Controlled Substances (CS) Mandates, including amendments in AB 239 of 2019

(effective June 3, 2019)

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Learning Objectives

- Describe a licensee's duty to report conduct in violation of a Board statute or regulation
- List the diagnostic exceptions to the mandates for treating pain with a controlled substance
- Know the requirements for a written prescription of controlled substances
- Identify what tests are required of a patient before the initial prescription of a controlled substance for pain
- Articulate three components in a Prescription Medication Agreement
- Describe the mandates of SBIRT (AB442)

SBIRT CME mandate – AB442
2 hrs of training

Screening, **b**rief **i**ntervention and **r**eferral to **t**reatment approach to substance use disorder means

- an evidence-based method of delivering early intervention and treatment to persons who have or are at risk of developing a substance use disorder

- **Required** of physicians, PAs, APRNs, dentists, optometrists and podiatrists.

SBIRT CME mandate – AB442
2 hrs of training

SBIRT training consists of:

1. Screening to assess the severity of substance use and identify the appropriate level of treatment;
2. Brief intervention to increase awareness of the person's substance use and motivation to change his or her behavior; and
3. Referral to treatment for persons who need more extensive treatment and specialty care for substance use disorder

SBIRT CME mandate – AB442
2 hrs of training

Required of physicians, PAs, APRNs, dentists, optometrists and podiatrists

within 2 years after initial licensing

if licensed on January 1, 2024, must complete the 2 hours to renew license after that date

- A licensed physician may use SBIRT to satisfy CME in the substance use, addictive disorders and prescribing of opioids OR any requirement in ethics or pain management

SBIRT CME mandate – AB442
2 hrs of training

A physician, PA or APRN who holds a registration to treat opioid dependency with narcotic medications (Drug Addition Treatment Act of 2000) is exempt from SBIRT for the first license renewal after January 1, 2024.

After meeting the first SBIRT continuing education requirement, a physician, PA, APRN, dentist, optometrist or podiatrist can use either SBIRT credits or Opioid prescription and addiction CE for license renewal, but may not use SBIRT to satisfy required continuing education in ethics

SBIRT CME mandate – AB442
2 hrs of training

A physician, PA, or APRN who obtains a registration to treat opioid dependency with narcotic medications (Drug Addiction Treatment Act of 2000) is exempt from the training required for SBIRT for one period of licensure.

The Physician or PA may use such registration to satisfy 4 hours of the total number of hours of continuing education required by the licensing Board during one period of licensure.

Cultural Competency CME Mandate

AB327

A psychiatrist, PA supervised by a psychiatrist, nurse …must receive 2 hours of continuing education in cultural competency and diversity, equity and inclusion.

- This must address persons from different cultural backgrounds, including:

i. persons from various gender, racial and ethnic backgrounds; ii, persons from various religious backgrounds; iii, lesbian, gay, bisexual, transgender and questioning persons; iv, children and senior citizens; v, veterans; vi, persons with mental illness; vii, persons with an intellectual disability, developmental disability or physical disability; and viii, other populations designated by the applicable licensing Board.

Cultural Competency CME Mandate

AB327

- The biennial minimum 2 hours of instruction for each psychiatrist and each supervised PA may include the training provided pursuant to NRS 499.103.

NBME Existing Mandate to Report Violations

NRS 630.3062 The following acts, among others, constitute grounds for initiating disciplinary action or denying licensure:

6. **Failure to report any person** the licensee knows, or has reason to know, **is in violation of the provisions of this chapter or the regulations of the Board** within **30 days** after the date the licensee **knows or has reason to know** of the violation.

NRS 630.3062 The following acts, among others, constitute grounds for initiating disciplinary action or denying licensure:

3. Making or filing a report which the licensee knows to be false, **failing to file a** record or **report as required by law** or knowingly or willfully obstructing or inducing another to obstruct such filing.

NBOM Existing Mandate to Report Violations

NRS 633.511(1) The grounds for initiating disciplinary action pursuant to this chapter are:

(p) **Failure to report any person the licensee knows, or has reason to know, is in violation of the provisions of this chapter or the regulations of the Board within 30 days after the date the licensee knows or has reason to know of the violation.**

(o) Making or filing a report which the licensee knows to be false, **failing to file a record or report that is required by law** or knowingly or willfully obstructing or inducing another to obstruct the making or filing of such a record or report.

NRS 630.2535; NRS 631.344; NRS 632.2375; NRS 633.473; NRS 635.116; NRS 636.2881

Each (of the six) Board shall, by regulation, require each **practitioner certified or registered to dispense CS** to complete **2 hours of training relating to the misuse and abuse of CS, the prescribing of opioids or addiction during each relicensure period**.

These CMEs may be used to satisfy 2 hours of any continuing education requirement.

(FYI, AB 105, effective July 1, 2017, requires **2 CME** hours **every four (4) years** in **suicide prevention**.) By June 30, 2021, physicians, PAs, APRNs must comply.

NRS 639.23507

Practitioners treating patients for cancer, sickle cell disease, hospice, or palliative care are required to: satisfy *bone fide* patient rule, query PMP, obtain informed consent, which may be verbal, and issue a valid prescription.

A practitioner may issue a CS II, III, IV or an opioid in Schedule V for the treatment of a patient diagnosed with cancer or sickle cell disease or who is receiving hospice or palliative care without obtaining a patient utilization report if this will unreasonably delay care of the patient – obtain PMP later.

NRS 639.23507

PMP Mandate – Before initial CS prescription

Practitioner must obtain a PMP utilization report on the patient **before issuing** an **initial** prescription for a CS (II, III, IV) **and** at least **every 90 days** thereafter.

The practitioner shall:

a. Review the PMP (patient utilization) report, and
b. Determine whether the patient has been issued another prescription for the same CS for ongoing treatment; if so, the practitioner shall not prescribe the CS, **unless the practitioner determines that issuing the prescription is medically necessary.**

NRS 453.162; NRS 639.2353

Each prescription for Controlled Substances (CS) II, III, and IV must include:

i. DEA number of the prescriber
ii. ICD 10 diagnosis
iii. Fewest number of days to consume the quantity of CS prescribed; number of refills

(Example: Tylenol # 3, q. 4-6 h, 10 days. How many pills? 6 x 10 = 60)

Controlled Substances (CS) NOT for Pain (checklist)

- ✓ Check the PMP before prescribing , and every 90 days thereafter for same CS
- ✓ Review the PMP report
- ✓ Determine whether the patient has been issued another prescription for the same CS for ongoing treatment; if so, the practitioner shall **not** prescribe the CS, **unless it is medically necessary**
- ✓ Prescription: ICD 10 Diagnosis code; DEA # ; Minimum days to consume at maximum dosage

USING CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

NRS 639.235

Before issuing an **initial** prescription for CS (II, III, IV) **for the treatment of pain**, a practitioner must:

1. Have established a **bone fide relationship** with the patient (a *bona fide* relationship between the patient and the person prescribing the controlled substance shall be deemed to exist if the **patient was examined in person, electronically, telephonically or by fiber optics, including, without limitation, through telehealth, within or outside this State or the United States by the person prescribing the controlled substances within the 6 months immediately preceding the date the prescription was issued**)

NRS 639.23911

Before issuing a prescription for a CS (II, III, IV) for the treatment of pain, a practitioner must:

2. Establish a **preliminary diagnosis** of the patient and a **treatment plan** tailored toward treating the pain of the patient and the cause of that pain;
3. Document in the MR the reasons for prescribing the CS instead of an alternative treatment that does not require the use of a CS;

NRS 639.23911, NRS 639.23912

Before issuing an initial prescription for CS (II, III, IV) for the treatment of pain, a practitioner must:

4. Perform an evaluation and risk assessment which must include:
   a. Obtaining and reviewing a **relevant medical history**
   b. Conducting a **physical exam directed to the source of the patient's pain and within the scope of practice of the practitioner**
   c. **If the prescription is for a quantity of a CS II, III, or IV that is intended to be used in not less than 30 days,**
      i. **Making** a good faith effort to obtain and review **any** MRs from **any other provider** who have provided care to the patient **that are relevant to the prescription, and**
      i. **Documenting** efforts to obtain the MRs and conclusions from review in the MR of the patient
   d. Assessing the **mental health** and **risk of abuse, dependency and addiction** of the patient using "methods supported by peer-reviewed scientific research and validated by a nationally recognized organization" (Beck's Depression Inventory; POMI)

BOP R047-18AP

Sec. 5(2) – "good faith effort" … practitioner may consider:

a. The time needed to provide care to the patient;
b. The nature of the practice of the practitioner; and
c. Whether **the benefit of prescribing the controlled substance without obtaining the medical record outweighs the risk of doing so**.

(no apparent conflict with other NRS statutes)

NRS 639.239112; NRS 639.23912

e. Obtain **informed consent** to use a CS for the treatment of pain from:
   i. The patient, if the patient is 18 years of age or older or legally emancipated and competent to give such consent;
   ii. The parent or guardian of a patient who is less than 18 years of age and not legally emancipated; or
   iii. The legal guardian of a patient of any age who has been adjudicated mentally incompetent.

NRS 639.23911; NRS 639.23912(2)

The **informed consent** must include, **where applicable,** information concerning:

1. potential risks and benefits of treatment using the CS
   - ➢ including if a form of the CS that is designed to deter abuse is available
   - ➢ the risks and benefits of using that form
2. proper use of the controlled substance
3. any alternative means of treating the symptoms of the patient and the cause of such symptoms
4. the important provisions of the treatment plan established for the patient

NRS 639.23011; NRS 639.23912(2)

The informed consent must include:

5. the risks of dependency, addiction and overdose during treatment using the CS
6. methods to safely store and legally dispose of the CS
7. the manner in which the practitioner will address requests for refills of the prescription
8. if the patient is a woman between 15 and 45
   - the risks to a fetus of chronic exposure to CS during pregnancy
   - the risks of fetal dependency on the CS and neonatal abstinence syndrome

NRS 639.23911; NRS 639.23912(2)

The informed consent must include:

9. if the CS is an opioid
   - the availability of an opioid antagonist without a prescription, and
   - if the patient is an unemancipated minor
     - the risks that the minor will abuse or misuse the CS or divert the CS for use by another person, and
     - ways to detect such abuse, misuse or diversion

NRS 639.23912(3)

A practitioner shall document a conversation in which a patient provided informed consent that meets the requirements … in the medical record of the patient.

If a patient provides informed written consent, the practitioner must include the document on which the informed consent is recorded in the medical record of the patient.

NRS 639.2391

Acute Pain Treatment with a CS – including an opioid

Unless the practitioner determines that the prescription is medically necessary, a practitioner shall not prescribe CS II, III, or IV for acute pain for more than 14 days and, if the CS is an opioid, and the patient has never been issued an opioid or it has been more than 19 days since initial prescription for an opioid, prescription may not exceed 90 MMEs per day.

NRS 639.23911

If **a practitioner** prescribes a CS (II, III, IV) for the treatment of pain, **the practitioner** shall not issue more than one additional prescription that increases the dose of the CS unless the practitioner meets with the patient, in person or using telehealth, to reevaluate the treatment plan.

Initial Prescription for CS (II, III, IV) for Pain

Same as not for pain list, plus: (checklist)

- ✓ Bone fide relationship
- ✓ If **acute pain:** CS for no more than 14 days; if prescribing an opioid, no more than 90 MMEs if opioid naïve, **unless medically necessary**
- ✓ Evaluation and risk assessment
  - i. **Relevant** medical history
  - ii. Physical exam **directed to the source of the patient's pain and within the scope of practice of the practitioner**
  - iii. **If the prescription is intended for 30 days or more**, document good faith effort to obtain and review prior **relevant** medical records, and document conclusions of review in patient's MRs

Initial Prescription for CS (II, III, IV) for Pain (checklist)

iv. Access mental health and risk of abuse, dependency, and addiction with qualifying tests

- ✓ Preliminary diagnosis and treatment plan to treat the patient's pain and the cause of the patient's pain
- ✓ Document in the MR the reasons for prescribing the CS instead of an alternative treatment that does not require the use of a CS

Initial Prescription for CS (II, III, IV) for Pain

- ✓ Obtain an **informed consent** to use a CS for the treatment of pain from the appropriate authority (person, parent, legal representative)
  - ✓ The informed consent must include, **when applicable,** the required elements, plus, if an opiate, four (4) additional elements, and recorded in patient's MR.
  - ✓ If the informed consent is written, included a copy in the patient MR.

No more than one increase in dose of the CS for pain unless re-evaluation of treatment plan in-person or using telehealth

BOP mandate (new)

The Board shall develop and disseminate to each professional licensing board that licenses a practitioner, other than a veterinarian, or **make available on the Internet website of the Board [of Pharmacy]** an explanation or a technical advisory bulletin to inform those professional licensing boards of the requirements of NRS 639.23507 and 639.2391 to 639.23916, inclusive, and any regulations adopted pursuant thereto. The Board shall update the explanation or bulletin as necessary to include any revisions to those provisions of law or regulations. The explanation or bulletin must include, without limitation, an explanation of the requirements that apply to specific controlled substances or categories of controlled substances.

NRS 639.23914
Pain Treatment using a CS for > 30 days

If a practitioner intends to prescribe a controlled substance (II, III, IV) for more than 30 days for the treatment of pain, the practitioner must, not later than 30 days after issuing the initial prescription, enter into a **prescription medication agreement** with the patient, which must be:

Documented in the patient s MRs; and updated at least once every 365 days while the patient is using the CS, or updated whenever a change is made to the treatment plan.

NRS 639.23914
Pain Treatment using a CS for > 30 days

A prescription medication agreement must include:

a. The **goals of the treatment** of the patient
b. **Consent** of the patient to testing to monitor drug use when deemed medically necessary by the practitioner;
c. A requirement that the patient take the CS only as prescribed;
d. A prohibition on sharing medication with any other person;

NRS 639.23914
Pain Treatment using a CS > 30 days

A **prescription medication agreement must include:**

e. A requirement that the patient inform the practitioner:
i. Of **any other CS prescribed to or taken** by the patient;
ii. **Whether the patient drinks alcohol or uses marijuana or any other cannabinoid** while using the CS
iii. Whether the patient has been treated for side effects or complications relating to the use of the CS, including whether the patient has experienced an overdose; and
iv. **Each state in which the patient has previously resided or had a prescription for a CS filled**;

NRS 639.23914
Pain Treatment using a CS > 30 days

A prescription medication agreement **must** include:

f. Authorization for the practitioner to conduct random counts of the amount of the CS in the possession of the patient;
g. The reason the practitioner may change or discontinue treatment of the patient using the CS; and
h. Any other requirements that the practitioner may impose.

Using a CS for the treatment of pain for >30 days

Prescription Medication Agreement

- ✓ must contain all 10 elements (plus any additional desired by the practitioner)
- ✓ must be renewed every 365 days, and updated after any change in the treatment plan

NRS 639.23913
Pain Treatment using a CS > 90 days

Before prescribing a CS (II, III, IV) to continue to treat pain for 90 days or more, a practitioner must:

a. Require the patient to complete an assessment of the patient's risk for abuse, dependency and addiction that has been validated through peer-reviewed scientific research; (COMM)
b. Conduct an investigation, including appropriate hematological and radiological studies, to determine an evidence-based diagnosis for the cause of the pain;

NRS 639.23913
Pain Treatment using a CS > 90 days

Before prescribing a CS (II, III, IV) to continue **to treat pain** for 90 days or more, a practitioner must:

c. Meet with the patient, in person or using telehealth, to review the treatment plan to **determine whether continuation of treatment using the CS is medically appropriate**; and
d. If the patient has been prescribed a dose of 90 MMEs or more of an **opioid** per day for 90 days or longer, consider referring the patient to **a specialist**

NRS 639.2391
Pain Treatment using a CS

If practitioner prescribes more than 365 days of CS pain medication (II, III, IV) in 365 days, practitioner must document in MR the reasons, or

for a larger quantity of CS (II, III, IV) than will be used in 90 days, the prescriber must document in the MR the reasons.

NRS 639.23913
Pain Treatment using an opioid

If the practitioner decides to continue to prescribe a dose of 90 MMEs or greater per day, the practitioner must develop and document in the patient's MRs a revised treatment plan which must include an assessment of the increased risk for adverse outcomes.

Using a CS (II, III, IV) for the treatment of Pain > 90 days
(checklist)

- ✓ complete another assessment for the patient's risk of abuse, dependency, or addiction (COMM test)
- ✓ conduct an investigation to determine an evidenced-based diagnosis for the cause of the pain
- ✓ meet with patient, in-person or telehealth, to determine whether continuation with a CS for the treatment of pain is medically appropriate
- ✓ if patient is on a dose of 90 MMEs or greater, consider referring to a specialist
- ✓ if continuing 90 MMEs or >, document in MR the revised treatment plan, including risk for adverse outcomes

NRS 453.164

- Board of Pharmacy (BOP) may access the PMP to identify any suspected fraudulent, illegal, unauthorized or otherwise inappropriate activity related to prescribing, dispensing, or use of a CS.
- Discovered information shall be reported to law enforcement or licensing board.
- Dispensing Licensees must present proof of authorization to access the PMP to be relicensed [by BOP for CS certificate].

To NRS 453 (Controlled Substances) the following section is added:

The authority of the Board [of Pharmacy] *to take disciplinary action to enforce the provisions of this chapter is not limited by the authority of any other regulatory body that may be authorized or required to take disciplinary action for the same conduct with respect to any license, registration, certificate or other professional designation issued and regulated by that regulatory body.*

BOP R013-18AP

Sec. 5. The Executive Secretary of the BOP may suspend or terminate, before a hearing, the Internet access of a practitioner or other person to the PMP if the practitioner or other person accesses the database in violation …

NRS 630.323; NRS 631.364; NRS 632.352; NRS 633.574; NRS 635.152; NRS 636.338

If **licensing Board Executive Director (ED)** receives complaint from law enforcement, BOP, or any other source, that the licensee has:

- has issued a fraudulent, illegal, unauthorized or inappropriate CS prescription, or
- a pattern of such prescribing, or
- a patient (of the licensee) who has acquired, used or possessed a CS (II thru IV) as above, then:

"review and evaluation"
NRS 630.323; NRS 631.364; NRS 632.352; NRS 633.574; NRS 635.152; NRS 636.338

- ED, or designee, must notify licensee as soon as practicable (may delay notification if criminal investigation ongoing)
- **ED, or designee**, reviews PMP licensee's information
- After "**review and evaluation**," if ED, or designee, determines that the licensee may have issued a fraudulent, illegal, unauthorized or inappropriate prescription, the **ED, or designee, may refer for criminal prosecution** & **the Board must proceed as if a written complaint had been filed against the licensee**.
- After conducting an investigation and a hearing, if licensee is found guilty, the licensing Board must impose appropriate disciplinary action, to include additional CMEs.

NRS 630.323; NRS 631.364; NRS 632.352; NRS 633.574; NRS 635.152; NRS 636.338

If the Board determines from investigation that the public health, safety, or welfare, of any patient is at risk of imminent or continued harm, the Board may summarily suspend licensee's authority to prescribe CS (II, III, IV) pending a determination upon the conclusion of a hearing to consider a formal complaint against the licensee.

NRS 630.323; NRS 631.364; NRS 632.352; NRS 633.574; NRS 635.152; NRS 636.338

The licensing Board must hold a hearing and render a decision **concerning [whether to file] the formal complaint** within **60 days** of the summary suspension order for the Medical Board, Nursing Board, Podiatric Board, and Optometric Board,

Or, within **180 days** for Osteopathic Medical Board and Dental Board.

NRS 630.323; NRS 631.364; NRS 632.352; NRS 633.574; NRS 635.152; NRS 636.338

The licensing Board shall adopt regulations providing for disciplinary action against a licensee for inappropriately prescribing a CS (II, III, IV) or violation of any statutes or regulations of the BOP, to include additional continuing education concerning prescribing CS II, III, IV.

NRS 630.23916

The BOP may adopt any regulations necessary or convenient to enforce the provisions of NRS 639. Such regulations may impose additional requirements concerning the prescription of CS II, III, IV **for the treatment of pain.**

A practitioner who violates any provision of this act or any furthering regulations is:

a. Not guilty of a misdemeanor; and [is]
b. **Subject to professional discipline**.

In Summary, AB239 (2019)

- Mandates for initial prescription for all controlled substances – materially improved
- Mandates for prescribing controlled substances for pain less than 30 days – materially improved
- Mandates for prescribing controlled substances for 30 days or more – no significant change

- The **BOP** now has authority to independently discipline licensees of other Boards as to their CS certificate

Thank God He Stopped Talking!!!