

BEFORE THE NORTH CAROLINA STATE BOARD OF DENTAL EXAMINERS

IN THE MATTER OF:

ROBERT LAYTON HARRELL, D.D.S.
(License No. 6675; Permit No. 0637)

)
)
)
)
)

CONSENT ORDER

OCT 18 2023

THIS MATTER is before the North Carolina State Board of Dental Examiners [the "Board"] as authorized by N.C. Gen. Stat. § 90-41.1(b) for consideration of a Consent Order in lieu of a formal administrative hearing. Respondent Robert Layton Harrell, D.D.S. ["Respondent"] represented himself. Douglas J. Brocker represented the Investigative Panel [the "IP"]. Respondent acknowledges that the Board has sufficient evidence to prove and establish the Findings of Fact and Conclusions of Law and to warrant the Order of Discipline set out in this Consent Order.

Based upon the consent of the parties hereto, the Board enters the following:

FINDINGS OF FACT

1. The Board is a body duly organized under the laws of North Carolina and is the proper party to bring this proceeding pursuant to the authority granted to it in Chapter 90 of the North Carolina General Statutes, including the Dental Practice Act and the rules and regulations of the Board.
2. Respondent was licensed to practice dentistry in North Carolina on June 20, 1997, and holds license number 6675.



3. On May 27, 2010, Respondent was issued permit number 0637 for moderate limited conscious sedation.
4. On January 31, 2018, Respondent's permit number 0637 was converted to a minimal conscious sedation permit after the Board amended its regulations to eliminate limited moderate permits.
5. Respondent continued to hold minimal conscious sedation permit number 0637 until March 31, 2023, at which time his sedation permit expired upon Respondent's failure to renew it.
6. At all times relevant to this Consent Order, Respondent was subject to the Dental Practice Act and the Board's rules and regulations.
7. On or about May 23, 2023, the Board received a complaint and information alleging that Respondent was administering sedation without an active sedation permit.
8. On May 24, 2023, a Board Investigator [the "Investigator"] visited Respondent's office to speak with Respondent about the allegations and to conduct a facility inspection.
9. During the interview, Respondent admitted to the Investigator that he knew his sedation permit had expired as of March 31, 2023, and that a former staff member entrusted to submit his permit renewal application to the Board had not done so.
10. Respondent further admitted that he continued to perform sedation procedures through May 9, 2023, even though he knew he had not yet successfully renewed his sedation permit.
11. During the inspection, the Investigator reviewed a sample set of Respondent's patient records for patients undergoing sedation procedures.

A handwritten signature in black ink, appearing to be 'Rut', is located in the bottom right corner of the page.

12. One or more of Respondent's patient records did not document the types and amounts of the sedation medications administered to the patient.

13. By letter dated that same day, Respondent agreed to cease administering any level of sedation to patients that would require a permit, effective immediately, pending the outcome of the Board's investigation and the potential reinstatement of his expired sedation permit.

14. On June 5, 2023, the Investigator returned to Respondent's office to speak further with Respondent and obtain additional records.

15. Respondent stated that he has had to administer the reversal drug flumazenil two or three times per year to reverse the effects of triazolam.

16. However, upon inspection that same day, the facility was not equipped with any unexpired flumazenil.

17. Respondent provided the Investigator with the requested patient records.

18. Respondent's patient records showed that, on multiple occasions in 2022 and 2023, Respondent administered triazolam to patients for sedation procedures in amounts exceeding the manufacturer's maximum recommended dose of no more than 0.5 mg for adults, and 0.25 mg for geriatric or debilitated patients.

19. For example, on August 31, 2022, Respondent administered 0.75 mg of triazolam to a geriatric female patient (then 76 years old), on top of instructing her to take 20 mg of diazepam the night before, and then had to administer flumazenil as a reversal agent because the patient "was very drowsy and unable to stay awake."

20. Further, on five separate occasions after Respondent's sedation permit expired as of March 31, 2023, Respondent administered triazolam to patients in amounts



exceeding the manufacturer's maximum recommended dose, including another geriatric female patient (then 74 years old) to whom Respondent administered 0.75 mg of triazolam.

21. Pursuant to the Board's rules, Respondent's administration of triazolam in these amounts, both before and after his minimal permit expired, required a moderate conscious sedation permit.

22. Triazolam is a sedative agent requiring a permit, and not an anxiolytic, and therefore Respondent should not have administered it to patients after his permit expired, even if the amounts did not exceed the manufacturer's maximum recommended dose.

23. Respondent desires to enter into this Consent Order for the purpose of resolving the foregoing issues identified by the IP.

24. Respondent has been fully cooperative with the Board during the inspection process and throughout the investigation.

Based upon the foregoing Findings of Fact and with the consent of the parties hereto, the Hearing Panel enters the following:

CONCLUSIONS OF LAW

1. The Board has jurisdiction over the subject matter of this action and over Respondent.

2. Respondent was properly notified of this matter and has consented to the entry of this Consent Order.



3. Respondent violated N.C. Gen. Stat. § 90-41(a)(6) and the Board's rules as follows:

- a. 21 NCAC 16Q .0504(a) and .0506 concerning renewing a sedation permit before administering minimal conscious sedation, and displaying a permit and its current renewal;
- b. 21 NCAC 16Q .0504(b) concerning ensuring the level of sedation administered does not exceed minimal conscious sedation as defined in 21 NCAC 16Q .0101(27) to include not exceeding the manufacturer's maximum recommended dose; and
- c. 21 NCAC 16Q .0505(a) concerning maintaining all required equipment and medications including unexpired reversal agents, and documenting in the patient record the type and dosage of the drugs administered during a procedure.

Based upon the foregoing Findings of Fact and Conclusions of Law, and with the consent of the parties hereto, it is ORDERED as follows:

ORDER OF DISCIPLINE

1. License number 6675 issued to Respondent for the practice of dentistry in North Carolina is hereby suspended for a period of one year but conditionally restored with no active suspension, provided that for a period of three years Respondent complies with the requirements in Paragraph 2 of this Order.



2. Respondent shall adhere to the following probationary terms and conditions:

- a. Respondent shall violate no provision of the Dental Practice Act or the Board's rules.
- b. Respondent shall neither direct nor permit any of his employees to violate any provision of the Dental Practice Act or the Board's rules.
- c. Respondent shall permit the Board or its agents to inspect and observe his office, conduct a random review of patient chart records, and interview employers, employees, and coworkers at any time during normal office hours.

3. Permit number 0637 issued to Respondent for the administration of minimal conscious sedation is expired. Unless and until Respondent's sedation permit is reinstated, Respondent shall not administer sedation to patients except in full compliance with the conditions set forth in this Paragraph. Notwithstanding the expiration of permit number 0637, Respondent:

- a. may administer to patients, if clinically appropriate to do so: (i) local anesthetic; (ii) nitrous oxide; and (iii) anxiolytic medications, but only in strict compliance with 21 NCAC 16Q .0101(3) and the interpretive statements attached to this Consent Order;
- b. may utilize a permittee with a mobile/itinerant permit issued by the Board to administer sedation to his patients; and

A handwritten signature in black ink, appearing to be the initials 'RA', is located in the bottom right corner of the page.

c. shall keep records demonstrating his use of a mobile/itinerant permit holder for each patient to whom sedation is administered, and shall provide such records to the Board upon request.

4. In the future, Respondent may apply for reinstatement of permit number 0637 by submitting a reinstatement application in accordance with 21 NCAC 16Q .0506. Alternatively, Respondent may apply for a new sedation permit to administer any level of sedation by submitting an application in accordance with the Board's rules applicable to the level of permit sought. In either event, Respondent shall meet all applicable requirements in effect at the time of his application, and satisfy the following additional requirements:

a. Prior to submitting his application, Respondent shall complete the following continuing education courses especially designed for him by the University of North Carolina Adams School of Dentistry or the East Carolina University School of Dental Medicine in conjunction with and approved in advance by the IP, including a comprehensive remedial course covering: (i) administering sedation, including doses and titration with respect to individual patients; (ii) emergency drugs, protocols, equipment, and staff training; and (iii) clinical and sedation recordkeeping. This requirement shall be in addition to the continuing education required by the Board for annual renewal of Respondent's dental license. Respondent shall submit to the Board's Director of Investigations written proof of satisfactory completion of these courses before they will be accepted in satisfaction of this requirement. It is

A handwritten signature in black ink, appearing to be the initials 'RA' with a stylized flourish.

Respondent's responsibility to make all arrangements for and bear the costs of these courses within the specified time; and

b. As part of the application process, Respondent must successfully complete an inspection and evaluation by the Board consistent with the requirements in the Board's rules in effect at the time concerning the issuance of a new sedation permit.

5. If, in the future, Respondent's permit number 0637 is reinstated or Respondent is issued a new sedation permit, as a condition of obtaining such a permit, for three years after its issuance, Respondent shall permit the Board or its agents to inspect and observe his office on issues related to sedation including for all required sedation equipment, medications, and documentation; conduct a random review of records for patients to whom he administered sedation; and interview employers, employees, and coworkers at any time during normal office hours related to these issues.

6. Respondent recognizes that the conditions, limitations, or requirements set forth in this Consent Order may present him with certain practical difficulties. The Board concludes that each one is necessary to ensure public protection and it does not intend to modify or eliminate any of the conditions, limitations, or requirements set forth herein based on such potential difficulties.

7. If Respondent fails to comply with any provision of this Consent Order or breaches any term or condition thereof, the Board shall promptly schedule a public Show Cause Hearing to allow Respondent an opportunity to show cause as to why the suspension of Respondent's license shall not be activated for violating a valid order of the Board. If after the Show Cause Hearing, the Board is satisfied that Respondent failed to



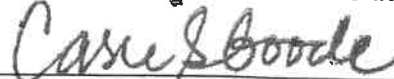
comply or breached any term or condition of this Consent Order, the Board shall activate the suspension and may enter such other discipline or conditions as the evidence warrants for proven violations of the Dental Practice Act or of the Board's rules occurring after entry of this Decision.

8. This Consent Order and the provisions contained herein shall be effective upon the Board's entry of this Consent Order.

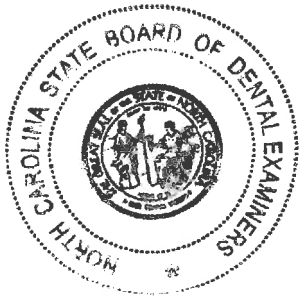
9. The Board shall retain jurisdiction of this matter and Respondent to enforce the provisions herein or enter orders as necessary in the future.

This the _____ day of _____ 2023.

THE NORTH CAROLINA STATE
BOARD OF DENTAL EXAMINERS



Casie S. Goode
Director of Investigations



STATEMENT OF CONSENT

I, Robert Layton Harrell, D.D.S., do hereby certify that I have read the foregoing Consent Order in its entirety. I assent to its terms and conditions set out herein. I freely and voluntarily acknowledge that there is sufficient evidence to form a factual basis for the findings of fact herein, that the findings of fact support the conclusions of law, that I will not contest the findings of fact, the conclusions of law, or the order in any future proceedings before or involving the Board, including if future disciplinary proceedings or action is warranted in this matter. I knowingly waive any right to seek judicial review, appeal, or otherwise later challenge this Consent Order once entered. I agree to service of the Consent Order to the email or mailing address of record with the Board and waive service by any other method. I understand that the Board will report the contents of this Consent Order to the National Practitioner Data Bank and that this Consent Order will become part of the Board's permanent public record. I further acknowledge that this required reporting may have adverse consequences in other contexts and any potential effects will not be the basis for a reconsideration of this Consent Order. I have had the opportunity to consult with an attorney prior to signing this Consent Order.

This the 17th day of October 2023.


Robert Layton Harrell, D.D.S.