

HENRY MCMASTER ATTORNEY GENERAL

June 23, 2010

The Honorable Tracy R. Edge Representative, District No. 104 - Horry County PO Box 2095 North Myrtle Beach, SC 29577

Dear Representative Edge:

We received your letter requesting an opinion of this Office concerning sedation and the use of propofol by a registered nurse across all practice settings. You asked whether a professionally licensed Registered Nurse (RN) may administer propofol for moderate (conscious) sedation when used with FDA-approved technologies, across all practice settings, when under the prescriptive order of a licensed South Carolina Physician. As noted in your request, there is much concern regarding a recent South Carolina Ambulatory Surgery Center (ASC) Rule and South Carolina Board of Nursing (SCBON) Advisory Opinion. The ASC Rule and SCBON Opinion may be interpreted as prohibiting licensed nurses from accessing such FDA-approved technologies with respect to the administration of propofol for moderate (conscious) sedation even when used under the supervision of a physician. This opinion will use prior opinions of this Office, statutes, and caselaw to clarify the ASC Rule and SCBON Opinion, and to resolve ambiguity for professionally licensed registered nurses and for physicians.

Marsha McKenna, Professional Affairs Director of Ethicon Endo-Surgery, Inc., A Johnson & Johnson Company and George Irving, Director of State Government Affairs for Johnson & Johnson Services, Inc., also expressed concern that there is ambiguity between the SCBON ruling and the SC Medical Practices Act. Both seek clarification from this Office in the form of an opinion.

Law/Analysis

The South Carolina Medical Practices Act is found in Chapter 47 of Title 40 of the South Carolina Code of Laws of 1976. § 40-47-60 explains that the practice of medicine should not be restricted in the following circumstances:

[N]othing in this article shall be construed . . . to prohibit a licensed physician from delegating tasks to unlicensed personnel in his employ and on his premises if: a) the task is of a routine nature involving neither the special skill of a licensed person nor significant risk to the patient if improperly done; b) the task is performed while the physician is present on

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the premises and in such close proximity as to be readily available to the *unlicensed* person if needed

S.C. Code Ann. § 40-47-60 (emphasis added).

Professionally licensed Registered Nurses would be considered *licensed* personnel; however, if a doctor is permitted to delegate tasks to "unlicensed personnel," then logically a doctor would be permitted to delegate tasks to licensed personnel. A Registered nurse "means a person to whom the board has issued a license as a registered nurse." S.C. Code Ann. § 40-33-10(d).

The "practice of professional nursing" is defined in § 40-33-10(g) as "the performance for compensation of any acts in the health care process involving the process of assessment, intervention, and evaluation . . . [including] **the administration of medication**, and treatments as authorized and prescribed by a licensed physician." The definition further explains that a "professional nurse may perform additional acts in the extended role requiring special education and training which are agreed to jointly by both the Board of Nursing and the Board of Medical Examiners. Those additional acts agreed to by both boards must be promulgated by the Board of Nursing in its regulations." S.C. Code Ann. § 40-33-10(g) (emphasis added).

The powers of the SC Board of Nursing are delineated in S.C. Code Ann. § 40-33-210, <u>et. seq.</u> Specifically, § 40-33-270 gives the Board the authority to "make such rules and regulations as it may deem necessary for the purposes of carrying out the provisions of this chapter." S.C. Code Ann. § 40-33-270.

Generally, "administrative bodies have the authority to make or adopt rules and regulations with respect to matters which are within the province of the body. The provisions of the statute control as to what areas rules and regulations may deal with. The rules and regulations can properly function to effectuate the purpose of the legislation." Op. S.C. Atty. Gen., February 15, 1978 (citing 91 C.J.S. Public Administrative Bodies and Procedures, § 112).

While the South Carolina Board of Nursing has the general authority to promulgate rules and regulations concerning nursing practice, Marsha McKenna and George Irving suggest that "there are no restrictions in the South Carolina Medical Practices Act that prohibit a licensed Professional Nurse (RN) from administering any form of medication under the prescriptive order of a licensed South Carolina Physician."

In an opinion of the Georgia Attorney General's Office dated May 10, 1988, a distinction was made between administering and dispensing a drug.

¹ S.C. Code Ann. § 40-47-60(b).

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There is a statutory distinction between the act of "administering" a drug versus the act of "dispensing" a drug. The administration of a drug generally means giving a unit dose of medication to an individual patient as a result of the order of an authorized practitioner of the healing arts. O.C.G.A. § 26-4-[5](1) [sic]. For example, the administration of a controlled substance can be given by a practitioner or, in his presence, by his authorized agent. O.C.G.A. § 16-13-21(1). Indeed, O.C.G.A. § 43-26-1(3) defines the practice of nursing to include the administration of medications as prescribed by a physician. See also O.C.G.A. § 43-26-30(2)(D) (licensed practical nurse may administer medications upon supervision of licensed practitioners or registered nurses).

On the other hand, the act of prescribing refers to an order for drugs either written or telephoned in by a practitioner of the healing arts, and the subsequent dispensing of such drugs for later use by a patient. O.C.G.A. § 26-4-2(20).

Ga. Op. Atty. Gen. No. 88-9 (1988).

In other words, professionally licensed Registered Nurses can be considered an extension of the physician when the physician gives a prescriptive order. The practice of nursing includes the administration of medicine. <u>Ga. Op. Atty. Gen.</u> No. 88-9 (1988).

Article Three, Chapter 53 of Title 44 of the South Carolina Code of Laws of 1976 governs Narcotics and Controlled Substances. Propofol is not classified in the South Carolina Code. However, the U.S. Department of Justice, Drug Enforcement Administration has classified propofol as a Schedule IV controlled substance. 21 CFR §1308; 21 U.S.C. § 812.

S.C. Code § 44-53-240 explains the tests for inclusion of a controlled substance in Schedule IV as follows:

The Department shall place a substance in Schedule IV if it finds that:

- (a) It has a low potential for abuse relative to the substances in Schedule III;
- (b) It has a currently accepted medical use in treatment in the United States; and
- (c) Abuse of the substance may lead to limited physical or psychological dependence relative to substances in Schedule III.

S.C. Code § 44-53-240.

In November of 2004, the <u>Association of periOperative Registered Nurses (AORN) Journal</u> addressed whether nurses should administer propofol. The <u>AORN Journal</u> concluded that "[p]ropofol should be administered only by people trained in the administration of general anesthesia." The Journal explains that having RNs administer propofol is a safety issue because of "the unpredictability of a patient's reaction to propofol, the potential for rapid and profound changes in

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the depth of sedation, and the lack of a reversal agent." Debra T. Moore, <u>Nurses Administering Propofol</u>, AORN Journal (2004). <u>See also</u>, Deb A. Huber, MSN, RN, ARNP, CGRN, <u>Use of Propofol in Gastroenterology Practice</u>, Gastroenterology Nursing, vol. 27, No. 5, 242-43 (2004).

John Roark explains in his article, "The Great Debate: Nurse-Administered Propofol Sedation (NAPS)," that nurse and attorney Debrah A. Krohn, RN, BA, JD, contacted every state's nursing board across the country and found that no concensus has been reached as to whether RNs may administer "propofol for the purposes of procedural sedation." John Roark, "The Great Debate: NAPS;" available at https://www.endonurse.com/articles/521feat4.html (2/1/2005). On one hand, states such as the Wyoming State Board of Nursing concluded that "it is not within the scope of practice for a RN to administer Propofol[;]... Propofol must be administered by persons trained in the administration of anesthesia." Wyoming State Board of Nursing, Advisory Opinion No. 06-163, July 14, 2006. On the other hand, states such as the Louisiana State Board of Nursing determined that "the administration of intravenous conscious sedation is within the realm of practice of a RN as delineated by the Board's specific criteria." Louisiana State Board of Nursing, available at http://www.lsbn.state.la.us (3/16/2005).

Conclusion

The administration of propofol for the purpose of minimal to moderate (conscious) sedation when using a FDA-approved computer assisted personalized sedation system (CAPS) by a South Carolina professionally licensed Registered Nurse (RN) under the direct supervision of a licensed South Carolina physician (MD), in a clinical or hospital setting, does not violate the South Carolina Code of Laws even though the SCBON's Advisory Opinion and ASC Rule currently restricts the use of propofol administration by an RN.

² "Krohn did independent research on the subject, emailing literally every nursing board in the country. In response to the standard question, 'Does your nurse practice act allow for the practice of nurse - (meaning RN, not CRNA) administered propofol for the purposes of procedural sedation?' The results were enlightening:

²² states: Permitted/no prohibition

²¹ states: not permitted 5 states: no position/unclear 2 states: did not respond."

³ The proposed language encouraged this Office to conclude that RNs may administer propofol across all practice settings: "in an office based practice, ambulatory surgical center, or hospital." While there is no express restriction under South Carolina law for RNs to administer propofol in any setting, the dangers of such a drug merit that this opinion suggests that RNs only administer propofol in a clinical or hospital setting where there is close supervision and monitoring of the patient.

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Under South Carolina law, there is no express prohibition against a RN administering propofol under the direction and supervision of a physician. Finding no prohibition, we believe such practice is permitted under current state law; however, because of the dangerous and rapid potential effects of propofol, one must exercise extreme caution when administering the drug. Based upon current information, propofol is best administered in a clinical or hospital setting because close monitoring is imperative as a patient's condition can change in a matter of seconds. The nurse's administration of the drug and the patient's response to it must be closely monitored by one trained in administering anesthetics, such as a physician, anesthesiologist, or nurse anesthetist.

Sincerely,

Henry McMaster Attorney General

By:

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REVIEWED AND APPROVED BY:

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Deputy Attorney General