Overview and Open Forum on HB 21 – Controlled Substances

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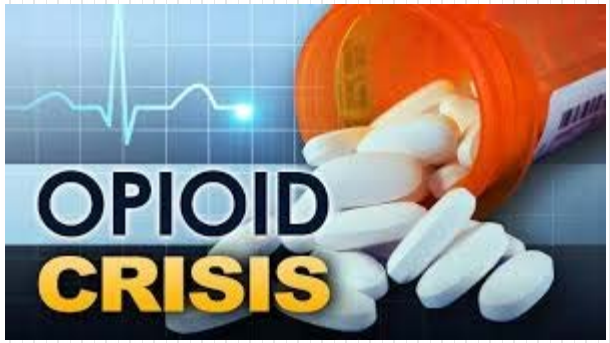

Disclaimer

- Implementation of the law is ongoing.
- Professional Boards will be passing rules and offering opinions well past the initial effective date of July 1st
- Many professionals and stakeholders will interpret the language slightly differently.
- When in doubt… go to the source document.

FL Department of Health FAQ:

http://www.flhealthsource.gov/FloridaTakeControl/faqs

Frequently Asked Questions

- When is the effective date of HB 21?
- What is a prescribing practitioner?
- What is the definition of acute pain?
- 3-day limit for acute pain
- When can a 7-day supply be prescribed?
- What are the exceptions to the prescribing limits?
- What is a terminal condition?

Agenda

1. Mandatory Physician Education
2. Mandatory Review of the Prescription Drug Monitoring Database (E-FORCSE)
3. Limitations on Prescribing Controlled Substances
4. Mandatory Emergency Opioid Antagonist
5. Mandatory Application for a Certificate of Exemption
6. Board of Medicine to Adopt Standards of Practice for Treatment of Acute Pain
7. Dispensing Practitioner Impact

Physician Education

Effective Date January 31, 2019

Effective date of 2019…why worry now?

- Best way for physicians and other impacted practitioners to receive this education and work towards compliance.
- Mandated Courses are going to include all of the key statutory provisions and penalties for non-compliance.
- Even though the bill does not take effect until July 1, 2018, Board of Medicine has already approved providers of the mandated course and **APPROVED** courses taken now will count towards the mandate.

BUSINESS

Thousands of N.C. doctors are over-prescribing opioids despite a new state law

BY JOHN MURAWSKI
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May 02, 2018 12:37 AM
Updated May 04, 2018 10:03 AM

RALEIGH — Thousands of North Carolina doctors appear to be breaking a new state law that limits opioid prescriptions for patients using the addictive drugs for the first time, according to preliminary data from the N.C. Department of Health and Human Services and the state's largest health insurer, Blue Cross and Blue Shield.

The NC STOP Act, enacted June 29 and effective Jan. 1, limits opioid prescriptions to five days for first-time patients with short-term pain, or seven days if the patient had surgery. The law, which is intended to stop patients from getting more opioids than they need, is a response to a grave public health concern that leftover narcotics could be taken recreationally or sold, feeding an opioid epidemic that claimed 12,590 lives in North Carolina between 1999 and 2016.

Mandatory Education

- 2-Hour Approved Course must be taken by 1/31/19.
- AND every license renewal moving forward.
- Approved course can only be provided by

  " a statewide professional association of physicians in this state that is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category I Credit or the American Osteopathic Category 1-A continuing medical education credit as part of biennial license renewal."

- Approved Providers: FMA, FOMA, FAFP, FCEP

Impacted Professionals

"each person registered with the United States Drug Enforcement Administration and authorized to prescribe controlled substances"

MDs, DOs, Dentists, Podiatrists,

What about PAs and ARNPs

"This paragraph does not apply to a licensee who is required by the applicable practice act to complete a minimum of 2 hours of continuing education on the safe and effective prescribing of controlled substances."

PAs and ARNPs are already required to take a 3-hour course to prescribe as required by the legislation that passed in 2016 that gave them the capability to prescribe controlled substances.

Where do I get this course?

- Approved Providers: FMA, FOMA, FAFP, FCEP
- Online Courses will be available – some free, some not.
- In-Person Courses will also be available once these providers have determined how to partner with other organizations in the community.
- FOS Annual Meeting is likely to have the course on Saturday, June 23rd

Questions on Physician Education?

Mandatory Review of the Prescription Drug Monitoring Database (E-FORCSE)

Effective Date July 1, 2018

Who, What, and When?

*"A **prescriber or dispenser or a designee** of a prescriber or dispenser must consult the system to review a patient's controlled substance dispensing history **before prescribing or dispensing** a controlled substance for a patient **age 16 or older**. This requirement does not apply when prescribing or dispensing a **nonopioid** controlled substance listed in **Schedule V** of s. 893.03 or 21 U.S.C. 812."*

Technical Difficulties

If the database is not operational or cannot be accessed by the prescriber or dispenser, the practitioner can go ahead and prescribe or dispense the controlled substance, but must document the reason why the database was not consulted and cannot prescribe or dispense more than a three-day supply of the controlled substance.

E-FORCSE

E-FORCSE (Drug Monitoring Database) Home Page:

http://www.floridahealth.gov/statistics-and-data/e-forcse/

Appriss is the new technology vendor

- **Improved performance & functionality**
- **Enhanced Sharing (34% of States)**
- **Interface Opportunities (70% of EMRs)**
  - **$50 per user per year**

Insight on the Database

- Designees are allowed. **CAUTION**
  - Restrictions on the use of the data, no phishing, duplication, distribution, etc.
  - Unique Log In Credentials
- New system will capture a screen shot of what the physician sees.
- There is no strict timeframe on when you had to check prior to writing the script. Use common sense and best practice.
- New platform will let you develop a patient queue for the physician to view.

How will they monitor compliance?

- Most likely scenario:
- Pharmacist views the PDMP prior to dispensing your script to your patient.
- They log in and see the patient has 3 additional active scripts for opioids.
- They file a complaint to the Board that you failed to consult the patients drug history prior to writing a new script.
- Board of Medicine views your PDMP activity and screen shot.

- What do you do if you see the patient has active scripts? Law is silent on that. But Standards of Care from the Board of Medicine may address?????

Penalties

- Board of Medicine appreciates the learning curve ahead.
- The first instance will be a non-disciplinary citation and a fine.
- Penalties and fines will increase for additional violations.

Questions on PDMP?

Limitations on Prescribing Controlled Substances

Effective Date July 1, 2018

ACUTE PAIN is the key

- This does not impact the Chronic Pain Statutes

(a) "Acute pain" means the normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness. The term does not include pain related to:

1. Cancer.

2. A terminal condition. As used in this subparagraph, the term "terminal condition" means a progressive disease or medical or surgical condition that causes significant functional impairment; is not considered by a treating physician to be reversible without the administration of life-sustaining procedures; and will result in death within 1 year after diagnosis if the condition runs its normal course.

3. Palliative care to provide relief of symptoms related to an incurable, progressive illness or injury.

4. A traumatic injury with an Injury Severity Score of 9 or higher.

Restrictions – 3 Days is the Law

"(a) a prescription for a Schedule II opioid, as defined in s. 893.03 or 21 U.S.C. 360 s. 812, for the treatment of acute pain must not exceed a 3-day supply."

Do I hear 7?

(b) An up to 7-day supply of an opioid described in paragraph (a) may be prescribed if:

1. The practitioner, in his or her professional judgment, believes that more than a 3-day supply of such an opioid is medically necessary to treat the patient's pain as an acute medical condition.

2. The practitioner indicates "ACUTE PAIN EXCEPTION" on the prescription.

3. The prescriber adequately documents in the patient's medical records the acute medical condition and lack of alternative treatment options that justify deviation from the 3- day supply limit established in this subsection.

What are the exceptions again?

1. Cancer.

2. A terminal condition. As used in this subparagraph, the term "terminal condition" means a progressive disease or medical or surgical condition that causes significant functional impairment; is not considered by a treating physician to be reversible without the administration of life-sustaining procedures; and will result in death within 1 year after diagnosis if the condition runs its normal course.

3. Palliative care to provide relief of symptoms related to an incurable, progressive illness or injury.

4. A traumatic injury with an Injury Severity Score of 9 or higher.

Getting Beyond the 7 Days

For a prescription for a Schedule II opioid, as defined in s. 893.03 or 21 U.S.C. s. 812, for the treatment of pain, other than acute pain, the practitioner must indicate "NONACUTE PAIN" on the prescription.

Traumatic Injury Severity Score > 9 - you can go above. Remember your antagonist.

Scripts, Refills, and Evals

- Federal Law prohibits "refills" of controlled substances. all additional scripts will be a new prescription.
- This is not a hard cap.....Board of Medicine will develop rules on the Standards of Practice for Treating Acute Pain to include how often you have to see that patient and review the treatment plan.
- Board Attorney does not believe an in-person evaluation will be required for ongoing treatment of a condition already diagnosed and performance of a treatment plan.

Managing Increased Volume

- State and Federal Law permits E-prescribing for Schedule II.

https://www.deadiversion.usdoj.gov/ecomm/e_rx/index.html

- Some states are starting to mandate e-prescribing (Not FL yet)
- Those that do it say it is great.

- Telemedicine is quickly advancing in orthopaedics. Several vendors available.

Remember the Magic Words

- To go from 3 to 7 days.

"Acute Pain Exemption"

- To use an exemption to go beyond 7 days.

"Non Acute Pain"

Remember you don't need new pads.

Questions about the restrictions?

Mandatory Emergency Opioid Antagonist

Effective July 1, 2018

And you get an antagonist….And you get an antagonist….

"For a prescription for a Schedule II opioid, as defined in s. 893.03 or 21 U.S.C. s. 812, for the treatment of pain related to a traumatic injury with an Injury Severity Score of 9 or higher, the prescriber must concurrently prescribe an emergency opioid antagonist."

**This applies even if you are writing less than the 7 day limitation. Any Schedule II Opioid written to any patient with a trauma score over 9 must receive a script for the antagonist.

Questions about the antagonist?

Mandatory Application for a Certificate of Exemption

Effective Date January 1, 2019

Background on Cert of Exemption

On Oct. 1, 2010, the Florida Statutes began to require "pain-management clinics" to register with the Florida Department of Health.

In 2011, the Legislature amended the definition of a "pain-management clinic" to require registration for all publicly or privately owned facilities that (1) advertise in any medium for any type of pain management services, or (2) where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.

Exemptions

The Legislature (in 2011) exempted the following entities from the registration requirement:

- A clinic in which the majority of the physicians who provide services in the clinic primarily provide surgical services
- The clinic is wholly owned and operated by a physician multispecialty practice where one or more board-eligible or board-certified medical specialists, who have also completed fellowships in pain medicine approved by the Accreditation Council for Graduate Medical Education or who are also board-certified in pain medicine by the American Board of Pain Medicine or a board approved by the American Board of Medical Specialties, the American Association of Physician Specialists, or the American Osteopathic Association, perform interventional pain procedures of the type routinely billed using surgical codes

What to do if you are exempt?

Prior to the passage of HB 21, a facility that met the definition of a "pain-management clinic" but did not have to register as a pain-management clinic because it fit into one of the exemptions, did not have to take action to comply with the pain-clinic legislation. The facility could determine on its own whether it was required to register.

Prior to HB 21, filing for an exemption was voluntary.

So what changes with HB 21?

Filing the Exemption is now Mandatory if you fit into that definition….every 2 years.

If a facility advertises in any medium for any type of pain-management service or prescribes in any month the above mentioned medications to a majority of the facility's patients for the treatment of chronic nonmalignant pain, but fits within one of the eight exceptions, that facility has to apply for a certificate of exemption. The DOH will have to adopt a form for the application, and will have to approve or deny the certificate within 30 days after receipt of the application.

Feedback from AHCA

- They claim they need practices to file these exemptions so they can focus their regulatory and inspection efforts on the real pain clinics.
- They have stated their intent is to make this easy to apply for and "cost effective".
- Similar to checking the box that you are a controlled substance prescriber.

- Our major concern is having to re-apply every two years. Once you have applied once, that should be good until your status as a practice/clinic changes.

Questions on Certificate of Exemption?

Board of Medicine to Adopt Standards of Practice for Treatment of Acute Pain

Unknown implementation date – stay tuned

Board to Develop Standards

"The Board of Medicine/Department of Health shall adopt rules establishing guidelines for prescribing controlled substances for acute pain, which may include evaluation of the patient, creation and maintenance of a treatment plan, obtaining informed consent and agreement for treatment, periodic review of the treatment plan, consultation, medical record review, and compliance with controlled substance laws and regulations. The rules shall take into account the applicability of the guidelines in different practice settings. Failure of a prescriber to follow such guidelines constitutes grounds for disciplinary action pursuant to s. 456.072(1)(gg), punishable as provided in s. 456.072(2)."

This could get ugly

- The Board of Medicine has decided to meet with the other health professionals Boards to see if they can come up with some consistent standards across the professions
  - MD, DO, Podiatry, Dentist, PA, ARNP, Pharmacy
- BOM has existing rules on treatment of pain, but they are outdated and need to be revised.
- They are likely to be the framework they start from.
- 64B8-9.013 Treatment of Pain

Major issues to monitor

- Evaluation of the patient – Can we issue a new script without physically examining the patient? How many times can we issue a new script?
- Informed Consent standards
- Periodic review of the treatment plan

Questions about the Standards of Care for Acute Pain?

Dispensing Practitioner Impact

Effective July 1, 2018

Dispensing Practitioners

a. For an opioid drug listed as a Schedule II controlled substance in s. 893.03 or 21 U.S.C. s. 812, the amount dispensed pursuant to this subparagraph may not exceed a 3-day supply unless the criteria in s. 456.44(5)(b) are met, in which case the amount dispensed may not exceed a 7-day supply.

b. For any Schedule II controlled substance that is not an opioid or for Schedule III controlled substance, the amount dispensed pursuant to this the subparagraph may not exceed a 14-day supply.

Total Cap on Dispensing

c. The exception in this subparagraph does not allow for the dispensing of a controlled substance listed in Schedule II or Schedule III more than 14 days after the performance of the surgical procedure.

As a dispensing practitioner you are capped at 14 days after the performance of a surgical procedure.

Questions on Dispending Practitioners?

Final Thoughts

- Reclassified some of the controlled substances into different Schedules. So make sure you check the updated schedules. Line 780 of the bill.
- Pharmacist interpretation will be key to smooth (or rough) implementation
  - Increased pressure on them from corporate/legal
  - How will they interpret our instructions?
  - Communication is likely to increase (hopefully, rather than just turning them away)
  - Consider more active engagement or use of preferred pharmacies

Identification Required

(d)1. Before dispensing a controlled substance to a person not known to the dispenser, require the person purchasing, receiving, or otherwise acquiring the controlled substance to present valid photographic identification or other verification of his or her identity. If the person does not have proper identification, the dispenser may verify the validity of the prescription and the identity of the patient with the prescriber or his or her authorized agent. Verification of health plan eligibility through a real-time inquiry or adjudication system is considered to be proper identification.

Resources

FL Department of Health FAQ:

http://www.flhealthsource.gov/FloridaTakeControl/faqs

DEA Registration for Electronic Prescribing Controlled Substances:

https://www.deadiversion.usdoj.gov/ecomm/e_rx/index.html

E-FORCSE (Drug Monitoring Database) Home Page:

http://www.floridahealth.gov/statistics-and-data/e-forcse/

Register for the Drug Monitoring Database:

https://florida.pmpaware.net

Effective Dates

July 1, 2018

Mandatory Checking the PDMP

Restrictions in Opioid Prescriptions

January 1, 2019

Certificate of Exemption for Pain Management Clinic

January 31, 2019

2-Hour CME - All Providers with DEA license

To Be Determined:

Board of Medicine Standards for Treating Acute Pain

Questions or Scenarios????

Keep us posted on issues – fcobbe@cobbemanagement.com

Thank you!