

**STATE OF TENNESSEE
OFFICE OF THE ATTORNEY GENERAL**

December 30, 2021

Opinion No. 21-19

Disciplinary Proceedings Against Physicians Who Prescribe Medications “Off-Label” for COVID-19

Question

Does the Tennessee Board of Medical Examiners have to promulgate a rule before a disciplinary proceeding can be instituted against a physician who prescribes a medication—such as ivermectin or hydroxychloroquine—for “off-label” use for the treatment of COVID-19?

Opinion

Yes. While disciplinary proceedings may generally be instituted against physicians under Tenn. Code Ann. § 63-6-214(b) in the absence of a rule, Tenn. Code Ann. § 14-4-104 requires the Board of Medical Examiners to promulgate a rule before it conducts a disciplinary proceeding against a physician “regarding the dispensing or prescribing of medication for COVID-19.”

ANALYSIS

Under the Tennessee Medical Practice Act, the Board of Medical Examiners (the “Board”) has the duty to conduct disciplinary hearings involving physicians. *See* Tenn. Code Ann. § 63-6-101(a)(3). Tennessee Code Annotated § 63-6-214(b)(1)-(22) lists twenty-two grounds on which the Board may discipline a physician. Other conduct not specifically listed in § 63-6-214(b)(1)-(22) can also result in discipline since the list, by its own terms, is not exhaustive. *Perez v. Tenn. Bd. of Med. Exam’rs.*, M2018-00960-COA-R3-CV, 2019 WL2880980, at *6 (Tenn. Ct. App. July 3, 2019) (observing that the Board is not limited in its action to the specific circumstances listed in subsections (b)(1)-(22) because Tenn. Code Ann. § 63-6-214(b) states: “The grounds upon which the board shall exercise power, include, *but are not limited to . . .*”) (emphasis in original).

Disciplinary actions against physicians for allegedly prescribing and dispensing unsuitable medications or inappropriate amounts of medications typically involve grounds listed in Tenn. Code Ann. § 63-6-214(b)(1), (4), and (12), respectively:

- (1) Unprofessional, dishonorable or unethical conduct;
- (2) Gross health care liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence in the course of medical practice; and

- (3) Dispensing, prescribing or otherwise distributing any controlled substance or any other drug not in the course of professional practice, or not in good faith to relieve pain and suffering, or not to cure an ailment, physical infirmity or disease, or in amounts and/or for durations not medically necessary, advisable or justified for a diagnosed condition.

See, e.g., Johnson v. Tenn. Bd. of Med. Exam'rs., M2002-00048-COA-R3-CV, 2003 WL 1442413 (Tenn. Ct. App. Mar. 19, 2003) (physician disciplined under §§ 63-6-214(b)(1) and (4) for “unorthodox” hydrogen peroxide treatment for skin condition); *Williams v. State Dep't of Health and Env't*, 880 S.W.2d 955 (Tenn. Ct. App. 1994) (physician disciplined under § 63-6-214(b)(12) for prescribing large amounts of inappropriate drugs for patients with obesity problems); *see also Rich v. Tenn. Bd. of Med. Exam'rs*, 350 S.W.3d 919 (Tenn. 2011) (remand to Board for failing to articulate the applicable standard of care in proceeding brought under §§ 63-6-214(b)(1), (4) and (12) for physician’s administration of chelation therapy, intravenous hydrogen peroxide therapy, and the use of methadone to treat patients suffering from opioid dependency).

Thus, by specifying these three grounds for disciplinary action, Tenn. Code Ann. § 63-6-214(b) allows for disciplinary proceedings against physicians who prescribe a medication—such as ivermectin or hydroxychloroquine—for “off-label” use in the treatment of COVID-19. “Off-label” use of a medication refers to a circumstance in which a patient uses a prescribed drug in a manner that varies in some way from the Federal Drug Administration-approved labeling of the drug. *Richardson v. Miller*, 44 S.W.3d 1, 9 (Tenn. Ct. App. 2000) (citations omitted).

Off-label use of an FDA-approved drug is not prohibited by the FDA, *Association of Am. Physicians & Surgeons v. United States Food and Drug Admin.*, 13 F.4th 531, 534 (6th Cir. 2021), nor are decisions made by physicians regarding off-label use subject to the broad authority of the FDA over prescription drugs, *id.*; *Richardson*, 44 S.W.3d at 12-13; *see* 21 U.S.C. § 396. But a physician must still exercise his or her medical judgment and discretion in accordance with the applicable standard of care when prescribing a medication for off-label use. *See Rich*, 350 S.W.3d at 926-29; *Johnson*, 2003 WL 1442413, at *8. Consequently, whether the decision to prescribe a medication for off-label use to treat a particular patient for COVID-19 falls below the applicable standard of care might subject the physician to disciplinary action would depend on the totality of the relevant facts and circumstances in any given case. *See Richardson*, 44 S.W.3d at 20 (“Physicians may be found negligent if their decision to use a drug off-label is sufficiently careless, imprudent or unprofessional.”); *see, e.g., Johnson*, 2003 WL 1442413, at *5, *8. (court disciplined physician for the “dangerous” intravenous administration of hydrogen peroxide, which was not an FDA-approved use of hydrogen peroxide).

However, effective November 21, 2021, the Board may not conduct a disciplinary action against a physician who prescribes a medication for off-label use in the treatment of COVID-19 unless and until the Board complies with Tenn. Code Ann. § 14-4-104, which provides that,

[n]otwithstanding title 63 or 68, to the contrary, any disciplinary process, or action taken pursuant to such process, that is implemented by a health-related board

regarding the dispensing or prescribing of medication for COVID-19¹ must be promulgated as a rule pursuant to title 4, chapter 5.

In sum, while the Board is typically not required to promulgate a rule before conducting a disciplinary proceeding,² Tenn. Code Ann. § 14-4-104 unequivocally requires the Board to promulgate a rule in accordance with title 4, chapter 5 of the Tennessee Code before it conducts any disciplinary proceeding “regarding the dispensing or prescribing of medication for COVID-19.”

HERBERT H. SLATERY III
Attorney General and Reporter

ANDRÉE SOPHIA BLUMSTEIN
Solicitor General

LAURA T. KIDWELL
Assistant Solicitor General

Requested by:

The Honorable Kerry Roberts
State Senator
425 Rep. John Lewis Way N.
Suite 730 Cordell Hull Building
Nashville, Tennessee 37243

The Honorable John Ragan
State Representative
425 Rep. John Lewis Way N.
Suite 614 Cordell Hull Building
Nashville, Tennessee 37243

¹ “COVID-19,” for purposes of Tenn. Code Ann. § 14-4-104, means “the novel coronavirus, SARS-CoV-2, and coronavirus disease 2019, commonly referred to as COVID-19, including any variant of SARS-CoV-2 or COVID-19.” Tenn. Code Ann. § 14-4-101(4).

² See *Gate Pharms. v. Tenn. Bd. of Med. Exam’rs*, 01A01-9510-00451, 1996 WL 648424, at *5 (Tenn. Ct. App. Nov. 8, 1996) (observing that the Board has authority to discipline physicians for conduct not in the course of professional practice “even in the absence of a rule defining nonconforming conduct”).