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August 12, 2020

Via Email: Opinion.committee@texasattorneygeneral.gov
The Honorable Ken Paxton
Attorney General of Texas
Attn: Opinions Committee
P.O. Box 12548
Austin, Texas 78711-2548

Dear Attorney General Paxton:

In order to be able to issue proper guidance to the physicians, certified registered nurse anesthetists (CRNAs), and patients of Texas, the Texas Medical Board ("TMB") requests an opinion from the Attorney General. This request seeks an Attorney General Opinion regarding the following issue:

1. *Does the Texas Occupation Code, Chapter 157 et. seq. require any level of physician supervision of a Certified Registered Nurse Anesthetists (CRNA)?*

2. *Is the liability of the delegating physician limited solely to the determination of competency to initially delegate to CRNA under Section 157.060, or does it include liability for all delegated medical acts under Section 157.001?*

SUMMARY OF TMB POSITION AND AUTHORITY-

Texas law requires both delegation to and supervision of a Certified Registered Nurse Anesthetist (CRNA) by physicians under Tex. Occ. Code, Subtitle B, Chapter 157. The level of supervision is flexible. This supervision is undisputed based on the Medical Practice Act, Texas Controlled Substance and Dangerous Drug Act, and Pharmacy Act.

State and federal case law supports the need for CRNA supervision by a physician. The Center for Medicaid and Medicare Services (CMS) also require CRNA supervision. The only way that supervision is not required is if a state is an "opt-out" state. Texas has not "opted out." Texas Critical Access Hospitals (CAH) are CMS certified and reimbursement of anesthesia services requires supervision of CRNAs.

Even the Federal Trade Commission (FTC) and the Texas Board of Nursing has stated that "independent practice" regarding CRNAs means something other than "no supervision." TMB knows the term "independent practice" is being misapplied by certain Texas professional nursing associations and CRNAs when presenting services to patients and the public.

TMB requests an opinion to unequivocally clarify that Texas law requires supervision of CRNAs by physicians under Tex. Occ. Code, Section 157.

STATUTORY CONSTRUCTION

The supervision of CRNAs and liability of the delegating physician is a matter of statutory construction under Tex. Gov. Code, Section 311. The principles of statutory construction require effect be given to the entire statute.[1, 2, 3]

The requirement of supervision and liability is clearly stated in the Texas Occupation Code a/k/a Medical Practice Act (MPA). These provisions must be read in conjunction with other statutory provisions related to administration of drugs, including the Texas Controlled Substance Act and the Pharmacy Act.

The statutory authority of physician delegation to a non-physician healthcare provider is found in MPA, Section 157.001:

> (a) A physician may delegate to a qualified and properly trained person acting under the physician's supervision any medical act that a reasonable and prudent physician would find within the scope of sound medical judgment to delegate if, in the opinion of the delegating physician:
> (1) the act:
> (A) can be properly and safely performed by the person to whom the medical act is delegated;
> (B) is performed in its customary manner; and
> (C) is not in violation of any other statute; and
> (2) the person to whom the delegation is made does not represent to the public that the person is authorized to practice medicine.
>
> (b) The delegating physician remains responsible for the medical acts of the person performing the delegated medical acts.
>
> (c) The board may determine whether:
> (1) an act constitutes the practice of medicine, not inconsistent with this chapter; and
> (2) a medical act may be properly or safely delegated by physicians.
> (Emphasis added.)

[1] *Exxon Mobil Pipeline Co. v. Coleman*, 512 S.W.3d 895 (2017), ("If the statute's language is unambiguous, we interpret the statute according to its plain meaning.")
[2] *Jaster v. Comet II Constr., Inc*., 438 SW3d 556, 562 (Tex. 2014), ("A statute must be read as a whole and its parts cannot be read in isolation.")
[3] Tex. Gov't Code, §311.021, ("a statute will not be interpreted in a manner that leads to absurd results, and the public interest is favored over private interest.")

The plain language of Section 157.001 allows physician delegation. But the delegated acts must be performed under the delegating physician's supervision. This requirement is supported by Opinion No. JC-0117 (1999). This opinion examined the CRNA supervision under MPA, section 157.058. Specifically, on pg. 7, last paragraph, the opinion states:

> "Consequently, section 157.058 does not require that a physician **directly supervise** a CRNA's selection and administration of the anesthesia. Rather, the extent of physician involvement is left to the physician's professional judgment **in light of other relevant** federal and **state laws**, facility policies, medical staff bylaws, and ethical standards. *See id.* **157.001**, .007, .058." (Emphasis added.)

On pg. 8 of the Opinion:

> "In sum, the authority to delegate provided by the Nursing Practice Act and Section 157.058 of the Occupations Code does not eliminate the need to comply with all other applicable statutes, regulations, bylaws, and ethical standards. (Emphasis added.)

The direct referral back to Section 157.001 reinforces that any delegation also requires physician supervision. Section 157.001's use of, "may delegate" is directly conditioned upon the CRNA acting under a physician's supervision. And Section 157.001 is clearly an "other applicable statute."

The MPA expressly states the delegating physician is liable for the acts delegated under Section 157.001. Moreover, a CRNA cannot administer anesthesia without physician delegation.

In 2019, Attorney General Paxton issued Opinion KP-0266 concerning delegation to a CRNA by a physician. This opinion states that "anesthesia is a medical act, therefore can only be delegated by a physician." More importantly, at pg. 4, the Opinion concludes that: "Thus, a certified registered nurse does not possess independent authority to administer anesthesia without delegation by a physician."

Additionally, Section 157.058 relates specifically to CRNAs and uses the phrase "physician may delegate":

> (a) In a licensed hospital or ambulatory surgical center, a physician may delegate to a certified registered nurse anesthetist the ordering of drugs and devices necessary for the nurse anesthetist to administer an anesthetic or an anesthesia-related service ordered by the physician.
> (b) The physician's order for anesthesia or anesthesia-related services is not required to specify a drug, dose, or administration technique.
> (c) Pursuant to the physician's order and in accordance with facility policies or medical staff bylaws, the nurse anesthetist may select, obtain, and administer those drugs and apply the medical devices appropriate to accomplish the order and maintain the patient within a sound physiological status.

> (d) This section shall be liberally construed to permit the full use of safe and effective medication orders to use the skills and services of certified registered nurse anesthetists. (Emphasis added.)

The use of "may delegate" language mirrors Section 157.001(a), "A physician may delegate to a qualified and properly trained person acting under the physician's supervision….". Section 157.058 provides for greater flexibility for the utilization of CRNAs, but only via delegation and a physician's order. The phrase in Section 157.058(d), "full use of safe and effective medication orders" does not negate the requirement of supervision of Section 157.001. Therefore, Section 157.058 allows delegation of certain anesthesia-related services, via a physician's order subject to Section 157.001's supervisory requirement. With these two elements in place, a CRNA can carry out the delegated act(s).

Section 157.058 does not stand alone from the other provisions of Chapter 157. (See footnote 2, pg. 2). Section 157.058(d) refers specifically to medication orders regarding the utilization of CRNA skills. The legislature defined "medication order" in Section 157.002 of the MPA as follows:

> (7) "Medication order" has the meanings assigned by Section 551.003 of this code and Section 481.002, Health and Safety Code.

The Health and Safety Code, Section 481, *a/k/a* Texas Controlled Substances Act (CSA), must be construed in harmony with the MPA. Specifically, Section 481.002 of the CSA defines the following terms:

> (28) "Medication order" means an order from a practitioner to dispense a drug to a patient in a hospital for immediate administration while the patient is in the hospital or for emergency use on the patient's release from the hospital.
>
> (39) "Practitioner" is:
> (A) a physician, … ; or
> (D) an advanced practice registered nurse or physician assistant to whom a physician has delegated the authority to prescribe or order a drug or device under Section 157.0511, 157.0512, or 157.054, Occupations Code.

Section 481.071 of the CSA provides further clarification:

> (a) A practitioner defined by Section 481.002(39)(A) may not prescribe, dispense, deliver, or administer a controlled substance or cause a controlled substance to be administered under the practitioner's direction and supervision except for a valid medical purpose and in the course of medical practice. (Emphasis added)

Section 157.051 also refers to Tex. Occ. Code, Sec. 551.003 (Pharmacy Act) regarding the definition of "medication order." The Pharmacy Act also defines "administer" and "practitioner" in the same way as the CSA. Specifically, Section 551.003 defines the following terms:

> (24) "Medication order" means an order from a practitioner or a practitioner's designated agent for administration of a drug or device.
>
> (1) "Administer" means to directly apply a prescription drug to the body of a patient by any means, including injection, inhalation, or ingestion, by:
> (A) a person authorized by law to administer the drug, including a practitioner or an authorized agent under a practitioner's supervision; or
> (B) the patient at the direction of a practitioner. (Emphasis added.)
>
> (39) "Practitioner" means:
> (A) a physician… ; or
> (D) an advanced practice registered nurse or physician assistant to whom a physician has delegated the authority to prescribe or order a drug or device under Section 157.0511, 157.0512, or 157.054, Occupations Code.

The legislative intent is clear in these statutes that physician supervision is required when delegating anesthesia-related services to a CRNA. Section 157.058 allows greater professional latitude than other delegates[4] but some degree of physician supervision is still required.

If Section 157.001 were not intended to apply to CRNAs, the legislature would have added language such as "notwithstanding the provisions,…" which is used in a multitude of statutes. Both the Pharmacy Act and the CSA deliberately use the term "supervision" in a manner consistent with MPA, Section 157.001. Neither of these Acts exempt the CRNAs from supervision. The level of required supervision of a CRNA is governed by the MPA, as is enforcement of such provision.

This requirement for CRNA supervision is also found in MPA, Section 157.054, referring to a facility-based practice at a hospital. This provision uses the terms "may delegate," "supervision'" and "administration." Moreover, Section 157.054 and Section 157.058, both specifically refer to administration of drug in a hospital or facility. Section 157.054 states:

> (a) One or more physicians licensed by the board may delegate, to one or more physician assistants or advanced practice registered nurses acting under adequate physician supervision whose practice is facility-based at a

[4] See, Tex. Occ. Code, Sec. 206.001. Surgical Assistant Act, which is an advisory board to the Medical Board: (3) "Direct supervision" means supervision by a delegating physician who is physically present and who personally directs delegated acts and remains immediately available to personally respond to any emergency until the patient is released from the operating room or care and has been transferred, as determined by medical board rule, to another physician. (Emphasis added.)

> hospital or licensed long-term care facility, the administration or provision of a drug and the prescribing or ordering of a drug or device if each of the delegating physicians is: …
> (b) A physician's authority to delegate under Subsection (a) is limited as follows:
> (1) the delegation must be made under a physician's order, standing medical order, standing delegation order, or another order or protocol developed in accordance with policies approved by the facility's medical staff or a committee of the facility's medical staff as provided by the facility bylaws;
> …
> (c) Physician supervision of the prescribing or ordering of a drug or device must conform to what a reasonable, prudent physician would find consistent with sound medical judgment but may vary with the education and experience of the particular advanced practice registered nurse or physician assistant. A physician shall provide continuous supervision, but the constant physical presence of the physician is not required. (Emphasis added.)

Overall, there are three different acts that use the statutory terms "delegate", "supervision", and "administer/administration" in a consistent manner.[5]

Any assertion that Section 157.001 does not apply to Section 157.058, can only be supported by completely ignoring the tenets of statutory construction and two opinions of the Attorney General. Both the delegating physician and APRNs, including CRNAs, are subject to requirements of these statutes. And the assertion that CRNA regulation is limited just to MPA, Section 157.058 is legally unsupported. Moreover, the requirement of physician supervision of CRNAs is recognized by federal statutes and rules, as well judicial decisions as described below.

TEXAS JUDICIAL DECISIONS

The issue of supervision and liability is the subject of Texas judicial decisions. These decisions clarify that the delegating physician is liable for the acts of their delegate. In, *Davis v. Tex. Med. Bd.*, 2018 Tex. App. LEXIS, 2662, April 2018, the issue of delegation, supervision and the applicability of Section 157.001 and 157.060 of the MPA was addressed.

This case involved a "pill mill" and an Advanced Practice Nurse (APN *a/k/a* APRN) delegate of a physician. However, the Court applied statutory construction and clarified that both provisions Sections 157.001 and 157.060 of the MPA apply to APNs, which includes CRNAs. [6, 7]

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[5] See also, 25 TAC §135.11 Anesthesia and Surgical Services, (2) The anesthesia department shall be under the medical direction of a physician approved by the governing body upon the recommendation of the ASC medical staff.

[6] APRN is statutorily defined in MPA, Sec. 157.051(1) "Advanced practice registered nurse" has the meaning assigned to that term by Section 301.152.

[7] Nursing Act, Sec. 301.152. (a) In this section, "advanced practice registered nurse" means a registered nurse licensed by the board …. . The term includes a nurse practitioner, nurse midwife, nurse anesthetist, and clinical nurse specialist. The term is synonymous with "advanced nurse practitioner" and "advanced practice nurse.

In *Davis*, the 3rd Court of Appeals resoundingly rejected the argument that only Section 157.060 applies to CRNA delegation and not Section 157.001.

> "Although Tex. Occ. Code Ann. § 157.060 is more specific than Tex. Occ. Code Ann. §157.001(b), §157.060 does not mean that a physician may never be responsible for delegated medical acts unless he has reason to believe that the advanced practice registered nurse (APN) lacked the competency to perform the act. Instead, the provision means that a physician will not be held responsible for delegated medical acts in the absence of such knowledge solely because of the supervisory relation he has with the APN, but he may still be held responsible for other reasons—including a failure to appropriately supervise the APN." (Emphasis added.)

In, *Cotropia v. Tex. Med. Bd*., 2018 Tex. App. LEXIS 6829, the 3rd Court of Appeals relied on *Davis* and stated:

> "[S]ection 157.060 does not mean that a physician may never be responsible for delegated medical acts unless he has reason to believe that the APN lacked the competency to perform the act. Instead, the provision means that a physician will not be held responsible for delegated medical acts in the absence of such knowledge solely because of the supervisory relation he has with the APN... . **In other words, section 157.060's more specific provision does not eliminate the general rule of section 157.001(b), it only limits it in certain circumstances.**
>
> "By contrast, the parameters of a physician's duty to supervise APNs and others performing delegated medical acts depends on the type of the act. See, e.g., Tex. Occ. Code §§157.0511-.0514 (addressing agreements allowing prescription of medication), **.058 (addressing delegation agreements with nurse anesthetists)**(emphasis added), .101 (addressing delegation agreements with pharmacists)."

In, *Denton Regional Med. Ctr. v. LaCroix*, 947 S.W.2d 941, 943 (Court of Appeals of Texas, Second District, Fort Worth) (1997), the Court stated:

> "The evidence showed that the practice of anesthesia is a specialized practice of medicine by a physician--an anesthesiologist. An anesthesiologist is also trained in the practice of taking care of a patient just as any other physician is trained. An anesthesiologist is the most highly trained person who practices anesthesia. A certified registered nurse anesthetist (CRNA) is a registered nurse who has additionally completed a two-year study in nurse anesthesia and has been certified by the American Association of Nurse Anesthetists. **Nurse anesthetists may administer anesthesia, but only under the medical direction or supervision of a physician.** Nurse anesthetists cannot practice medicine. (Emphasis added)

Texas Revised Civil Statutes Annotated, Article 4495, Section 3.06(d), in effect at the time of *LaCroix*, stated in part:

> "This Act shall be construed that: (1) A person licensed to practice medicine shall have the authority to delegate to any qualified and properly trained person or persons acting under the physician's supervision any medical act which a reasonable and prudent physician would find within the scope of sound medical judgment to delegate if, in the opinion of the delegating physician, the act can be properly and safely performed by the person to whom the medical act is delegated and the act is performed in its customary manner, not in violation of any other statute and the person does not hold himself out to the public that the person is authorized to practice medicine. …" (Emphasis added.)

In, *Webb v. Jorns***,** 488 S.W.2d 407, 411 (Tex. 1973), the Court while focused on the "captain of the ship" doctrine, also stated physician supervision is required:

> "The application of the captain of the ship doctrine was not an issue since the physicians conceded that they were subject to liability for actions of any of the persons under their supervision in the operating room."

These cases establish that Texas law requires physician supervision of CRNAs if there is to be delegation of medical acts to a CRNA. Once there is physician delegation, there must be physician supervision under the plain language of the statute, MPA, Section 157.001.

FEDERAL JUDICIAL DECISIONS

The federal courts have a large body of case law related to delegation and supervision from various jurisdictions. This body of law includes many decisions related to Medicare that are discussed in the next section related to the Centers for Medicare and Medicaid Services (CMS).

In, *Tatro v. Texas,* 703 F.2d 823**,** (5th Cir. 1987), the U.S. 5th Court of Appeals, while not directly involving CRNAs, squarely addressed delegation and supervision:

> "As the district court found, it has been long settled that physicians in Texas may prescribe treatment and delegate its administration to others. *Thompson v. Texas State Board of Medical Examiners*, 570 S.W.2d 123, 129-30 (Tex.Civ.App. -- Tyler 1978, writ ref'd n.r.e.); *McKinney v. Tromly*, 386 S.W.2d 564 (Tex.Civ.App. -- Tyler 1964, writ ref'd n.r.e.); see also *Op. Tex.Atty.Gen. No. WW-1403* (1962). Subsequent to the district court's decision on remand, this principle was codified in Texas' new Medical Practice Act:
> a person licensed to practice medicine shall have the authority to delegate to any qualified and properly trained person or persons acting under the physician's supervision any medical act which a reasonable and prudent physician would find is within the scope of sound medical judgment to delegate if, in the opinion of the delegating physician, the act can be properly and safely performed by the person to whom the medical act is delegated and the act is performed in its customary manner,

not in violation of any other statute, and the person does not hold himself out to the public as being authorized to practice medicine. The delegating physician shall remain responsible for the medical acts of the person performing the delegated medical acts." (Emphasis added.)

"**The Medical Practice Act's requirement that a physician supervise those to whom he delegates a medical act has appeared in a number of prior statutes**, and has been construed by the Texas Attorney General "not [to] require the constant physical presence of a physician to authorize the performance of professional nursing acts by one not otherwise licensed to perform them, so long as the responsible physician personally assumes control and supervision of the employee or instructs him in what is to be done, and remains reasonably available to see that the nursing acts are properly performed." *Op.Tex.Atty.Gen. No. H-395* (Sept. 9, 1974). See also *Op.Tex.Atty.Gen. No. H-1295* (Dec. 19, 1978) (nurses may administer treatment without direct supervision by doctor).[8] (Emphasis added.)

In, *Swayze v. McNeil Labs., Inc***.,** 807 F.2d 464 (5th Cir. 1987), the Court noted there may be issues with level of supervision, but clearly supervision is required:

> Under Mississippi law, fentanyl is a prescription drug that may be prescribed, administered, and dispensed only under the direction and supervision of a licensed physician. Miss. Code Ann. § 41-29-305 (1972).

In, *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.,* 863 F.2d 1173 (5th Cir. 1988), the Court indirectly addressed supervision in the operating room:

> In Swayze, although the surgeon was present, he did not intervene or otherwise make any professional judgment whether an anesthetic should be given, or in what dosage, to a patient about to undergo surgery. The patient ultimately died as a result of an overdose. Nevertheless, because the physician-patient relationship existed, and because the doctor had thus assumed the role of learned intermediary, the fact that he had made no individualized judgment did not bar the application of the learned intermediary doctrine to relieve the manufacturer of liability. We held: "Drug manufacturers must adequately warn physicians of the potential side-effects of their prescription drugs; thereafter, the physician, with his special knowledge of the patient's needs, assumes the burden of presiding over the patient's best interests." *Id. at 472.*

In addition to these relevant 5th Circuit decisions there are extensive cases from other federal courts throughout the country. See, *Hicks v. Bryan Med. Grp., Inc.,* 287 F. Supp. 2d 795 (N.D. Ohio 2003), "These provisions are consistent with Ohio law on nurse anesthetists, which provides that CRNAs can only administer anesthesia "with the supervision and in the immediate presence of a physician." Ohio Rev. Code § 4723.43(B); see also Ohio Rev. Code § 4731.35."

[8] These earlier AG opinions are consistent with both Opinion No. JC-0117 (1999) and KP-0266 previously cited above.

In, *Labzda v. Purdue Pharma, L.P.*, 292 F. Supp. 2d 1346 (S.D. Fla. 2003), the Florida District Court looked to the 5th Circuit precedent and found, "…The court held that it was "the physicians who have undertaken the responsibility of supervising the CRNAs, and that responsibility cannot be shunted onto, or shared with, drug manufacturers." Swayze, 807 F.2d at 471. (Emphasis added.)

Blevins v. Sheshadri, 313 F. Supp. 2d 598 (W.D. Va. 2004), "Virginia licensure law requires that a CRNA be under the medical direction and supervision of a licensed physician when administering anesthesia. -… if an anesthesiologist was not present at the hospital, the surgeon performing the operation was the supervisor of the CRNA. …."

Morvillo v. Shenandoah Mem'l Hosp., Civil Action No. 5:07CV00046, 2008 U.S. Dist. LEXIS 68595 (W.D. Va. 2008), "The applicable Virginia licensing regulation "requires that a CRNA be under the direction and supervision of a licensed physician when administering anesthesia.")

In, *Luckey v. Cty. of Essex of N.J.*, No. 04-3847 (GEB), 2006 U.S. Dist. LEXIS 91537 (D.N.J. 2006), "We are not allowing liability to be imposed on the doctors merely because they were attending physicians on duty at the time of plaintiff's injury, but rather because the jury could find they had specific duties to train and supervise the other employees on duty." (Emphasis added.)

These cases reinforce the need for physician supervision of CRNAs. While several cases are not from the 5th Circuit, the issues are the same. Federal case law holds supervision of CRNAs is required. Further, the state laws cited in these cases closely resemble the applicable provisions of the Texas MPA.

CMS STANDARDS

CMS has explicit standards and guidelines related to physician supervision of CRNAs. Although, most of the decisions discussed below are brought under the False Claims Act, these show CRNA supervision is required. The following CMS standards and guidelines apply to Texas hospitals and medical facilities.

The specifically applicable CMS rules are 42 C.F.R.:

> §482.52 Condition of participation: Anesthesia services.
> If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.
>
> (a) Standard: Organization and staffing. The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered only by-
> (1) A qualified anesthesiologist;
> (2) A doctor of medicine or osteopathy (other than an anesthesiologist); …

(4) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter, who, unless exempted in accordance with paragraph (c) of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or
(5) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter, who is under the supervision of an anesthesiologist who is immediately available if needed.

(c) Standard: State exemption.
(1) A hospital may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (a)(4) of this section, if the State in which the hospital is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.
(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission. (Emphasis added.)

§485.639-Critical Access Hospitals (CAHs)-Condition of participation: Surgical services.[9] If a CAH provides surgical services, surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body, or responsible individual, of the CAH in accordance with the designation requirements under paragraph (a) of this section. In addition, the section addresses anesthesia services under (c) that states,

(c) Administration of anesthesia. The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope-of-practice laws.
(1) Anesthesia must be administered by only -
(v) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter;

(2) In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist. (Emphasis added.)

[9] In Texas, as of October 2019, there are 87 CAH and 187 federally qualified healthcare systems located outside of urban hubs. There also over 500 Ambulatory Surgery Centers (ASCs).

(e) Standard: State exemption. (1) A CAH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (c)(2) of this section, if the State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.[10, 11, 12]

It is critical to understand Texas is not an opt-out state under CMS. The Governor has neither requested, nor concluded, that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law. See, *https://www.aana.com/docs/default-source/sga-aana-com-web-documents-(all)/801-fact-sheet-concerning-state-opt-outs-pdf.pdf?sfvrsn=450743b1_8*

CMS CASE LAW

Federal courts consistently apply the CMS standards related to CRNA supervision in a manner that directly correspond with Chapter 157 of the MPA. Persons qualified to perform anesthesia services are expressly noted as "conditions of participation" in 42 C.F.R. §482.52.

In**,** *MA v. Ostroff***,** No. 12-cv-00200-JCS, 2013 U.S. Dist. LEXIS 57433 (N.D. Cal. 2013), "….The regulation states five categories of persons who may administer anesthesia services: … (4) A certified registered nurse anesthetist (CRNA) . . . [who] is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or (5) An anesthesiologist's assistant . . . who is under the supervision of an anesthesiologist who is immediately available if needed." 42 C.F.R. §§ 482.52(a).

[10] Federal law states that for a hospital, a Critical Access Hospital (CAH) or Ambulatory Surgical Center (ASC), to participate in the Medicare program, that facility must comply with requirements such as having a physician supervise Certified Registered Nurse Anesthetists (CRNAs) unless a state chooses to opt-out of the supervision requirement (42 CFR §§ 482.52; 485.639; 416.42). To opt-out, a state's governor must ensure that the state meets three conditions before sending a letter to the Center for Medicare & Medicaid Services (CMS) requesting the opt-out.

[11] CMS defines medical direction and Texas law related ASC's applies virtually the same standards to provide anesthesia under medical direction of a physician, See 25 TAC §135.11. The opt-out requirements are also the same for ASCs under 42 CFR 416.42(c) as those for CAHs.

[12] *Green v. Springfield Med. Care Sys.*, No. 5:13-cv-168, 2014 U.S. Dist. LEXIS 87911 (D. Vt. 2014))"… to opt-out of a federal Medicare regulation requiring CRNAs to work under the supervision of the operating surgeon or an anesthesiologist who is immediately available if needed. States may elect to opt-out of this Medicare requirement, but Vermont's Governor Peter Shumlin has not done so. …" (Emphasis added.)

In, *United States ex rel. Estate of Donegan v. Anesthesia Assocs. of Kan. City, PC,* No. 4:12-CV-0876-DGK, 2015 U.S. Dist. LEXIS 74239 (W.D. Mo. 2015),[13] the Court reviewed the CMS standards for billing anesthesia services:

> i. Personally Performed.
> Generally speaking, an anesthesiology service is Personally Performed when the anesthesiologist performs "the entire anesthesia service alone." 42 C.F.R. § 414.46(c)(1). For such service, the anesthesiologist is paid at a rate determined by a formula. Id. § 414.46(c)(2).
>
> ii. Medical Direction.
> Anesthesiology service is paid at the Medical Direction rate when the anesthesiologist is directing Certified Registered Nurse Anesthetists ("CRNAs") in two to four cases concurrently and the anesthesiologist satisfies all conditions of the so-called "Seven Steps" regulation. Id. §§ 414.46(d), 415.110(a)(1).
>
> As for how the provider documents compliance with these steps, subsection (b) of the regulation states:
>
> For each Medical Direction service, CMS pays the anesthesiologist 50 percent of the amount that he or she would have earned had he or she Personally Performed the service. Id. § 414.46(d)(3)(v). …. The practice can bill the remaining 50 percent for each of the four CRNAs the anesthesiologist directed. … .
>
> iii. Medical Supervision.
> Anesthesiology service is reimbursed at the Medical Supervision rate when an anesthesiologist: (1) directs more than four cases concurrently, or (2) directs two to four cases but fails to comply with one or more of the seven conditions. The reimbursement rate is lower for Medical Supervision than for Medical Direction.

In, *Bryant v. United States,* No. CIV 98-1495 PCT RCB, 2000 U.S. Dist. LEXIS 23939 (D. Ariz. 2000), the Court declined a semantics argument of "supervise" versus "direct:"

> … The court does not find a material difference between one's authenticity to "supervise" and one's authority to "direct". Each involves a level of control which is dispositive here. (Emphasis added.)

Anesthesia care requires physician's supervision of CRNA's, unless the state has "opted out." Texas is not a CMS "opt-out" state. And CRNA must be supervised by a physician in order for the practitioner and facilities to receive reimbursement for anesthesia services.

[13] See also, *United States ex rel. Lord v. NAPA Mgmt. Servs. Corp.*, No. 3:13-2940, 2017 U.S. Dist. LEXIS 188104 (M.D. Pa. 2017); *United States ex rel. Branigan v. Bassett Healthcare Network*, 234 F.R.D. 41 (N.D.N.Y. 2005).

FTC's COMMENTS AND INDEPENDENT PRACTICE

When the Board proposed language changes to 22 TAC 193.13, in mid-2019, the Federal Trade Commission (FTC) filed comments. The FTC expressed concern over CRNA supervision in Texas. However, the FTC has historically recognized the appropriateness of CRNA supervision. Specifically, in a November 2, 2015 letter to Hon. Jenny A. Horne, South Carolina House of Representatives, the FTC's Footnote # 14 states:

> The phrase "independent practice" here, and commonly, refers to state regulatory schemes that do not require direct supervision of an APRN by a particular physician for an APRN to deliver services otherwise within his or her scope-of-practice. "Independent practice" does not, however, mean isolated or unregulated practice. Collaboration and professional oversight are the norm in states that do not require direct physician supervision.[14] Patterns of collaboration are independently established by institutional providers, from large hospital systems to small physician practices, to individual practitioners, with the particulars varying according to resources and demands at the point of service, and standards of care, as well as other regulations. … . (Emphasis added.)

This same statement concerning "independent practice" is found in Jan. 17, 2014 letter to The Hon. Kay Khan, Mass. House of Representatives at Footnote #15 and appears in several other FTC letters regarding APRNs and CRNAs.

Even more compelling is the following statement in the FTC letter to Representative Horne:

> "Based on an extensive review of the safety literature, the IOM has recommended that state laws permit nurses to practice to the full extent of their education, training, and experience."

This is exactly what Texas law states. Section 157.058(d) states: "This section shall be liberally construed to permit the full use of safe and effective medication orders to use the skills and services of certified registered nurse anesthetists." (Emphasis added.) Texas law is fully compliant with long-standing FTC guidance on the meaning of "independent practice" and supervision.

The importance of this language is two-fold. First, it parallels the FTC letters and statements. Second, it refers back to Section 157.001 that sets the general standard for delegation and supervision that applies to Section 157.058(d).[15]

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[14] Opinion No. JC-0117, "Consequently, section 157.058 does not require that a physician directly supervise a CRNA's selection and administration of the anesthesia. Rather, the extent of physician involvement is left to the physician's professional judgment in light of other relevant federal and state laws, facility policies, medical staff bylaws, and ethical standards. See id. 157.001, .007, .058."

[15] See, *Davis* and *Cotropia,* cited on page 6 and 7.

The FTC repeatedly acknowledges that direct supervision is not required; however, that does not mean "no supervision," instead that supervision is very flexible but not absent. The FTC statements mirror both the Cornyn and Paxton opinions. Specifically, the Cornyn opinion states:

> "Rather, the extent of physician involvement is left to the physician's professional judgment in light of other relevant federal and state laws, facility policies, medical staff bylaws, and ethical standards."

Texas statutes and rules are consistent with the FTC position recognizing and allowing the full use of the skills and knowledge of CRNAs, under supervision and delegation.

CONCLUSION

There are certain individuals and groups, promoting self-interests, who are creating confusion over the relationship and legal obligations between delegating and supervising physicians and CRNAs.

Specifically, CRNAs claim they have "independent" practice in the field of anesthesia. While there is a great latitude in utilizing these professionals and their skills, it is legally incorrect and misleading to claim they have independent practice, not to mention impossible, as CRNAs cannot anesthetize patients without a physician order or authorization.[16]

The statute is clear when it states: "A physician may delegate to a qualified and properly trained person acting under the physician's supervision …." The Attorney General has repeatedly found that "direct" supervision is not required but has never maintained that "no supervision" is required. The AG has repeatedly stated:

> "… the extent of physician involvement is left to the physician's professional judgment in **light of other relevant federal and state laws**, facility policies, medical staff bylaws, and ethical standards." [17]

Texas is not an "opt-out" state for CMS related to anesthesia services, CRNA supervision and reimbursement. In order to receive CMS reimbursement for anesthesia services, a CRNA must be supervised. CMS standards articulate the relevant federal law that requires CRNA supervision. Both state and federal case law also support the need for supervision of CRNAs under Texas law.

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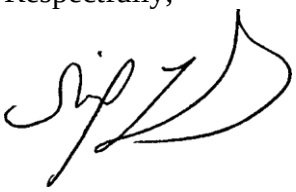
[16] In KP-0266, the AG's deliberate use of term "independent" is reflected in the statement, "A certified registered nurse anesthetist does not possess independent authority to administer anesthesia without delegation by a physician, consistent with Section 157.001 of the Act."

[17] The following is a response by the Texas Nursing Board, in Tex. Reg., 2/22/2019, Vol 44, No. 8, to comments regarding rules they proposed related to APRN's: A commenter states that the Medical Practice Act includes numerous examples of the Texas Legislature's clear intent that APRNs perform medical acts only when those acts are delegated by a physician and performed under adequate physician supervision or a prescriptive authority agreement. The Board does not disagree, nor has the Board proposed any amendment that would alter this interpretation of Texas law. The Board agrees that an APRN may only perform medical aspects of care through proper physician delegation, supervision, and collaboration. The Board also agrees than an individual must be properly educated and qualified to perform such delegated functions.

Finally, Texas' approach and laws correlate with FTC guidance and statements.

Based on the above arguments, TMB respectfully requests an opinion to resolve the issue of physician supervision and delegation to CRNAs under the provisions of the MPA.

Respectfully,



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