

AB 474

WHAT YOU NEED TO KNOW ABOUT PRESCRIBING CONTROLLED SUBSTANCES IN NEVADA

Presented By:
Nevada State Board of Dental Examiners
Website: www.dental.nv.gov
702-486-7044

AB 474

- ▶ Sections 21-29
 - Amend NRS 631 (Dental Practice Act)
 - Requirements for Board investigation and discipline
- ▶ Sections 52–58
 - 52: Requirements for prescribing; Prescribing guidelines; required documentation
 - 53: Requirements for initial prescription of CS for pain
 - 54: Informed consent; Evaluation and Risk Assessment
 - 55: Prescribing guidelines for 90 days or more
 - 56: Prescription Medication Agreement (Rx for more than 30 days)
 - 57: Factors to consider before prescribing CS
 - 58: Pharmacy Board to adopt regulations
 - 60: PMP requirements



- Applies to all prescribers of controlled substances for human use, including dentists
- Does NOT apply to veterinarians
- Applies to all prescriptions for controlled substances written for use by a patient on an out-patient basis
- Applies individually to each practitioner

AB 474 WHAT YOU NEED TO KNOW ABOUT PRESCRIBING CONTROLLED SUBSTANCES IN NEVADA



- Controlled Substances Prescribing Law
- > Signed into law June 16, 2017
- ▶ Effective January 1, 2018
- Governor Sandoval's response to the opioid crisis
- Intended to "prioritize patient safety while preserving clinical decision-making"
- Expands and updates state laws related to the reporting of drug overdoses
- Provides prescribing protocols for healthcare providers that are prescribing controlled substances for the treatment of pain

Stated Goals of AB 474

- Prioritize patient safety and responsibility
- Preserve clinical decision-making
- Promote the patient-prescriber relationship
- Reduce the amount of inappropriate prescribing
- Prevent addiction to prescription drugs through monitoring and mitigating risk
- Enhance the quality of care for patients with acute and chronic pain

THE BASICS

AB 474 has five (5) major requirements:

- 1. Two (2) units of continuing education per licensing cycle is required for all licensed prescribers on the misuse and abuse of controlled substances, prescribing of opioids or addiction.
- 2. Mandated Registry and Use of PMP
- 3. New Prescribing Guidelines for Controlled Substances (CS)
- 4. New Prescription Requirements: what must be included on the actual prescription
- 5. Overdose Reporting Requirements



- Currently in effect
- AB 474 applies <u>any time</u> you are writing an Rx for a controlled substance for outpatient use
- > Applies if being prescribed for one day or one year
- Different requirements based upon length of prescription
- Most dentists will not have to worry about requirements for anything other than the initial Rx, which is up to 14 days
- No exception for prescriptions for less than 7 days AB474 is applicable from first pill
- No exceptions for acute pain
- Requirements must be met before prescribing the controlled substance



- Applies to all controlled substance prescriptions written for <u>OUTPATIENT</u> use
- Does NOT apply to chart orders for controlled substances ordered for on-site, in-patient administration in a hospital, ER, skilled nursing facility, facility of intermediate care or clinic
- Outpatient prescriptions for hospice patients is not an exception to AB474



Factors to Consider Before Writing Any Prescription for a Controlled Substance:

- Reason to believe patient won't use CS as prescribed or is diverting the CS for use by another;
- Previous prescriptions for the CS and whether it had the intended/expected effect:
- Whether the patient has informed you, or you have reason to believe, the patient is using alcohol or other drugs that (1) may interact negatively with the CS you are prescribing or (2) was not prescribed by a practitioner who is treating the patient, or has increased his or her dose of a CS without medical authorization or any diagnosis or health change that would affect the appropriateness of prescribing the CS
- 4. Number of times the patient has claimed the CS has been lost or stolen;
- Information on the PMP that may indicate inappropriate use of the CS by the patient;
- 6. Whether the patient has demonstrated aberrant behavior or intoxication;
- 7. Whether the patient has been reluctant to stop using a CS or has requested or demanded a CS that is likely to be abused or cause dependency or addiction:
- Whether the patient has been reluctant to cooperate with any exam, analysis
 or recommended test;
- 9. Whether the patient has a history of substance abuse;
- Any other evidence or factor to help you make an informed decision about prescribing

After considering each of the foregoing factors, if, in your professional judgment, a controlled substance is medically necessary and appropriate, you may prescribe the controlled substance as long as you comply with the requirements set forth in AB 474, Sections 52-60

AB 474 PRESCRIBING GUIDELINES

- Initial Prescription
 - "Initial prescription' means a prescription originated for a new patient of a practitioner, other than a veterinarian, or a new prescription to begin a new course of treatment for an existing patient of a practitioner, other than a veterinarian."
 - The term does not include any act concerning an ongoing prescription that is issued by a practitioner to continue a course of treatment
- 30 Days
- ▶ 90 Days
- ▶ 365 Days
- Treatment of pain vs. other reasons for controlled substance prescription

INITIAL PRESCRIPTION

Before writing an Initial Prescription for a Controlled Substance, each Practitioner Must:

- 1. Have a bona fide relationship with the patient;
- Establish a preliminary diagnosis and treatment plan (document rationale);
- 3. Perform a Patient Risk Assessment;
- Obtain and personally review the patient's PMP Report;
- Discuss non-CS treatment options with the patient and indicate in the medical record why a CS was prescribed (document reason for CS vs non-CS treatment)
- 6. Obtain informed consent

Bona Fide Relationship

- Established through an examination
- Does not exist where the practitioner has never examined the patient or has not seen the patient in the last six months
- Must examine the patient at least every 90 days for ongoing treatment

DIAGNOSIS AND TREATMENT PLAN

- Think before you prescribe a controlled substance and show your thinking in your records; establish a preliminary diagnosis and treatment plan tailored toward treating the pain of the patient and the cause of that pain
- You may raise the dosage of a controlled substance <u>once</u> but before a second increase in dosage, you <u>must meet</u> with the patient in person or by telehealth to evaluate the treatment plan

PATIENT RISK ASSESSMENT

- Obtain and review the patient's medical history/records
- Make a good faith effort to obtain records from other providers and document those efforts and any conclusions reached from reviewing the records
- Conduct a physical exam
- Assess the patient's mental health, risk of abuse, addition and dependency using methods supported by peer reviewed scientific research

PATIENT RISK ASSESSMENT

- Sample Opioid Risk Tool/Questionnaire
 - https://www.drugabuse.gov/sites/default/files/files/OpioidRiskTool.pdf
 - Developed by Lynn R. Webster, M.D. to assess risk of opioid addiction
 - Administer to patients prior to beginning opioid therapy for pain management

Mark each box that applies	Female	Male
Family history of substance abuse		
Alcohal	1	3
Illegal drugs	2	3
Rx drugs	4	4
Personal history of substance abuse		
Alcohal	3	3
Illegal drugs	4	4
Rx drugs	5	5
Age between 16—45 years	1	1
History of preadolescent sexual abuse	3	0
Psychological disease		
ADD, OCO, bipolar, schizophrenia	2	2
Depression	1	1
Scoring totals		

Scores

- <3 indicates low risk for opioid abuse
- 4-7 indicates moderate risk for opioid abuse
 - ≥8 indicates high risk for opioid abuse

*SAMPLE ONLY

INFORMED CONSENT

- Must obtain written informed consent prior to writing initial prescription for a controlled substance for the treatment of pain
- Informed consent must include:
 - 1. The potential risks and benefits of the controlled substance selected;
 - Proper use of the controlled substance
 - Any alternative means of treating symptoms and the cause of the symptoms;
 - A clear and simple explanation of the important provisions of the treatment plan
 - 5. The risks of dependency, addiction, or overdose;
 - Methods to safely store and legally dispose of the controlled substances;
 - 7. The manner in which the practitioner will address refill requests;
 - If the patient is a female between 15 and 45 years of age, the risk to a potential fetus;
 - If the controlled substance is an opioid, the availability of an opioid antagonist;
 - 10. If the patient is an unemancipated minor, the risks that the minor abuse, misuse, or divert the controlled substance.

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This is a sample for prescribers' use as they deem appropriate, but it is each prescriber's responsibility
to remove a special reformed a month in a majorice, with 40424. Informed Consent for Controlled Salestance Therapy for Pain . I understand that I must store prescriptions in a secure place and out of the reach of chald family members and others and/or use a locked medione abbeet. To safely dispose of its action, I can return the crusced medications in the beat or a bell pharmacy, a local single-deg, or a local society or and the safely of the safely of the safely of the safely of the deg, or a local society specific understand that it am out of ossible of times of medications. I understand that 8 em being prescribed medications, including controlled substances for the ment of pain. ______I understand that all pain medications, including controlled substances, have different benefits and risks in the treatment of any armatoms. I have been advised of the potential risks and benefits of treatment using controlled substances. stand thes when I take controlled substances. I may become physically dependent or gray hold will became actuationed to taking the medications every day, and i vocab thinkware scheme II stup them or unt back on other to quickly. Windressel aprenties git the fig. and may include abdommal pain, neures, vormistig, charrhee, sweeting, body Carmac, Jurier Nove, velowith, anotick, and schep profiles. Parent/Suardian Harne printed. Parent/Guardian Signature http://dental.nv.gov/Home/Features/AB_474/ Controlled Substance Sample Forms

Prescription Monitoring Program

Controlled Substance - Informed Consent Sample Form

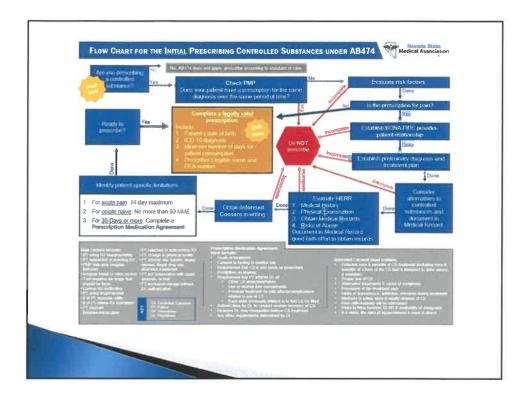
- You are required to register with the PMP if you have a NV controlled substance permit
- http://bop.nv.gov/links/PMP/
- Mandatory Query Requirements
 - Self-query by each practitioner who is authorized to write CS prescriptions:
 - Dental Board requires once per year (NAC 631.045(4))
 - · Pharmacy Board requires at least once each six months (NRS 453.165(6))
 - Review information for accuracy notify Pharmacy Board if incorrect
 Verify continued access and that you have accessed as required
 - Patient queries
- Information confidential except as otherwise provided by statute
 - Law Enforcement
 - Licensing Boards
- Pharmacy Board will notify you if it is determined that there was intentional unauthorized access to your PMP information (either unauthorized person or unauthorized purpose)

PATIENT PMP REPORT

- Must be reviewed before writing an initial prescription and at least every 90 days thereafter (while prescribing CS)
- Review to:
 - Assess whether the Rx for the CS is medically necessary
 - Determine whether the patient has been issued another Rx for the same CS that will provide for the reasons you are prescribing it
 - If it is determined (from the PMP or elsewhere) that the patient has been issued such a prescription, you "shall not" prescribe the CS

BOARD ACCESS TO PMP

- Boards May Access the PMP to Search for Inappropriate Prescriber Behaviors
 - An occupational licensing board that is provided access to the database pursuant to this section may access the database to investigate a complaint, report or other information that indicates fraudulent, illegal, unauthorized or otherwise inappropriate activity related to the prescribing, dispensing or use of a controlled substance. NRS 453.164(1)
- Mandatory Reporting by PMP to the Board or Law Enforcement
 - Reports any activity it reasonably suspects may be fraudulent, illegal, unauthorized or otherwise inappropriate activity related to the prescribing, dispensing or use of a controlled substance
 - Provides the law enforcement agency or occupational licensing board with the relevant information obtained from the program for further investigation. NRS 453.164(3)
- Mandatory Board Investigation (AB 474, Sec. 22)



WRITING THE PRESCRIPTION

- The Physical Prescription Must Include:
 - · Patient's date of birth
 - ICD-10 Code for the condition being treated with a controlled substance (CS)
 - The fewest number of days necessary to consume the quantity of the CS dispensed to the patient if the patient consumes the maximum dose of the CS authorized by the prescribing practitioner
 - · i.e.: Rx for 16 units; one unit to be taken every 6-8 hours for pain
 - Fewest number of days necessary = 4
 - Practitioner's DEA number
 - Can have multiple on one Rx pad clearly indicate which is the prescriber
 - If any of this is missing, the pharmacy will not fill the prescription

LIMITS ON THE INITIAL PRESCRIPTION

An initial prescription for a controlled substance for acute pain is limited to:

- 1) A 14-day supply; and
- The dose may not exceed 90 morphine milligram equivalents (MME) per day if the prescription is for an opioid *and* the patient has not before had an opioid *or* was not prescribed one within 19 days before the prescription at issue, then.

After the Initial Prescription

- After 30 days of Treatment
 - Must enter into a *Prescription Medication Agreement* with the patient, not later than 30 days after issuing the initial prescription.
 - Must be made part of the patient's record
 - Must update it at least every 365 while the patient is using the controlled substance <u>or</u> whenever the practitioner changes the treatment plan
 - Agreement must include:
 - 1. The goals of the treatment of the patient;
 - Consent by the patient to testing to monitor the patient's usage;
 - 3. A requirement that the patient use the controlled substance only as directed;
 - 4. A prohibition of sharing the controlled substance with anyone else;
 - 4. A prohibition of sharing the controlled substance with anyone else, A requirement that the patient inform the practitioner (a) of any other controlled substances prescribed or taken by the patient, (b) whether the patient drinks alcohol or uses cannabls, (c) whether the patient has experienced an overdose or been treated for side effects or complications related to controlled substances, and (d) each state in which the patient has resided and obtained controlled substances;
 - 6. Authorization for the practitioner to perform random counts;
 - 7. Reasons the practitioner may change or discontinue the treatment;
 - 8. Any other condition the practitioner might impose.

Sample form can be found on NSBDE website at http://dental.nv.gov/Home/Features/AB_474/

After 90 Days of Treatment

- A practitioner who prescribes a controlled substance to treat pain for more than 90 consecutive days from initiation must:
 - a. Complete a risk for abuse, dependency and addiction assessment that has been validated through peer reviewed scientific research;
 - b. Conduct an investigation, including, without limitation, appropriate hematological and radiological studies, to determine an evidence-based diagnosis for the cause of the pain;
 - Obtain and review the PMP at least every 90 days during the course of treatment
 - d. Meet with the patient to review the treatment plan established at the time of the initial prescription to determine whether continuation of treatment using the controlled substance is medically appropriate; and
 - e. If the patient is receiving a dose that exceeds 90 morphine milligram equivalents daily:
 - 1. Consider referring patient to a pain management specialist;
 - 2. If continue to prescribe, develop and document in the patient's medical record a revised treatment plan, including an assessment of increased risk for adverse outcomes

After 365 Days of Treatment

- "Prescribe 365" Rule
- AB 474, Section 52
- White Paper statement:
 - "A practitioner should not prescribe a controlled substance to a patient who has already received 365 days' worth of that controlled substance for a particular diagnosis in any given 365 day rolling period. Similarly, a practitioner should not prescribe more doses of a controlled substance than the patient needs if he or she adheres to the practitioner's dosing instructions for the treatment period. In either scenario, the practitioner may choose to prescribe a larger quantity than the patient needs for the treatment period, so long as the practitioner documents his or her rationale in the patient's medical record."

MANDATORY REPORTING OF OVERDOSE

- "Overdose" means a condition including, without limitation, physical illness, a decreased level of consciousness, respiratory depression, coma or death resulting from intentional or accidental consumption of a drug in excess of its prescribed or intended use.
- An overdose or suspected overdose is reportable if the suspected drug is scheduled as a schedule I, II, III or IV drug by the US DEA.
- "Patient discharge" means the physical release from medical facility or a provider of health care's care to another place, including but not limited to their home, transitional medical facility, treatment center, coroner's office or funeral home.
- Not later than seven (7) days from patient discharge, a provider of health care who knows of or provides services to a patient who has suffered a known or suspected drug overdose shall report the incident to the Chief Medical Officer or his or her designee in the manner prescribed by the regulations of the Board of Health.
- Regulation and additional information can be found at: http://dpbh.nv.gov/Resources/opioids/Prescription_Drug_Abuse_Prevention/

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MANDATORY Review, Investigation and Discipline

- Review of Information: Exec. Director or designee shall review and evaluate any complaint or other information received from any source indicating
 - A fraudulent, illegal, unauthorized or otherwise inappropriate Rx for CS
 - A pattern indicative of fraudulent, illegal, unauthorized or inappropriate prescriptions
 - A patient of a licensee has acquired, used or possessed a CS in a fraudulent, illegal, unauthorized or inappropriate manner
- Notification to Licensee: Board must notify you of the receipt of this information/complaint "as soon as practicable"
- Review and Evaluation must include:
 - Review of the relevant information contained in the database
 - Licensee attestation that s/he has complied with the PMP query requirements
 - Request for additional relevant information from the licensee
- Complaint: If there is a determination after review and evaluation that a licensee may have issued a fraudulent, illegal, unauthorized or otherwise inappropriate prescription for CS, the Board <u>must</u> proceed as if a written complaint had been filed against the licensee
- **Discipline:** If, after investigation and hearing (if applicable), the Board determines that the licensee issued a fraudulent, illegal, unauthorized or otherwise inappropriate Rx, the Board **must** impose appropriate disciplinary action.

DISCIPLINE

- AB 474, Section 22(6) mandates that the Board adopt regulations providing for disciplinary action against a licensee for inappropriately prescribing a controlled substance or violating the provisions of AB 474 and/or any regulations of Board of Pharmacy
 - PMP query violations
 - Prescribing guidelines violations (no consent, no patient risk assessment, no treatment plan, no documentation)
 - No bona fide relationship
 - Prescription medication agreement violation (where applicable)
- Discipline must include, but is not limited to, required completion of additional continuing education concerning prescribing controlled substances
- If the Board determines that the health, safety or welfare of the public or any patient is at risk of imminent or continued harm because of the manner in which the licensee prescribed, administered, dispensed or used a controlled substance, the board may summarily suspend the licensee's authority to prescribe, administer, or dispense a controlled substance pending a determination upon the conclusion of a hearing to consider a formal complaint against the licensee.
 - The Board must hold the hearing and render a decision concerning the formal complaint within 180 days after the date on which the summary suspension order is issued, unless the Board and licensee agree otherwise.

DENTAL BOARD REGULATIONS

- Disciplinary regulations speak in terms of "unprofessional conduct."
- NAC 631.230 outlines acts that are considered "unprofessional conduct."
 - NOT an exclusive list
 - Examples of unprofessional conduct also found at NRS 631.3475, NRS 631.349 and elsewhere in statutes and regs
- NRS 631.350 authorizes the Board to impose discipline upon a finding of, among other things, unprofessional conduct
- Already had regulation concerning improper prescribing of controlled substances as the basis for a finding of "unprofessional conduct."

 NAC 631.350(b): "Writing prescriptions for controlled substances in such excessive amounts as to constitute a departure from prevailing standards of acceptable dental practice."

 - NAC 631.350(d): "The acquisition of any controlled substances from any pharmacy or other source by misrepresentation, fraud, deception, or subterfuge."

 NAC 631.350(u): The failure to fulfill the self-query requirement
- To comply with the mandate of AB 474, Section 22(6) to implement regulations specific to the enforcement of AB474, the Board has approved changes to NAC 631.230 to ensure that failure to comply with AB474 is included in the enumerated examples of "unprofessional conduct" for which the Board is authorized to impose discipline
 - those changes are proceeding through the rulemaking process

NRS 631.3472

Amended by AB 474, Section 25, to include violations of AB 474 as conduct constituting unprofessional conduct:

631.3475 The following acts, among others, constitute unprofessional conduct:

- Failure to comply with the provisions of NRS 453.163, [or] 453.164 [;], 453.226, and 639.23507 and sections 52 to 58, inclusive, of this act and any regulations adopted by the State Board of Pharmacy 10. pursuant thereto.
- Fraudulent, illegal, unauthorized or otherwise 11. inappropriate prescribing, administering or dispensing of a controlled substance listed in schedule II, III or IV;

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Changes to NAC 631.230

NAC 631.239 Unprofessional Conduct

 $_{\rm L}$. In addition to those specified by statute and subsection 3 of NAC 631.177, the following acts constitute unprofessional conduct:

- (b) Writing prescriptions for controlled substances in such excessive amounts as to constitute a departure from the prevailing standards of acceptable dental practice.
- (a) The consistent use of dental procedures, services or treatments which constitute a departure from prevailing standards of acceptable dental practice even though the use does not constitute malpractice or gross malpractice.
- (d) The acquisition, *Issuance*, use or possession of any controlled substances from any pharmacy or other source by misrepresentation, fraud, deception, or subterfuge.
- The failure of a dentist who is registered to dispense controlled substances with the State Board of Pharmacy [pursuant to chapter 453 of NRS] to conduct [annually a minimum of one] the required self-query (ies) and/or patient inquiry (ies) regarding the issuance of controlled substances through the Prescription Monitoring Program of the State Board of Pharmacy pursuant to chapter 453 of NRS and/or as required by section 60 of Assembly Bill No. 474, chapter 605, Statutes of Nevada 2017.

ADDITION TO NAC 631.230

NAC 631.230 Unprofessional Conduct

- 1. In addition to those specified by statute and subsection 3 of NAC 631,177, the following acts constitute unprofessional conduct:
 - (v) Fraudulent, illegal, unauthorized or otherwise inappropriate prescribing of a controlled substance listed in schedule II, III or IV as set forth in section 22 of Assembly Bill No. 474, chapter 605, Statutes of Nevada 2017 and/or violations of the provisions of sections 52 to 58, inclusive, of Assembly Bill No. 474, chapter 605, Statutes of Nevada 2017 and/or violation(s) of any regulations adopted by the State Board of Pharmacy pursuant to Assembly Bill No. 474, chapter 605, Statutes of Nevada 2017.

→ If, following the investigation and disciplinary procedures conducted pursuant to the provisions of NRS Chapter 631 and NAC Chapter 631, it is determined, by a preponderance of the evidence, that a dentist has committed an act or acts constituting unprofessional conduct as set forth in NAC 631.230(1)(v), the Board shall impose disciplinary action including, but not limited to, required additional continuing education pursuant to NRS 631.350(1)(k). The Board or its agent or investigator may, in its discretion, take into consideration a dentist's good-faith attempts at compliance with the provisions of sections 52 to 58, inclusive of Assembly Bill No. 474, chapter 605, Statutes of Nevada 2017 in the determination of whether the dentist has committed an act or acts constituting unprofessional conduct as set forth in NAC 631.230(1)(v).

AB 474 and MEDICAL MARIJUANA

- NRS Chapter 453A regulates the medical use of marijuana
- AB 474 does **not** apply to medical marijuana
- Dentists are not "attending physician[s]" as defined by NRS 453A.030
- Neither AB 474 nor NRS 453A should have any effect on your dental practice, prescribing habits or permissible actions.

THE BOTTOM LINE

- Get a History
- Conduct an Exam
- Document, Document, Document
 - Diagnosis and Treatment Plan
 - · Any information supporting use of CS vs non-CS
 - Information supporting use of CS even if Risk Assessment indicates moderate or high risk
 - Patient Risk Assessment
 - · Have patient sign
 - · Dentist initial to indicate review
 - · Make sure it's in the chart
 - Informed Consent
- Register and run your PMP every six months
 Advise Pharmacy Board of Mistakes
- Run PMP on every patient at least once/90 days
 - Keep it in the chart
- If receiving CS elsewhere, don't prescribe
- Include all required information on the prescription
- Additional requirements after 30, 90 and 365 days
- Report drug overdose or suspected overdose