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October 31, 2019

Via E-Mail and FedEx

Mr. David Wuest, Executive Secretary
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste. 206
Reno, Nevada 89521

Re: Petition Requesting a Declaratory Order or Advisory Opinion

Dear Mr. Wuest:

The Nevada Association of Nurse Anesthetists ("Petitioner"), acting by and through Fennemore Craig, P.C., respectfully submits to the Nevada State Board of Pharmacy (the "Board of Pharmacy") pursuant to Section 639.150 of the Nevada Administrative Code ("NAC"), this Petition for a Declaratory Order or an Advisory Opinion (the "Petition"). Specifically, Petitioner requests that the Board of Pharmacy make a determination, consistent with the current scope of practice, that a certified registered nurse anesthetist ("CRNA") licensed by the Nevada State Board of Nursing (the "Board of Nursing") need not obtain a license from the Board of Pharmacy and/or a registration from the Drug Enforcement Administration ("DEA") to select and administer preanesthetic medications, intraoperative anesthesia and postanesthetic medications when such medications are ordered by the CRNA for surgical procedures from a DEA registered institutional pharmacy providing services for a Nevada licensed hospital or medical facility.

BACKGROUND

Petitioner is a professional organization for CRNAs in Nevada. CRNAs are professional registered nurses who have obtained, through additional education and successful completion of a national examination, certification as anesthesia nursing specialists.¹ This specialized education focuses on all aspects of clinical anesthesia practice, including pharmacology and pharmacotherapeutics. The Board of Nursing first adopted regulations establishing standards and authorizing functions that CRNAs may perform in 1986.² The Nevada State Legislature subsequently recognized CRNAs in 1987.³ Under Nevada law, CRNAs are authorized "to administer anesthetic agents to a person under the care of a licensed physician, a licensed dentist

¹ See NEV. REV. STAT. § 632.014(1).

² NEV. ADMIN. CODE § 632.500 to 632.550, inclusive.

³ S.B. 458, 64th Leg. (Nev. 1987) (adding definition of CRNAs to the NRS).

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or a licensed podiatric physician.”⁴ CRNAs practice in every setting in which anesthesia is delivered, including, but in no way limited to, traditional hospital surgical suites and obstetrical delivery rooms, critical access hospitals, ambulatory surgical centers and rural clinics.⁵ Historically, CRNAs have not been required to obtain a license from the Board of Pharmacy or DEA registration in order to select, order, and administer anesthetic agents to inpatients for preoperative, intraoperative, or postoperative use when the anesthetic agents are ordered by the CRNA solely from the institutional pharmacy. A Declaratory Order or an Advisory Opinion is necessary to confirm that this customary practice of CRNAs authorized by Nevada regulations does not constitute “prescribing” under Nevada law and to clarify that CRNAs do not need a license from the Board of Pharmacy or DEA registration so long as the CRNA performs services for patients in a Nevada licensed hospital or medical facility, and orders preanesthetic medications, intraoperative anesthesia and postanesthetic medications solely from the hospital’s or facility’s institutional pharmacy that is licensed by the State Board of Pharmacy and registered with the DEA. Such a Declaratory Order or Advisory Opinion would be consistent with Nevada statutes and regulations and would not change practices that have been acceptable in Nevada for over two decades.

LEGAL AUTHORITY

A person may petition the Board of Pharmacy for a declaratory order or advisory opinion as to the applicability of any statutory provision, regulation or decision of the Board of Pharmacy.⁶ The Board of Pharmacy is responsible for regulating the practice of pharmacy in Nevada, including the dispensing, prescribing and administration of drugs.⁷ Additionally, the Board of Pharmacy may “issue certificates, licenses and permits required” by Chapters 639, 453, or 454 of the Nevada Revised Statutes (“NRS”).⁸ The Board of Pharmacy, therefore, has discretion to determine which acts constitute the prescribing of drugs under Nevada law and which practitioners are required to obtain a license from the Board of Pharmacy and/or DEA registration under specific circumstances. For these reasons, the Board has authority under both the NRS and NAC to issue a declaratory opinion in response to this Petition.

⁴ NEV. REV. STAT. § 632.014(2).

⁵ CRNAs are often the exclusive anesthesia providers to a majority of rural Nevadans.

⁶ NEV. ADMIN. CODE § 639.150; NEV. REV. STAT. § 233B.120.

⁷ NEV. REV. STAT. § 639.070(1); *See also* NEV. REV. STAT. §§454.211 and 639.0065 (defining the term “dispense” to include prescribing and administering controlled substances and dangerous drugs).

⁸ NEV. REV. STAT. § 639.070(c).

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DISCUSSION

1. **The practice of CRNAs - selecting, ordering, and administering anesthetic agents preoperatively, intraoperatively, and postoperatively – does not constitute “prescribing” under Nevada law and is consistent with Nevada statutory law.**

CRNAs in Nevada are authorized to select, order, and administer anesthetic agents in preoperative, intraoperative, and postoperative settings.⁹ This regulatory authority does not contravene any applicable Nevada statutory authority. Neither the Nevada State Legislature nor the Board of Pharmacy has defined the term “order” in the context of administration of anesthetic agents. Rather, the focus of the current Nevada statutory and regulatory framework is who is authorized to possess, administer, prescribe or dispense controlled substances and dangerous drugs.

There is no dispute that a registered nurse, including a CRNA, may possess and administer a drug or medicine.¹⁰ Further, the furnishing of anesthetic agents by a pharmacy in a medical facility to an inpatient during the inpatient’s procedure, test, or treatment at a medical facility does not constitute “dispensing.”¹¹ The statutory definition of “dispense” in Chapter 454 and 639 does not include the furnishing of a dangerous drug or controlled substance by a hospital pharmacy for inpatients.¹² The Board of Pharmacy regulations further clarify that the term “dispense” refers to furnishing drugs in quantities greater than that necessary for the needs of the ultimate user.¹³ “The term does not include the furnishing of a controlled substance or dangerous drug by a pharmacy in a medical facility to an inpatient of the medical facility in which the pharmacy is located.”¹⁴

Similarly, the practice of CRNAs does not constitute “prescribing” under Nevada law because a “chart order” for an inpatient specifying drugs for inpatient use does not constitute “prescribing” drugs under Nevada law.¹⁵ The Nevada State Legislature defines “prescription” as follows:

NRS 639.013 “Prescription” defined.

1. “Prescription” means:
 - a. An order given individually for the person for whom prescribed, directly from the practitioner to a pharmacist or indirectly by means of an order

⁹ NEV. ADMIN. CODE § 632.500, attached hereto as **Exhibit 1**; *see also* NEV. REV. STAT. § 632.014.

¹⁰ NEV. REV. STAT. § 454.213(1)(c).

¹¹ NEV. ADMIN. CODE § 639.450.

¹² NEV. REV. STAT. §§ 639.0065(2) (regulating controlled substances) and 454.211(2) (regulating dangerous drugs).

¹³ NEV. ADMIN. CODE § 639.450.

¹⁴ *Id.*

¹⁵ NEV. REV. STAT. §§ 639.013(2) and 454.00961(2).

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signed by the practitioner or by an electronic transmission from the practitioner to a pharmacist.

- b. A chart order written for an inpatient specifying drugs which the inpatient is to take home upon discharge.
2. The term does not include a chart order written for an inpatient for use while he or she is an inpatient.

NRS 454.00961 "Prescription" defined.

1. "Prescription" means:
 - a. An order given individually for the person for whom prescribed, directly from the practitioner, or the practitioner's agent, to a pharmacist or indirectly by means of an order signed by the practitioner or an electronic transmission from the practitioner to a pharmacist.
 - b. A chart order written for an inpatient specifying drugs which he or she is to take home upon discharge.
2. "Prescription" does not include a chart order written for an inpatient for use while he or she is an inpatient.

The term "inpatient" is not defined in NRS Chapter 639 or 454. However, its usage throughout the pharmacy statutes and regulations suggests a broader connotation than that conferred by the Nevada State Board of Health.¹⁶ The pertinent distinction between "patient" and "inpatient" appears to be whether the order from practitioner to patient requires (1) the patient to fill the order at a pharmacy for the patient's own use or (2) the practitioner to fill the order at an institutional pharmacy for the practitioner to administer to patient at a medical facility. Whether the patient is technically an "inpatient" or "outpatient" at a hospital or medical facility is of little import to this analysis.

Indeed, an "institutional pharmacy" is defined as a pharmacy that is part of or is operated in conjunction with a medical facility as defined in NRS 449.0151.¹⁷ The definition of a "medical facility" includes:

1. A surgical center for ambulatory patients;
2. An obstetric center;

¹⁶ NEV. ADMIN. CODE § 449.289 defines "inpatient" as "a person who has been formally admitted into a hospital for diagnosis or treatment." NEV. ADMIN. CODE § 449.297 defines "outpatient" as "a person who has been registered or accepted for care in a hospital but who has not been formally admitted as an inpatient, and who does not remain in the hospital for more than 48 hours. Even this distinction may relate more to reimbursement status rather than whether or not drugs are being dispensed since in both the case where a patient is admitted to the hospital and when a patient remains in a hospital for observation for 48 hours, drugs may be administered to the patients in the hospital pursuant to a chart order.

¹⁷ NEV. REV. STAT. § 639.0085.

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3. An independent center for emergency medical care;
4. An agency to provide nursing in the home;
5. A facility for intermediate care;
6. A facility for skilled nursing;
7. A facility for hospice care;
8. A hospital;
9. A psychiatric hospital;
10. A facility for the treatment of irreversible renal disease;
11. A rural clinic;
12. A nursing pool;
13. A facility for modified medical detoxification;
14. A facility for refractive surgery;
15. A mobile unit; and
16. A community triage center.¹⁸

The term “institutional pharmacy” further includes “[a] pharmacy on the premises of the medical facility which provides a system of distributing and supplying medication to the facility, whether or not operated by the facility” and “[a] pharmacy off the premises of the medical facility which provides services only to the patients of the facility and provides a system of distributing medication based upon chart orders from the medical facility.”¹⁹ The overall statutory framework clearly contemplates a system of distributing medication to medical facilities so medical facilities can administer medication to their patients. To adopt a limiting definition of the term “inpatient” would lead to an absurd result given the breadth of medical procedures, tests and treatments that do not require a patient’s formal admission to a hospital or medical facility.

Importantly, the scope of practice for CRNAs is limited to “preoperative, intraoperative, and postoperative” settings.²⁰ As such, CRNAs are only authorized to select, order and administer anesthetic agents for patients during the patients’ procedure, test, or treatment at a licensed hospital or medical facility. The statutory definition of a “chart order” is an order entered on the chart of an inpatient in a hospital or medical facility licensed by the Division of Public and Behavioral Health of the Department of Health and Human Services.²¹ Given the limited scope of CRNAs practice and the distinction between a “prescription” and “chart order” under Nevada law, the “ordering” authorized to be performed by CRNAs is synonymous to a chart order and is clearly not a prescription.

The current statutory and regulatory framework does not define who is permitted to make a chart order. Although CRNAs are not expressly included in the statutory definition of a

¹⁸ NEV. REV. STAT. § 449.0151.

¹⁹ NEV. REV. STAT. § 454.00905(1) and (2).

²⁰ NEV. ADMIN. CODE § 632.500.

²¹ NEV. REV. STAT. § 639.004 and NEV. ADMIN. CODE § 639.442.

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“practitioner,” the hospital or institutional pharmacies from which CRNAs “order” anesthetic agents are included in the statutory definition of a “practitioner” to the extent they are licensed or registered to distribute, dispense or administer drugs.²² The logical rationale for including hospitals and institutional pharmacies as “practitioners” in this context would mean that it is unnecessary for a CRNA to obtain a license from the Board of Pharmacy or DEA registration when ordering anesthetic agents from a licensed and DEA registered hospital or institutional pharmacy for the CRNA to administer to the patient at the hospital or medical facility. Moreover, it is unnecessarily duplicative and does not address any State or Federal policy goals to have CRNAs obtain such a license from the Board of Pharmacy or DEA registration under these circumstances, since CRNAs are performing services solely for patients within the hospital or medical facility.

2. The practice of CRNAs does not constitute “prescribing” under Federal law.

The current statutory and regulatory framework under Federal law also suggests that the practice of CRNAs does not constitute “prescribing.” “Prescription means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).”²³ Further, the DEA has promulgated clear exceptions to the requirement of DEA registration for individual practitioners administering, dispensing or prescribing controlled substances under the registration of the hospital or institutional pharmacy.²⁴ 21 C.F.R. § 1301.22 provides, in pertinent part:

(c) An individual practitioner who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered him/herself, provided that:

- (1) Such dispensing, administering or prescribing is done in the usual course of his/her professional practice;
- (2) Such individual practitioner is authorized or permitted to do so by the jurisdiction in which he/she is practicing;
- (3) The hospital or other institution by whom he/she is employed has verified that the individual practitioner is so permitted to dispense, administer, or prescribe drugs within the jurisdiction;
- (4) Such individual practitioner is acting only within the scope of his/her employment in the hospital or institution;

²² NEV. REV. STAT. §§ 639.0125(2) and 454.00958(2).

²³ 21 C.F.R. § 1300.01.

²⁴ 21 C.F.R. § 1301.22.

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(5) The hospital or other institution authorizes the individual practitioner to administer, dispense or prescribe under the hospital registration and designates a specific internal code number for each individual practitioner so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., APO123456-10 or APO123456-A12); and

(6) A current list of internal codes and the corresponding individual practitioners is kept by the hospital or other institution and is made available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner.

This regulation suggests that practitioners in institutional settings who issue orders for medications for direct administration to a patient, such as CRNAs in their normal scope of practice, are not prescribing within the meaning of 21 C.F.R. § 1300.01, and would be exempt from registration. Federal policy concerns have to do with controls and procedures against theft of controlled substances. Accordingly, the DEA distinguishes institutional settings where CRNAs issuing orders for anesthetic agents for direct administration to patients are subject to the controls or procedures of the DEA registrant, such as a hospital or institutional pharmacy, from situations outside institutional settings or where CRNAs dispense and administer their own drugs. Thus, if a CRNA does not “prescribe” and if the CRNA is an agent or employee of a DEA registrant, it follows that the CRNA does not have to register with the DEA.

CONCLUSION

The practice of CRNAs issuing orders for anesthetic agents from hospital or institutional pharmacies for direct administration to patients does not constitute “prescribing” pursuant to the definition of “prescription” in NRS 639.013 and NRS 454.00961 or 21 C.F.R. § 1300.01. Given the limited scope of CRNAs practice and the distinction between a “prescription” and “chart order” under Nevada law, the “ordering” performed by CRNAs is synonymous to a chart order and is clearly not a prescription. For these reasons, we respectfully request a declaratory order or advisory opinion concluding that a CRNA licensed by the State Board of Nursing is not required to obtain a license from the Board of Pharmacy and/or DEA registration to order anesthetic agents from an institutional pharmacy located at a Nevada licensed hospital or medical facility for patient services at the hospital or medical facility.

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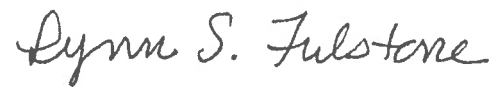
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Thank you for your time and consideration. Please do not hesitate to contact our office should you have any questions and/or comments.

Sincerely,

FENNEMORE CRAIG, P.C.



Lynn S. Fulstone

LFUL/cada

Cc: Robert Erickson, CRNA, President
Nevada Association Nurse Anesthetists

Paul Edwards, General Counsel
Nevada State Board of Pharmacy

EXHIBIT 1

Nevada Administrative Code § 632.500. Authorized functions. (NRS 632.120)

1. A certified registered nurse anesthetist may, in addition to those functions authorized for the registered nurse, perform the following acts, when it has been determined by a patient's physician, dentist or podiatric physician that an anesthetic is necessary for a procedure, test or other treatment, in accordance with the applicable policies and procedures regarding the administration of anesthetics:

- (a) Obtain a history of the patient's health, as appropriate to the anticipated procedure, test or treatment;
- (b) Assess the client's condition, as appropriate to the anticipated procedure, test or treatment;
- (c) Recommend, request and order pertinent diagnostic studies and evaluate the results of those studies;
- (d) Prepare a written preanesthetic evaluation of the patient and obtain the patient's informed consent for the anesthesia;
- (e) Select, order and administer preanesthetic medication;
- (f) Order, prepare and use any equipment and supplies necessary for the administration of anesthesia and perform or order any necessary safety checks on the equipment;
- (g) Order and prepare any drugs used for the administration of anesthesia;
- (h) Select and order anesthesia techniques, agents and adjunctive drugs;
- (i) Perform and manage general, regional and local anesthesia and techniques of hypnosis;
- (j) Perform tracheal intubation and extubation and provide mechanical ventilation;
- (k) Provide perianesthetic invasive and noninvasive monitoring, as appropriate, and respond to any abnormal findings with corrective action;
- (l) Manage the patient's fluid, blood and balance of electrolytes and acid base;
- (m) Recognize abnormal response by a patient during anesthesia, select and take corrective action;
- (n) Identify and manage any related medical emergency requiring such techniques as cardiopulmonary resuscitation, airway maintenance, ventilation, tracheal intubation, pharmacological cardiovascular support and fluid resuscitation;
- (o) Evaluate the patient's response during emergence from anesthesia and institute pharmacological or supportive treatment to ensure adequate recovery from anesthesia;
- (p) Provide care consistent with the principles of infection control and anesthesia safety to prevent the spread of disease and prevent harm to the anesthetized patient and others in the anesthetizing environment;

- (q) Select, order and administer postanesthetic medication;
 - (r) Report to the person providing postanesthetic care the patient's physical and psychological condition, perioperative course and any anticipated problems;
 - (s) Initiate, order and administer respiratory support to ensure adequate ventilation and oxygenation in the immediate postanesthetic period;
 - (t) Release the patient from the postanesthetic care unit or discharge the patient from the ambulatory surgical setting;
 - (u) Include in a timely manner as a part of the patient's medical records a thorough report on all aspects of the patient's anesthesia care; and
 - (v) Assess the patient's postanesthetic condition, evaluate the patient's response to anesthesia and take corrective action.
2. In addition, the nurse anesthetist may accept additional responsibilities which are appropriate to the practice setting and within his or her expertise. Such responsibilities may include, but are not limited to, the selection and administration of drugs and techniques for the control of pain in the preoperative, intraoperative and postoperative setting.