropriate to the patient's treatment needs and **documents the rationale for issuing the subsequent prescription**; and
  - The practitioner determines that issuing the subsequent prescription does not present an undue risk of abuse, addiction or diversion and documents that determination.

Discussions with Patient and Notations in the Patient's Record

- Prior to issuing the 1st prescription for acute **or** chronic pain, **and** again prior to issuing the 3rd prescription, the practitioner must discuss with the patient (or parent/guardian, as applicable):
  - The risks of addiction and overdose associated with opioid drugs and the dangers of taking opioid drugs with alcohol, benzodiazepines and other CNS depressants;
  - The reasons why the Rx is necessary;
  - Alternative treatments that may be available; and
  - Risks associated with the use of the drugs being prescribed (specifically, that opioids are highly addictive, even when taken as prescribed, there is a risk of developing a physical or psychological dependence, and the risks of taking more than prescribed or mixing them with sedatives, benzodiazepines or alcohol can be fatal)
  - This discussion must be noted in the patient's medical record

Note: Consider use of a form.

Enter into Pain Management Agreement

- At the time of issuance of the 3rd prescription, the practitioner must enter into a pain management agreement with the patient.

Note: It is unclear whether this is intended to be the third *month* of prescribing or just the third prescription. As written, it could be sooner than the third month.

New Prescribing Law for Treatment of Acute and Chronic Pain

- If the drug is prescribed for 3 months or more for chronic pain, the practitioner must:
  - Review, at least every 3 months, the course of treatment, any new information about the etiology of the pain, and the patient's progress toward treatment objectives and **document the results of that review**;
  - **Assess** the patient prior to every renewal to determine whether he/she is experiencing problems associated with physical or psychological dependence and document the results of the assessment;
  - Periodically make reasonable efforts, unless clinical contraindicated, to either stop the use of the drug, decrease the dosage, try other drugs or treatment modalities and document the efforts undertaken;
  - Review the PMP on a **quarterly basis**; and
  - Monitor compliance with the pain management agreement and any recommendations that the patient seek a referral.

New Prescribing Law: Exemptions

- Patients in active treatment for cancer;
- Patients receiving hospice care from a licensed hospice or palliative care;
- Residents of a long-term care facility;
- Medications that are prescribed in the treatment of substance abuse or opioid dependence (medication assisted treatment)

New Prescribing Law: Mandatory Continuing Education

- Physicians, physician assistants, dentists and optometrists: must complete one CME credit on topics that include responsible prescribing practices, alternatives to opioids for managing and treating pain and the risks and signs of opioid abuse, addiction and diversion.
- For advance practice nurses: the required 6 contact hours of continuing professional education in pharmacology related to controlled substances will include issues concerning prescription opioid drugs, including responsible prescribing practices, alternatives to opioids for managing and treating pain, and the risks and signs of opioid abuse, addiction and diversion.
- Other Health care professionals who do not have prescribing authority but who frequently interact with patients who may be prescribed opioids (including pharmacists, professional nurses, and practical nurses) must also complete 1 continuing education credit on topics that include alternatives to opioids for managing and treating pain and the risks and signs of opioid abuse, addiction and diversion.
- The continuing education credits required will be part of the professional's regular continuing education credits and will not increase the total number of continuing education credits required.
- **This will be effective for the 2017-2019 biennial license renewal.**

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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.

- Alternatively, patients can be referred to pain management specialists for appropriate monitoring and follow-up.
- Consideration can also be given to other clinical options such as abuse-deterrent opioids.

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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Biography

Andrew E. Blustein is the Vice Chairman of Garfunkel Wild, P.C. He joined the firm in 1993 and is a member of the firm's Health Care, Business, and Compliance and White Collar Defense practice groups. He is Co-Chair of both the HIPAA Compliance Group and the Health Care and Information Technology Practice Group and Chair of the Insurance Regulatory Practice Group.

Mr. Blustein's practice includes the representation of hospitals, physicians, ambulatory surgery centers and other healthcare industry-related clients (both for profit and not-for-profit). Mr. Blustein has been a leader in developing and implementing HIPAA Compliance Programs for healthcare providers and health plans, advising ambulatory surgery centers and assisting hospitals in strategic affiliations. He frequently lectures on HIPAA, physician practice issues, cyber-security, telemedicine, corporate transactions, legal aspects of opioid management and computer contracting.

Admitted to the New Jersey Bar, the New York Bar and the Connecticut Bar, Mr. Blustein is a member of the New York State Bar Association, the New Jersey State Bar Association (Health and Law Section); Past Co-Chairman of the Westchester County Bar Association (Hospital and Physician Law Section) and the American Health Lawyers Association.

Mr. Blustein graduated from Vassar College in 1987 (B.A., Phi Beta Kappa, cum laude) in 1987 and Benjamin N. Cardozo School of Law (J.D., magna cum laude) in 1990.

Publications

Seller Preparation in the Months Before the Sale, The Ambulatory M&A Advisor (quoted) September 28, 2016

Co-authored chapter of "Representing Physicians Handbook, Third Edition" entitled "Compliance, Compliance Plan, and Process for the Physician Practice," American Health Lawyers Association, January 2013

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Presentations

NY Metro ASC Symposium (Featured Speaker 2014-2016)

"Legal Aspects of Opioid Management," NJ Partnership For a Drug Free America (2013-2016)

"Protecting Your Practice from Cybercrime: Guidance from the Front Lines," NJ MGMA Practice Management Conference (June 2, 2016)

"Protecting Factors of Healthcare Receivables," Webinar for the International Factoring Association (May 18, 2016)

Honors
Top Healthcare Transaction Lawyers (2016)
The Ambulatory M&A Advisor Leading Lawyers List (2014-2015)
New York Super Lawyers - Metro Edition (2010-2016)

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