### Public Health Law §3309-a(3)

# New York State Requirements for Prescribing Opioid Drugs Course Provided By

## The Fifth District Dental Society of the State of New York

#### 1. Requirements

- a. All practitioners are required to take a 3 hour course before July 1, 2017, then
- b. Once within each 3-year period thereafter,
- c. Content must include pain management, palliative care, and addiction approved by the NYSDOH
- d. The Narcotic Education Attestation Tracker (NEAT) application *is* available online. The instructions are below, but should you have additional problems or questions, contact DOH directly at 1.866.811.7957
  - 1. Log into your HCS account.
  - 2. Go to My Content;
  - 3. All applications;
  - 4. Select the letter "N" and find Narcotic Education Attestation Tracker (NEAT) Application.
  - 5. You will find your name under individual attestation.
  - 6. You will enter your information, attest and submit.

### 2. Intent of Public Health Law §3309-a(3)

- a. Effort to curb opioid abuse by limiting Schedule II, III, or IV to seven days upon initial consultation or treatment of acute pain.
- b. Defines "acute pain" as pain from disease (accidental, intentional trauma or other cause) that is reasonably expected to last only a short period of time. Exclusions are: chronic pain from cancer care, hospice or other end-of-life care or pain being treated as part of palliative care practices.
- c. This limitation applies exclusively to the initial prescription. Subsequent visits for the same pain may provide a refill or new prescription for the opioid or other drug for 30-day or 90-day statutory limits for Schedule II, III and IV medications. Check HCS Website for drugs that may be refilled.

## 3. Contemporary <u>PAIN</u> Prevention Strategy

- P = Prevention preemptive NSAID
- A = Anti-inflammatory agents NSAID
- $\underline{I}$  = Individualize customize to patient w/ acetaminophen
- N = Narcotics (opioids) start low go slow; script for 3 days (if necessary, easily refilled via e-script)
- 4. Risk of addiction tied to leftover pills form family friends etc. for all ages and socioeconomic groups.
- 5. The authority and implementation requirements to prescribe controlled substances can be traced back to the: Controlled Substance Act (CSA) of 1970
- 6. 6601. Definition of practice of dentistry The practice of the profession of dentistry is defined as diagnosing, treating, operating, or prescribing for any disease, pain, injury, deformity, or physical condition of the oral and maxillofacial area related to restoring and maintaining dental health.
- 7. New York's Prescription Drug Reform Act Legislation "I-STOP" law took effect on August 27, 2013
  - a. Required practitioners consult the PMP before prescribing;
  - b. Required dispensing data be reported in real time;
  - c. Required electronic prescribing;
  - d. Placed hydrocodone on C-II and tramadol on C-IV (2-23-2013)
  - e. Created a workgroup to advise the Department of Health

# 8. Duty to Consult PMP Registry

- a. Practitioners *must* consider their patient's information presented in the PMP Registry prior to prescribing or dispensing any controlled substance listed in Schedule II, III, IV or V.
- b. The data considered by the practitioner must be obtained from the PMP Registry no more than 24 hours before the prescription is issued.

- c. Prescribers may utilize a designee to obtain the information for them, but may not designate the actual review of data.
- d. Providers should be aware that an increase in benzodiazepines prescriptions has been reported and should be considered when reviewing an individual patient report.
- e. Can report diversion concerns through the PMP system
- 9. Evidence-based dentistry (EBD) uses current scientific evidence to guide decision-making.
  - a. requires the application and examination of relevant scientific data
  - b. related to patient's oral and medical health
  - c. dentist's professional skill and expertise
  - d. EBD allows dentists to stay up to date on the latest procedures and patients to receive improved treatment.
  - e. recommendations derived from current scientific evidence that serves as a tool to use in addressing clinical situations, it is not meant to be dogma
  - f. Barriers involved in the application of evidence-based dentistry principles, JADA 151(1) January 2020
  - g. Evidence-based clinical practice guideline on antibiotic use for the urgent management of pulpal- and periapical-related dental pain and intraoral swelling, JADA 150(11) November 2019
- 10. Pain Management, Appropriate Prescribing & Managing Acute Pain

The Federal Food and Drug Administration (FDA) has classified drugs into the following schedules. However, it should be noted that New York State has placed Vicodin into Schedule II from Schedule III. These schedules are included for historical reference.

Schedule II - High abuse potential, potential for severe psychological and/or physical dependence. Management of acute dental pain can be accomplished with nonopioid as well as opioid analgesics. It is important to be familiar with pharmacological principles and appropriate dosage strategies for each analgesic classis. Drugs to be reviewed include opioids and nonopioids including: aspirin, acetaminophen and nonsteroidal anti-inflammatory agents (NSAIDS).

Pain is a complex experience consisting of a specific sensation and the reactions evoked by that sensation. Analgesics either interrupt nociceptive impulses or depress their interpretation within the central nervous system.

Several "analgesic adjuncts" may be effective for managing chronic pain. These include various antidepressants and anticonvulsants that either enhance descending inhibitory pathways or modulate excitatory neural traffic that amplifies pain interpretation.

Patient education is important to establish realistic expectations for the post-operative course. A patient handout emphasizing important considerations may be a helpful tool ( JADA 147(12) December 2016 ).

Recommended analgesic considerations for "acute pain" levels:

- 1. Mild acetaminophen, aspirin, celecoxib, ibuprofen, naproxen
- 2. Moderate acetaminophen w/ codeine, Synalgos DC, Ultracet, Vicodin, Vicoprofen
- 3. Severe Dilaudid, Percocet, Percodan

## 11. Nonopioid Analgesics

- a. The nonopioid analgesics include: aspirin, acetaminophen and the nonsteroidal anti-inflammatory drugs (NSAIDs).
- b. It is commonly felt the analgesic efficacy of these agents is usually underestimated. This is unfortunate because they generally are equivalent or superior to opioids for managing musculoskeletal pain, and they have a lower incidence of side effects, including the potential for abuse.
- c. Dental pain is included in the musculoskeletal category, and for decades studies have repeatedly found that NSAIDs are generally superior to opioids at conventional dosages.

- d. It is important to individualize pain control by maximizing non-opioids use before moving to an opioid.
- e. Consider the sides effects and medical history including kidney, liver and cardiovascular issues.
- f. "Clock-based" timing with an NSAID dose that provides anti-inflammatory benefits will give maximum benefit and comfort.
- g. Provide realistic patient education relative to post-operative course. Some pain or discomfort is not unusual.

#### 12. NSAIDs

- a. Actions and Effects Ibuprofen is the prototype of this group of synthetic compounds known for their analgesic, antipyretic, and anti-inflammatory efficacy. These therapeutic effects and their side effects can be explained entirely by their ability to inhibit the cyclooxygenase (COX).
- b. Precautions and Side Effects Clinical use of NSAIDs is based on the ability to reduce the synthesis of prostaglandins implicated in pain, fever, and inflammation.
- c. The most frequent side effects of NSAIDs are related to their gastrointestinal toxicity. NSAIDs should be avoided in patients who suffer bleeding disorders and those taking anticoagulants such as warfarin and antiplatelet drugs such as clopidogrel (Plavix). Patients receiving monotherapy with low-dose aspirin are not a significant concern but should be considered.

### 13. Acetaminophen

- a. Compared with NSAIDs, the acetaminophen mechanism is believed to involve an inhibition of prostaglandin synthesis within the CNS. It has little influence on peripheral prostaglandin synthesis, especially within inflamed tissues.
- b. Hepatotoxicity is the most important adverse effect of acetaminophen. It is caused by a toxic metabolite that cannot be adequately conjugated when dosages exceed 200–250 mg/kg in a 24-hour period. The dose may be less for patients who are poorly nourished, who have liver dysfunction, or who are being treated with other hepatotoxic medications.

## 14. Opioid Analgesics

- a. Opioids produce their therapeutic and adverse effects by acting as agonists at opioid receptors. They are activated by a variety of endogenous *endorphins*. Opioid receptors relevant to clinical practice are located within the CNS, but peripheral receptors have also been characterized.
- b. Unlike nonopioids, which exhibit a ceiling analgesic response, opioids demonstrate greater efficacy as the dose is increased. When pain is severe the side effects do preclude the use of higher doses to produce complete pain relief.
- c. Opioids act on the CNS receptors; prolonged usage inhibits the production endorphins.
- d. Reduced endorphin limits the ability to manage pain naturally. This leads to seeking increased doses of drug.
- e. The higher doses of drugs create feelings of well-being and euphoria.
- f. Addiction may be a result of the euphoria experience by some individuals paving the way for increased drug use.
- 15. Dependence, Tolerance, and Addiction Dependence occurs when the body accommodates to a drug and, upon sudden discontinuation, the patient experiences a withdrawal syndrome that includes reactions opposite those produced by the particular drug, e.g., opioids produce sedation, lethargy, and constipation. A patient who is experiencing withdrawal becomes excited and experiences abdominal cramping and diarrhea. If opioid doses are tapered gradually, a dependent patient will not experience withdrawal. Patients who consume opioids regularly for longer than a week can develop some degree of dependence. After repeated administration, patients develop tolerance to opioids. This is to say that greater doses are required to produce the same intensity of effect formerly provided by a smaller dose. Tolerance to analgesia, sedation, and respiratory depression occurs simultaneously.
- 16. Therapeutic Considerations Effective pain control is based on selecting an optimal dose, rather than selecting a particular agent. However, individual differences in patient response and pharmacokinetic differences (e.g., duration, elimination half-life) may favor the use of a particular drug.

## 17. Prescribing Paradigm Shift

- a. From: "Opioid as needed for pain"
- b. To: "Clock-based Time Interval" (to leverage the beneficial pharmacologic effects of NSAIDS/Acetaminophen)
- c. This change will require patient education to highlight the rationale
- d. When pain is anticipated, the analgesia may be enhanced by starting the NSAID before local anesthesia wanes (i.e., "preemptive analgesia"). Alternating NSAID doses with acetaminophen doses provides central analgesia and peripheral pain relief as well as a potential anti-inflammatory effect.
- e. Ibuprofen and acetaminophen may continue to be alternated up to the MDD of each drug.
- f. Be sure to maintain proper dosing intervals between doses of the same medication.
- g. Consider using long-acting regional/local anesthesia to increase the duration of tissue comfort while the NSAID and/or acetaminophen reaches desired therapeutic ranges
- 18. Preemptive Administration of NSAIDs and management of postoperative course
  - a. delays onset of pain by more than 100 minutes
  - b. lessens severity of postoperative dental pain
  - c. pre-& postoperative administration of NSAIDs achieves superior pain relief than APAP alone or in combination with oxycodone
  - d. Exparel
  - e. Alternative treatment modalities, e.g. laser
  - f. Medrol dose Pak

#### 19. Office protocol;

- a. Comprehensive Medical and Dental History
- b. Review Drug History thoroughly
- c. If appropriate consult with patient's physician
- d. Review prior treatment and adverse reactions
- e. Include naloxone in emergency armamentarium
- Elicit informed consent based on the Risk/Benefit analysis for all aspects of treatment (JADA 149(4) April 2018 & JADA 134(10), 1329-1333 October 2003)

### 20. Sample Drug History Questions

- a. Have you ever used drugs?
- b. How old were you when you started?
- c. Which drugs do you take?
- d. How do you take the drug?
- e. When was the last time you used a drug?
- f. How often do you use the drug?
- g. Do you ever use drugs when you are alone?
- h. Do you ever use drugs before or during social activities?
- 21. Role of Dentistry in Palliative Medicine & End of Life Care a "team" member. Oral comfort care measures will contribute to proper patient management and quality of life.
  - a. Provide or encourage oral hygiene
  - b. Alleviate Pain
  - c. Managing oral side-effects of cancer therapy (mucositis/candida/xerostomia)
  - d. Eliminating sites of infection (or potential infection)
  - e. Understand the patient's preferences enhancing oral function
  - f. Protect self-esteem through esthetic maintenance
- 22. Chronic Pain is a complex diagnostic and therapeutic challenge. If a practitioner does not have special training in this area refer the patient to a professional who does. Examples of chronic pain may include TMD, burning mouth syndrome, fibromyalgia and cancer or other end-of-life- care or pain being treated as part of palliative care practices.

- a. Cognitive therapy
- b. Physical therapy
- c. Acupuncture regional chronic pain
- d. Hypnosis modify response to various stimuli
- e. "Pain Clinic" referral
- f. Alternative pharmacologic agents, e.g. tricyclics, anticonvulsants, SNRI's, gabapentin etc.
- g. Capsaicin
- h. Bio feedback
- i. Transcutaneous nerve stimulation (TENS)
- j. Application of heat/cold or both alternating
- k. Injections and/or long-term regional anesthesia or blocks
- I. Medical marijuana and/or cannabidiol
- m. Homeopathic remedies (e.g. Relief Factor)?

#### 23. Role of the Oral Health Team

- a. Patient education
- b. Education through schools, clubs, faith-based organizations
- c. Educational posters and pamphlets in office waiting area, speaking to groups
- d. Publish articles in local papers
- e. Patient counseling is a component of care. Referral for evaluation, treatment and monitoring is within the standard of care and reasonably expected.
- f. Findings that may suggest need for referral may include:
- g. Opioid misuse
- h. Sharing medications
- i. Overdose sequelae, use of combination drugs
- j. Smoking and Alcohol as co-addictions

## 24. Research shows that some groups are particularly vulnerable to prescription drug overdose:

- a. Individuals who obtain multiple controlled substance prescriptions from multiple providers; a practice known as "doctor shopping."
- b. People who take high daily dosages of prescription pain killers.
- c. Patients prescribed multiple (abuse-prone) prescription drugs.
- d. Low-income people and those living in rural areas.
- e. People on public assistance are prescribed painkillers at twice the rate of other patients and are at six times the risk of prescription painkiller overdose.
- f. Individuals with mental illness.
- g. Those with a history of substance abuse.
- h. Drug seeking individual may be unfamiliar to you
- i. A person who claims to be from out-of-town
- j. A person who claims to have lost or forgotten a prescription
- k. A drug seeker may actually be familiar to you friend, relative, etc.
- I. Drug abusers and "doctor shoppers" have similar characteristics
- m. Often requests a specific drug
- n. Reluctant to try a different drug
- o. Minimal interest in comprehensive care
- p. Frequent broken appointments
- q. May exaggerate pain or simulate problems
- r. May exhibit moods disturbances, threaten suicide
- s. May show signs of drug abuse, e.g. needle tracks, scars, etc.

## 25. What to DO if confronted by a suspected Drug Abuse:

- a. Perform and document a thorough examination
- b. Request accurate copies of demographic documentation, e.g. picture ID, social security number, etc.
- c. Call previous providers, pharmacy or clinic to confirm patient's story

- d. Confirm phone number and address provided by patient
- e. If a prescription is written provide limited quantity
- 26. Standard Treatment Addiction Options
  - a. Psychosocial interventions
    - i. Contingency management
    - ii. Individual, group and family counseling
    - iii. Motivational interviewing
    - iv. Case management
    - v. 12-step interventions
  - b. Pharmacological interventions
    - i. Methadone (can be used for taper as well)
    - ii. Buprenorphine (can be used for taper as well)
    - iii. Naltrexone (also used for alcohol dependence in oral and injectable forms)
- 27. Safe disposal The Drug Enforcement Administration (DEA) has revised its regulations to expand the options available to collect controlled substances from ultimate users for purpose of disposal, including: take-back events, mail-back programs and collection receptacle locations. Check the DEA website for a search tool that identifies local geographic sites. (https://takebackday.dea.gov)
- 28. Selected internet reference sites

https://takebackday.dea.gov

https://ebd.ada.org/en

https://commerce.health.state.ny.us/public/hcs login.html

https://www.health.ny.gov/community/opioid epidemic/laws and regs.htm

https://www.cdc.gov/drugoverdose/pdf/guidelines\_at-a-glance-a.pdf

http://www.op.nysed.gov/opd/

http://www.op.nysed.gov/prof/dent/

https://www.deadiversion.usdoj.gov

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