OPIOID PRESCRIBING: PROTECTING YOUR PATIENTS AND YOUR LICENSE

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BY THE NUMBERS

Statistics:

US consumes 90% of world's opiates

1/3 of all opioid prescriptions are being abused

Annually

$55 billion in healthcare and social costs

$20 billion in emergency and inpatient care

Daily

650,000+ opioid prescriptions

3,900 initiate nonmedical use of Rx opioids

580 initiate heroin use

78 die in opioid-related overdose (more than car crashes)

According to recent provisional data from the CDC, the opioid epidemic kills about 130 Americans daily.

THE "MANAGEMENT" OF PAIN

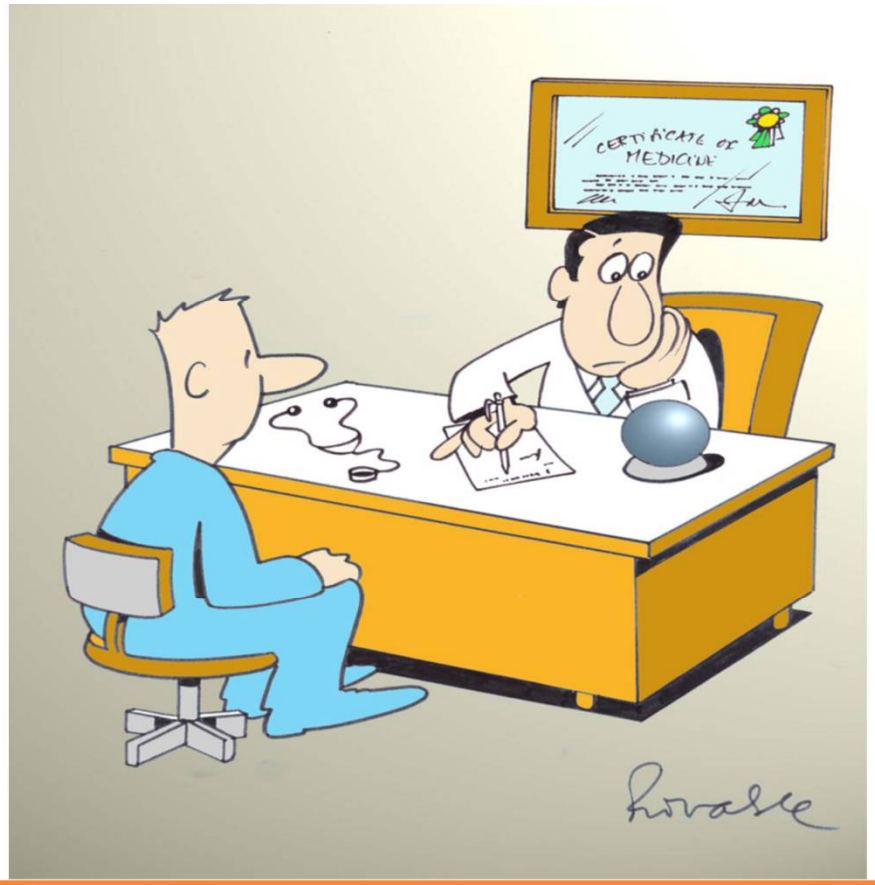
Challenge facing providers: managing patients' expectations with regard to *management* of pain vs. *eradication* of pain.

Day 4 soreness from a minimally invasive laparoscopic procedure may be normal. Breakthrough cancer pain may be something that justifies a more aggressive approach with regard to pain management.

February 12, 2019 Hearing of the U.S. Senate Committee on Health, Education, Labor & Pensions: Dr. Gazelka, who practices Pain Medicine and Palliative Medicine at the Mayo Clinic, described some general guidelines they developed there (i.e., 3 days for acute Emergency Room presentations and 15 days for knee replacement surgeries) and how the decision depends upon the individual patient and therefore, must be left to the discretion of the physician.

In the current enforcement environment, liability is being shared by all parties along the supply-chain continuum.

Prescribers, seen as the “gatekeepers,” continue to be targets.


CERTIFICATE OF
MEDICINE

Potential Liability for Negligent Prescribing

- Harm to patient
(e.g., addiction, fatal overdose)

- Harm to others
(e.g., motor vehicle accidents, diversion)

ENFORCEMENT

Recent prosecutions are a reminder that prescribers remain a focus of law enforcement efforts:

- A Houston doctor and the owner of the pain management clinic where she worked were each sentenced to **35 years in prison** by a federal judge in Texas for their roles in running what prosecutors described as the "most prolific hydrocodone pill mill in Houston." The scheme involved more than 18,000 prescriptions for more than 2.1 million hydrocodone pills and more than 15,600 prescriptions for more than 1.3 million carisoprodol pills. Notably, the business was operated on a cash-only basis.
- "Operation Busted Script" in New Jersey: A physician pled guilty to charges that he wrote **prescriptions without a medical purpose** to supply a drug ring with tens of thousands of high-dose pills of oxycodone, and second-degree charges of conspiracy and distribution of a controlled dangerous substance. Under the plea agreement, the State is recommending **surrender of his medical license** and a **10-year prison sentence**. A co-conspirator of the physician shared an office with the physician and operated a hearing aid company.
- An **elderly married couple** from Westchester County, New York was targeted for operating a primary care medical practice that transformed into a $77M black market pill mill. The practice was found to have generated thousands of **illegitimate prescriptions for Oxycodone** in exchange for illegal cash payments. The physician (who surrendered his medical license in 2016 while charges were pending) and his practice manager wife were each sentenced to **prison terms** and will be subject to **civil asset forfeiture** proceedings.

CDC GUIDELINES ON PAIN MANAGEMENT

Determining when to initiate or continue opioids for chronic pain

- Selection of non-pharmacologic therapy, non-opioid pharmacologic therapy, opioid therapy
- Establishment of treatment goals
- Discussion of risks and benefits of therapy with patients

Opioid selection, dosage, duration, follow-up and discontinuation

- Selection of immediate-release or extended-release and long-acting opioids
- Dosage considerations
- Duration of treatment
- Considerations for follow-up and discontinuation of opioid therapy

Assessing risk and addressing harms of opioid use

- Evaluation of risk factors for opioid-related harms and ways to mitigate/reduce patient risk
- Review of prescription drug monitoring program (PDMP) data
- Use of urine drug testing
- Considerations for co-prescribing benzodiazepines
- Arrangement of treatment for opioid use disorder

ISSUING AN INITIAL PRESCRIPTION FOR ACUTE PAIN IN NEW JERSEY

No authorized prescriber 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 *5-day supply for treatment of acute pain* (even post-operative pain). The law does NOT address what constitutes a 5-day supply; however it does provide that any prescription for *acute pain* shall be the lowest effective dose of immediate-release opioid drug.

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, reviewing the medical record and checking the PMP is necessary to determine whether your prescription would be the patient's "initial" prescription.

A CLOSER LOOK AT NEW JERSEY'S REGULATION

WHICH PROVIDERS ARE COVERED BY THE REGULATION?

Physicians, dentists, optometrists, podiatrists, physician assistants, certified nurse midwives, or advanced practice nurses authorized to prescribe controlled substances.

WHICH PATIENTS ARE EXEMPT FROM THE REGULATION?

The regulation provides a carve-out for a patient who is currently in active treatment for cancer, receiving hospice care from a licensed hospice or palliative care, or is a resident of a long term care facility, or to any medications that prescribed in the treatment of substance abuse or opioid dependence (medication assisted treatment), BUT NOTE, the standard of care still applies to these situations.

PRIOR TO ISSUING AN INTIAL PRESCRIPTION FOR ACUTE OR CHRONIC PAIN:

(i) 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;

(ii) develop a treatment plan, with particular attention focused on determining the cause of the patient's pain;

(iii) access relevant prescription monitoring information under the Prescription Monitoring Program; and

(iv) discuss the risks of opioid dependence/addiction with the patient.

ISSUING SUBSEQUENT PRESCRIPTIONS FOR ACUTE PAIN

No fewer than four days after the initial 5-day prescription, an authorized prescriber may issue a prescription for no more than a 30 day-supply, if necessary.

There are several options available to issue a subsequent prescription after the initial 5-day supply. The regulations require assessment of the patient prior to issuing any subsequent prescriptions, but this does not require a physical exam or office visit:

1. The patient comes into the office to pick up the prescription order, with or without a physical exam;

2. The prescriber can electronically prescribe the Scheduled II CDS or opioid prescription if your system is set up to e-prescribe CDS; or

3. If the patient is unable to come to the office and e-prescribing is unavailable, current NJ regulations authorize the prescriber to call in an emergency oral prescription for pharmacies to dispense a Schedule II controlled substance in an amount not to exceed a 72 hour quantity necessary to treat the patient during an emergency. However, a written prescription with "Authorization for Emergency Dispensing" and the date of the oral order must be written on it and sent within seven days to the dispensing pharmacist in person or by mail/postmarked within the seven day period. *See N.J.A.C. 13:45H-7.8*

Discussions with the patient should include:

- possible alternative treatments
- why the medication is being prescribed and the treatment goals
- the name of the medication, the strength, dosage and quantity being prescribed
- the risks associated with the drug being prescribed
  - the risk of developing a physical or psychological dependence or addiction, even when the medication is taken as prescribed
  - the risk of mixing the medication with alcohol, benzodiazepines (such as Xanax) and other central nervous system depressants
  - the risk of taking more opioids than prescribed
  - the risk of driving or operating machinery while taking opioids
  - the risk of overdose and potentially fatal respiratory depression
- the importance of safeguarding the medication and properly disposing of any leftovers

  (Project Medicine Drop or other collector registered with the DEA)
- the availability of an opioid antidote such as Narcan™ (naloxone)

PAIN AGREEMENTS NOW REQUIRED FOR TREATMENT OF CHRONIC PAIN

Pain management agreements are *mandatory when treating chronic pain*, defined as the continuous treatment for pain for 3 months or more. The law provides:

When a Schedule II CDS or any other opioid drug is continuously prescribed for chronic pain, the practitioner shall:

(1) review, at a minimum of 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;

(2) assess the patient prior to every renewal to determine whether the patient is experiencing problems associated with physical and psychological dependence and document the results of that assessment;

(3) periodically make reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled substance, decrease the dosage, try other drugs or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence and document with specificity the efforts undertaken;

(4) review the Prescription Drug Monitoring information; and

(5) monitor compliance with the pain management agreement and any recommendations that the patient seek a referral.

PRESCRIBING NALOXONE

A prescriber or other health care practitioner who prescribes or dispenses an opioid antidote in accordance with subsection a. of section 4 of P.L.2013, c. 46 (C.24:6J-4), shall ensure that overdose prevention information is provided to the antidote recipient. The requisite overdose prevention information shall include, but is not limited to: information on opioid overdose prevention and recognition; instructions on how to perform rescue breathing and resuscitation; information on opioid antidote dosage and instructions on opioid antidote administration; information describing the importance of calling 911 emergency telephone service for assistance with an opioid overdose; and instructions for appropriate care of an overdose victim after administration of the opioid antidote.

- N.J. Stat. Ann. § 24:6J-5

SUBSTANCE USE-DISORDER PREVENTION THAT PROMOTES OPIOID RECOVERY AND TREATMENT ("SUPPORT") FOR PATIENTS AND COMMUNITIES ACT

The new law was passed with sweeping majorities in the House and Senate.

Expands existing programs and creates new programs to prevent SUDs and overdoses, including reauthorization of the Office of National Drug Control Policy.

Expands programs to treat SUDs, including medication-assisted treatment (MAT), partially lifting—for five years—a restriction that blocks states from spending federal Medicaid dollars on residential addiction treatment centers with more than 16 beds, by allowing payments for residential SUD services for up to 30 days and allow Medicare to cover MAT, including methadone, in certain settings, to treat SUDs.

Increases funding for residential treatment programs for pregnant and postpartum women. The bill also requires the CDC to develop educational materials for clinicians to use with pregnant women for shared decision-making regarding pain management during pregnancy.

Authorizes an alternative payment model demonstration project developed by the American Society of Addiction Medicine, with support from the AMA, to increase access to comprehensive, evidence-based outpatient treatment for Medicare beneficiaries with opioid-use disorders.

Authorizes CDC grants for states and localities to improve their prescription drug-monitoring programs (PDMPs), collect public health data, implement other evidence-based prevention strategies, encourage data sharing between states, and support other prevention and research activities related to controlled substances, including education and awareness efforts.

Expands the use of telehealth services for Medicaid and Medicare SUD treatment.

Provides loan repayment for SUD-treatment professionals, including physicians, who agree to work in mental health professional shortage areas (HPSAs) or counties that have been hardest hit by drug overdoses. The bill clarifies that mental and behavioral health providers participating in the National Health Service Corps can provide care at a school or other community-based setting located in a HPSA as part of their obligated service requirements.

Helps stop the flow of illicit opioids into the country by mail, especially synthetic fentanyl and its analogs. Most opioid-related overdose deaths are linked to heroin and illicit fentanyl.

Provides funding to encourage research and development of new nonaddictive painkillers and nonopioid drugs and treatments.

Requires the Department of Health and Human Services (HHS) to study and report to Congress on the impact of federal and state laws and regulations that limit the length, quantity or dosage of opioid prescriptions.

Requires the Food and Drug Administration (FDA) to develop prescribing guidelines for the indication-specific treatment of acute pain where such guidelines do not exist. Any such guidelines will be accompanied by a clear statement of intent from the FDA commissioner stating that they are meant to inform clinical decisions by prescribers and patients and are not intended to restrict, limit, delay or deny coverage or access by individual health professionals.

Takeaways

• Prescribers must abide by the regulatory requirements and if, in the exercise of clinical judgment, they determine that a departure from strict adherence is necessary for a patent's well-being, THOROUGHLY DOCUMENT the situation.

• Exercise extreme caution in the decision to renew an opioid prescription beyond the initial 5-day limit for acute pain, ensuring that you thoroughly examine the patient and confirm clinically meaningful improvements in pain and function without significant risks or harm prior to continuing the use of any opioids. This, too, must be thoroughly documented.

• Implementing a formal opioid compliance plan may help to: (i) demonstrate to payors an aggressive protocol and being able to quantify shared savings* (fewer ER visits, addiction treatment costs, etc.); and (ii) minimize the risk of malpractice liability and/or sanctions by the Board of Medical Examiners and/or other regulatory bodies.

*$20 billion annually in opioid-related emergency department and inpatient care

ELEMENTS OF A COMPREHENSIVE COMPLIANCE PLAN

1. Implementation of written policies, procedures and standards of conduct;
2. Designation of a member of the organization to serve as compliance officer;
3. Effective staff training and education;
4. Enforcement of policies, procedures and standards through disciplinary action;
5. Internal monitoring and auditing; and
6. Prompt response to detected offenses and development of corrective action.

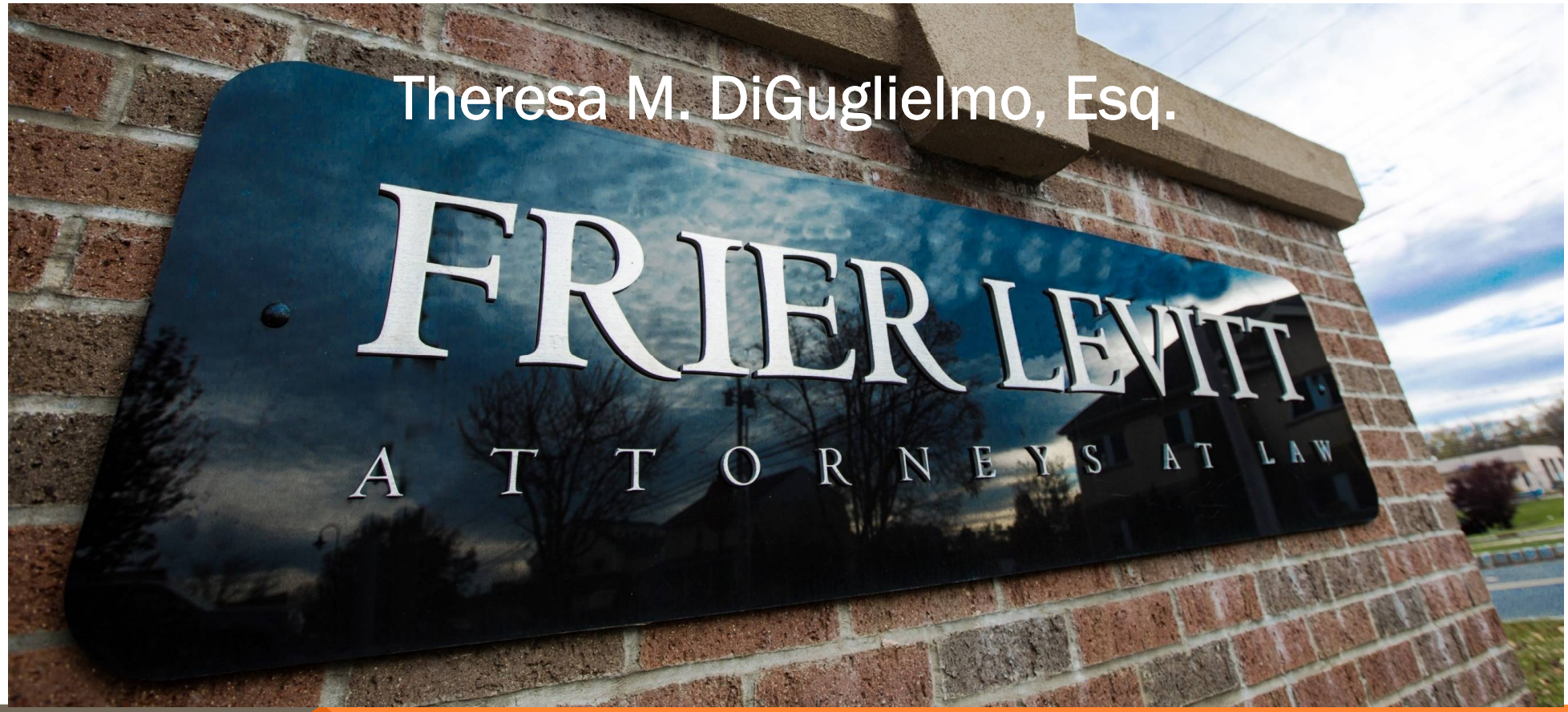
Published Guidance

What Practitioners Should Discuss With Their Patients:

http://www.njconsumeraffairs.gov/prescribing-for-pain/Documents/BME-Guidelines-What-Practitioners-Should-Discuss-With-Their-Patients.pdf

Patient Agreement:

http://www.njconsumeraffairs.gov/prescribing-for-pain/Documents/Pain-Treatment-with-Opioid-Medications-Patient-Agreement.pdf



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