

BEFORE THE
BOARD OF NATUROPATHIC MEDICINE
STATE OF OREGON

In the Matter of the License of:

Seth Burrell, ND

Case No. 21-03-13

**NOTICE OF PROPOSED DISCIPLINARY
ACTION AND
OPPORTUNITY FOR HEARING**

1.

The Board of Naturopathic Medicine (Board) is the State agency responsible for licensing, regulating, and disciplining naturopathic physicians in the State of Oregon, pursuant to Oregon Revised Statutes (ORS) chapter 685 and Oregon Administrative Rules (OAR) chapter 850. Dr. Seth Burrell, N.D. (Licensee) is a licensed naturopathic physician in Oregon and is subject to the jurisdiction of the Board.

2.

Pursuant to OAR 850-050-0010(1)(c)(B), 850-050-0010(1)(c)(D), and ORS 685.110 (8) and (14), the Board hereby proposes to take disciplinary action against Licensee's license to practice naturopathic medicine, on the grounds described in the following paragraphs. For each violation, the Board may impose a civil penalty up to \$5,000, a term of probation, a letter of reprimand and license limitation, suspension, or revocation.

3.

Dr. Seth Burrell has been a licensed naturopathic physician in the State of Oregon since October 1, 2012. Licensee is employed at Canyon Medical Center. The Canyon Medical Center website states Licensee's "specific areas of interest are diagnostic ultrasound and general medicine with an emphasis in treating those who suffer from chronic diseases" and that Licensee was "selected for a specialized one-year mentorship and maintained a three-year apprenticeship with Dr. Ed

Hofmann-Smith, former Dean of NCNM, where he gained many hours of clinical training in obstetrical, gynecological, and basic diagnostic ultrasound.”

4.

Patient was a 38-year-old female presenting at 20 weeks pregnant. Advanced maternal age is the description of a birth parent 35 or older. The risk of fetal aneuploidy rises with increasing maternal age. Advanced maternal age patients may be offered prenatal testing and monitored more closely. Patient’s pre-natal care was managed by a ND Physician at the Canyon Medical Center.

5.

A non-invasive prenatal test (NIPT) is a screening test, not a diagnostic test, it determines the risk of disorders such as Down syndrome (trisomy 21), Edwards syndrome (trisomy 18), and Patau syndrome (trisomy 13), as well as conditions caused by missing or extra X and Y chromosomes. A NIPT does not diagnose a genetic condition with certainty.

6.

On February 20, 2020, Patient had a NIPT at approximately 10 weeks gestational age. Patient underwent cell-free DNA testing (Innatale Prenatal Screen), a screening test for fetal aneuploidies where maternal blood is drawn and the fetal DNA in the maternal blood is sequenced to determine the likelihood the fetus has abnormal chromosomes. If the amount of fetal DNA (the fetal fraction) in the sample is low, it can give a false negative result. This is a known limitation of the cell-free DNA test. In the Patient’s NIPT test, the fetal fraction was reported as 2%; adequate fetal fraction is considered to be greater than 3-4%. Patient record showed a negative NIPT test, which due to the inadequate fetal fraction, was a false negative.

7.

On March 31, 2020, Licensee first saw Patient when she was 20 weeks pregnant for a second trimester fetal anatomic survey / fetal anomaly screen ultrasound, which is primarily used to assess fetal anatomy and detect the presence of any fetal anomalies. Licensee reviewed Patient’s February 20, 2020, NIPT records prior to the March 31, 2020, ultrasound. Prior to giving Patient

the ultrasound, he believed the Patient tested negative for fetal aneuploidies. During the ultrasound, Licensee observed Choroid Plexus Cysts (CPC), a build-up of fluid found in the choroid section of an unborn baby's brain. A CPC is considered a soft marker for aneuploidy. Licensee believed that soft marker was isolated. However, Licensee was unable to see facial features with a profile view which is the best view to prove there is a nasal bone which is often an anomaly in aneuploidy. Further, Licensee did not adequately depict the fetal profile, heart, outflow tracts, hands, or feet. Licensee reported these structures are indicated "normal" although he did not adequately visualize or document the profile and nasal bone, heart, hands, and feet. Licensee did not edit his template for the 20-week ultrasound report to reflect poor image quality at Patient's 20 week screen, and noted all images as "normal." Licensee recommended a follow-up ultrasound on Patient on May 18, 2020, to determine whether the CPC resolved.

8.

The American Institute of Ultrasound in Medicine (AIUM) is a multidisciplinary association dedicated to advancing safe and effective use of ultrasound in medicine. AIUM published guidelines for a fetal anomaly scan, minimal requirements include visualization of the fetal profile, heart, outflow tracts, hands, and feet; if they are not visible at the time of the exam because of fetal position or other scanning characteristics, a follow-up to visualize these structures is recommended. The obstetrical ultrasound exam performed March 31, 2020, did not meet these minimal requirements, because it did not adequately depict the fetal profile, heart, outflow tracts, hands, or feet. Based on the fetal position and image quality, these structures could have been visualized if adequate time and expertise were applied to the exam. Based on the above Licensee's performance during the ultrasound examination is a violation of ORS 685.110(8) – Negligent Treatment and 850-050-0010(B) -- Negligent Treatment.

9.

The standard of care is if soft markers of aneuploidy are found in an obstetric ultrasound, Patient should be referred to a specialist for a level 2 ultrasound. If additional soft markers are then found, an amniocentesis is recommended. Licensee did not refer the Patient for a level 2 ultrasound and is in violation of 850-050-0010(D) -- Failure to refer when referral is appropriate.

10.

Licensee did not communicate to Patient the CPC was a soft marker for aneuploidy and that he was unable to get adequate images of the fetus to determine the presence of other soft markers for aneuploidy. Licensee did not communicate or counsel Patient that if soft markers are found, Patient should seek a level 2 ultrasound and potentially an amniocentesis. Licensee's lack of communication and counsel with Patient is a violation of ORS 685.110(8) – Negligent Treatment and 850-050-0010(B) -- Negligent Treatment and 685.110 (14) -- Engaging in any conduct or practice ... that does or might constitute a danger to the health or safety of a patient or the public.

11.

Licensee conducted a follow-up ultrasound on Patient on May 18, 2020. Licensee only imaged the area of CPC to determine whether the CPC resolved. The images showed the CPC resolved. Resolution of a CPC is not indicative of whether there is a presence or absence of additional fetal findings or abnormalities. Licensee did not look for other soft markers for aneuploidy, particularly a cardiac defect, which would have been more indicative of the presence or absence of fetal findings or abnormalities than showing resolution of the choroid plexus cysts. The obstetrical ultrasound exam performed May 18, 2020, did not meet these minimal requirements, because it did not adequately depict the fetal profile, heart, outflow tracts, hands, or feet. Based on the fetal position and image quality, these structures could have been visualized if adequate time and expertise were applied to the exam. Based on the above Licensee's performance during the ultrasound examination is a violation of ORS 685.110(8) – Negligent Treatment and 850-050-0010(B) -- Negligent Treatment.

12.

Trisomy 18 is a chromosome disorder characterized by having three (3) copies of chromosome 18 instead of the usual 2 copies. Signs and symptoms include severe intellectual disability; low birth weight; a small, abnormally shaped head; a small jaw and mouth; clenched fists with overlapping fingers; congenital heart defects; and various abnormalities of other organs. Trisomy 18 is a life-threatening condition; many affected people die before birth or within the first month

of life. An amniocentesis is a procedure performed during pregnancy to obtain amniotic fluid to perform a diagnostic test for chromosomal abnormalities.

13.

Patient's daughter was diagnosed with trisomy 18 six days after birth and died six weeks later. Licensee never communicated with Patient the possibility of Patient's baby being born with trisomy 18 due to Licensee's lack of due diligence and practice knowledge. Licensee did not assess from the record that the NIPT was a false negative. Licensee placed undue weight on the incorrect assumption that Patient NIPT assessment "was negative" when performing both the second and third trimester ultrasound. Licensee conducted an exam titled and held out to the patient as a fetal anomaly screen, however, the obstetrical ultrasound exam performed March 30, 2020, was only adequate for determining due date or weight of the fetus, but was not adequate for evaluating fetal anatomy and presence or absence of anomalies. During the second trimester ultrasound exam Licensee did not properly image significant heart and other fetal defects present on the ultrasound images. During the second trimester ultrasound exam Licensee did not properly recognize the presence of significant heart and other fetal defects. Licensee did not adhere to his obligation to refer Patient for a level 2 ultrasound where an amniocentesis could have been recommended, and instead conducted a follow-up ultrasound where he erroneously focused on the resolution of a CPC and did not look specifically for identifying other soft markers for aneuploidy. Licensee's treatment of Patient during the course of her pregnancy is a violation of 850-050-0010(B) -- Negligent Treatment and 850-050-0010(D) -- Failure to refer when referral is appropriate ORS 685.110(8) – Negligent Treatment and 685.110(14) -- Engaging in any conduct or practice ... that does or might constitute a danger to the health or safety of a patient or the public.

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14.

For the violations described above; the Board proposes the following discipline:

- Civil penalty \$10,000
- Probation: Three (3) years – with the following conditions:
 - Practice Restriction: Cease all prenatal and pregnancy ultrasounds, sonograms, abdominal ultrasound, abdominal sonogram, and scans, including but not limited to topical, transvaginal, 3d or 4d for any purpose, until completion of Board approved education and training.
 - Continuing Education: Within 12 months of the start of probation, complete 21 hours diagnostic obstetric ultrasound examination training that focuses on thorough understanding of the indications and guidelines for ultrasound examinations as well as familiarity with the basic physical principles and limitations of the technology of ultrasound imaging, including anatomy, physiology, and pathophysiology of those organs or anatomic areas that are being examined. Training must provide requisite competence needed to successfully perform and interpret diagnostic obstetric ultrasound examinations, and methods of documentation and reporting of ultrasound studies.
 - Chart Review: After completion of required training, Licensee shall provide Board five new (5) patient charts (post order) quarterly. Patient charts will be selected by the Board at random from licensee's schedule for the prior quarter. Patient charts will be reviewed by a Board approved reviewer. Licensee will incur all costs associated with quarterly chart reviews.

15.

NOTICE OF OPPORTUNITY FOR HEARING

Licensee is entitled to a hearing as provided by the Administrative Procedures Act (ORS Chapter 183). If you want a hearing, you must file a written request for hearing with the Board within 21

days from the date this notice was mailed. You must submit request for hearing to either via email Naturopathic.Medicine@obnm.oregon.gov or U.S. Mail to Oregon Board of Naturopathic Medicine, 800 NE Oregon Street, Suite 407, Portland, OR 97232. The request for hearing must be received by the Board within 21 days from the date of mailing of this notice and must be accompanied by a written answer to the charges contained in this Notice. If a request for hearing is not received within 21 days, the right to hearing is waived.

16.

If you request a hearing, you will be notified of the time and place of the hearing. Before the hearing, you will receive information on the procedures, right of representation, and other rights of parties related to the conduct of the hearing. An administrative law judge from the Office of Administrative Hearings will preside at any hearing. ORS 183.635.

17.

An answer is required to this Notice, pursuant to OAR 850-001-0015, due to the complexity of the matters alleged above. The answer shall be made in writing to the Board and shall include an admission or denial of each factual matter alleged in this Notice, and a short plain statement of each relevant affirmative defense Licensee may have. Except for good cause, factual matters alleged in this notice and not denied in the answer shall be presumed admitted; failure to raise a particular defense in the answer will be considered a waiver of such defense; and new matters alleged in the answer (affirmative defenses) shall be presumed to be denied by the agency and evidence shall not be taken on any issue not raised in the Notice and answer.

18.

If you fail to request a hearing within 21 days, withdraw a request for a hearing, notify the Board or administrative law judge that you will not appear or fail to appear at a scheduled hearing, the Board may issue a final order by default revoking your license. If the Board issues a default order, the contents of the Board's file automatically becomes part of the evidentiary record of this disciplinary action for the purpose of proving a *prima facie* case.

NOTICE TO ACTIVE DUTY SERVICEMEMBERS: Active duty service members have a right to stay these proceedings under the federal Service members Civil Relief Act. For more information contact the Oregon State Bar at 800-452-8260, the Oregon Military Department at 503-584-3571 or the nearest United States Armed Forces Legal Assistance Office through <http://legalassistance.law.af.mil>.

DATED this 30 day of January 2023.

BOARD OF NATUROPATHIC MEDICINE
State of Oregon

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Mary-Beth Baptista, Executive Director