SUMMARY OF SENATE BILL 459 (2015)

(Prepared by the Nevada State Board of Pharmacy)

Governor Brian Sandoval signed Senate Bill (SB) 459 into law on May 5, 2015. It is effective immediately for purposes of adopting regulations and performing other preparatory administrative tasks, and on October 1, 2015 for all other purposes.

The bill addresses two primary topics, which are treated here in the order of which the Board of Pharmacy has received the most questions. Those primary topics are: (1) Mandatory access and use by practitioners of patient utilization reports (aka "Prescription Monitoring Program reports" or "PMP reports"); and (2) the Good Samaritan Drug Overdose Act (GSDOA), which authorizes the possession, storage, administration and dispensing of opioid antagonists.

I. MANDATORY ACCESS AND USE BY PRACTITIONERS OF PRESCRIPTION MONITORING PROGRAM

a. Practitioners are Required to Obtain a PMP Report Before Initiating Some Prescriptions for a Controlled Substance

Section 16 of the bill amended the applicable statute, NRS 639.23507(1), such that practitioners are now ***obligated*** **to obtain a PMP report** ***before*** **"initiating" a controlled substance prescription** in most cases. That obligation arises where:

1. The prescription is **for a controlled substance** listed in schedule II, III or IV, and
2. "The patient is a ***new patient*** of the practitioner;" or
3. "The prescription is for ***more than 7 days and is part of a new course of treatment*** for the patient."

For clarity, the Legislature defined "initiating a prescription" to mean "originating a new prescription for a new patient of a practitioner or originating a new prescription to begin a new course of treatment for an existing patient of the practitioner." NRS 639.23507(6). "The term does not include any act concerning an ***ongoing prescription*** that is written to continue a course of treatment for an ***existing patient*** of a practitioner." *Id.* (emphasis added).

Practitioners are also obligated to actually ***review*** the PMP reports they obtain. After obtaining a PMP report, "[t]he practitioner shall review [it] to assess whether the prescription for the controlled substance is medically necessary." Section 16(2). The term "medical necessity" is not defined in SB 459, so "medical necessity" remains a matter of professional discretion. A practitioner must exercise that discretion on a patient-by-patient basis, as guided by applicable law, standards of care and/or guidelines established by the practitioner's primary licensing board.

The statute further provides for penalties to be imposed against a practitioner who does not comply with the new law. A practitioner who fails to comply "[m]ay be subject to professional discipline if the appropriate licensing board determines that the practitioner's violation was intentional." NRS 639.23507(1). The bill provides that a practitioner will not be

deemed to be in violation if he or she attempted to obtain a report, but was unable to do so because the database "is unresponsive or otherwise unavailable." Such outages are extremely rare.

Notably, NRS 639.23507(1) ***does not apply to in-patient chart orders***. It does, however, apply to prescriptions written for out-patients by practitioners working in a hospital emergency department.

b. Periodic Training for Practitioners Concerning the Misuse and Abuse of Controlled Substances

Existing law requires every practitioner who is authorized to prescribe a controlled substance within this State to register biennially with the State Board of Pharmacy. NRS 453.226. In conjunction with that requirement, SB 459 sections 15.1 through 15.9 authorize ***each professional licensing board*** of the various practitioners who are eligible to obtain a controlled substance registration "to complete at least 1 hour of training related specifically to the misuse and abuse of controlled substances during each period of licensure." The bill does not authorize the Board of Pharmacy to impose or police such training requirements, so it will be incumbent upon each licensing board to address the training issue.

Notably, the language in sections 15.1 through 15.9 is *permissive*, not mandatory: Each board "may, by regulation, require . . . ." *See* sections 15.1 through 15.9 (emphasis added). If a licensing board requires such training, and a practitioner fails to complete it, that practitioner may be subject to disciplinary action by his/her board, including the denial of licensure. The Board of Pharmacy is not authorized by SB 459 to require the training, nor does the bill authorize the Board of Pharmacy to initiate discipline if a practitioner fails to complete it.

II. GOOD SAMARITAN OVERDOSE ACT

a. Authority to Prescribe and Dispense to Non-Patients

Section 7 of SB 459 applies to physicians, physician assistants and advanced practice registered nurses who are properly licensed and authorized to prescribe dangerous drugs and controlled substances. The section allows such prescribers to ***prescribe and dispense*** an opioid antagonist to a person ***other than the patient***. The statute describes other persons as "a family member, friend or other person in a position to assist a person at risk of experiencing an opioid-related drug overdose."

This is a significant departure from traditional pharmacy law. Outside the scope of SB 459, prescriptions must be written for the patient in a prescriber-patient relationship. *See* NRS 639.235(2) and (4). Prescribers cannot generally write prescriptions for persons who are merely related to or associated with the patient. *Id.*

Per the statute, such prescriptions are to be regarded as "being issued for a legitimate medical purpose in the usual course of professional practice." Section 7(1). Prescribers who write such a prescription in good faith and with care are immune from civil or criminal prosecution directly associated with writing the prescription. Section 7(2).

Importantly, SB 459 ***does not create a duty*** to prescribe or dispense an opioid antagonist. A prescriber who declines to prescribe the medication for any reason is immune from criminal, civil and administrative proceedings. Section 7(5).

b. Authority of Unlicensed Persons to Store, Possess and Administer Opioid Antagonists

The GSDOA also extends authority to ***possess and administer*** opioid antagonists. Per Section 7(3), notwithstanding any other provision of law, ***any person*** may ***possess and administer*** an opioid antagonist to another person whom he or she reasonably believes is experiencing an opioid-related drug overdose. The phrase "any person" is undefined, but the statute specifically states that law enforcement personnel, emergency medical technicians and paramedics are included.

Persons who act in good faith and with reasonable care in administering an opioid antagonist—although they would have no legal authority to administer other medications—are immune from criminal prosecution, civil liability and sanction from professional licensing boards. Section 7(4).

Similarly, Section 8 allows non-registered persons to ***store and dispense*** opioid antagonists pursuant to a standing order from a properly authorized prescriber. The caveat is that "those activities [must be] undertaken without charge or compensation." Where the person has a standing order from a prescriber, the person can possess and dispense without charge without a license from the Board of Pharmacy pursuant to NRS Chapter 639.

c. Authority of Pharmacists to Dispense Opioid Antagonists without a Prescription

Section 9 expands the authority of pharmacists by allowing them to dispense an opioid antagonist without a prescription. This authority will be governed by "standardized procedures or protocols" that the Board of Pharmacy will develop and approve. Section 9(1). Those procedures and protocols will include specific requirements as to education and training that each pharmacist must complete before furnishing an opioid antagonist. Section 9(3).

d. Immunity for Persons Who Seeks Medical Assistance for a Person Who is Experiencing a Drug or Alcohol overdose.

Finally, Section 12 of SB 459 provides protections for persons who seek medical assistance for another who is experiencing a drug or alcohol overdose. Section 12(1) says that if a person seeks aid in good faith on behalf of himself/herself, or for another, that person "may not be arrested, charged, prosecuted or convicted, or have his or her property subjected to forfeiture." or other penalty. Even in cases where the immunities in subsection 12(1) do not apply, the Court, before sentencing, "shall consider in mitigation any evidence or information that the defendant, in good faith, sought medical assistance for a person in connection with the events that led to the violation." Section 12(2).

III. ADDITIONAL MISCELLANEOUS PROVISIONS IN SB 459

a. Ability for Practitioners to "Red Flag" Doctor Shoppers

Section 13 amends NRS 453.1545 to authorize the Board of Pharmacy, "[t]o the extent money is available," to provide a means by which a practitioner may indicate in the PMP database that a patient is seeking a prescription for a controlled substance for an improper purpose. Section 13(e). The Board has discretion to determine whether a request is warranted. If the Board determines that the designation is warranted, it is authorized to inform pharmacies, prescribers and appropriate state agencies of the suspected activity. The statute does not indicate any factors to consider or the basis on which the Board is to make such a determination.

b. Next Day Reporting to the PMP Database

Section 13(2) changes the frequency with which pharmacies and dispensing practitioners must report their dispensing to the PMP database. Prior to SB 459, dispensers were required to report essentially on a weekly basis. SB 459 changed that reporting requirement to next-daily reporting, or more specifically: "not later than the end of the next business day after dispensing a controlled substance." Dispensing activities to patients in a healthcare facility (NRS 439.960), children residing in a child care facility (NRS 432A.024), and prisoners (NRS 208.085) are not reportable. The Board of Pharmacy will establish by regulation administrative penalties to be imposed upon dispensers who fail to report as required.