

BEFORE THE ARIZONA STATE BOARD OF NURSING

IN THE MATTER OF REGISTERED NURSE
LICENSE NO. RN056661 AND ADVANCED
PRACTICE CERTIFICATE NO. AP0213
ISSUED TO:
TRUDY RUMANN HEIL,
Respondent.

CONSENT AGREEMENT
AND
ORDER NO. 1203035 FOR
VOLUNTARY SURRENDER OF
Prescribing and Dispensing Certificate
PROBATION FOR
RN056661 (Registered Nurse License)
and AP0213 (Advanced Practice
Certificate)

CONSENT AGREEMENT

A complaint charging Trudy Rumann Heil (“Respondent”) with violation of the Nurse Practice Act has been received by the Arizona State Board of Nursing (“Board”). In the interest of a prompt and speedy settlement of the above-captioned matter, consistent with the public interest, statutory requirements and the responsibilities of the Board, and pursuant to A.R.S. § 41-1092.07(F)(5), the undersigned parties enter into this Consent Agreement as a final disposition of this matter.

Based on the evidence before it, the Board makes the following Findings of Fact and Conclusions of Law:

FINDINGS OF FACT

1. Trudy Rumann Heil (“Respondent”) holds Board issued registered nurse license number RN056661 and advanced practice certificate number AP0213 in the State of Arizona.
2. Respondent treated patient I.K., then an 11-year-old boy from on or about June, 2011 through on or about March 30, 2012.
3. Respondent treated patient I.K. for over nine months, for medical conditions including asthma, headache, obesity, hypothyroidism and fatigue. These medical conditions were

treated in accordance with the "Marshall Protocol," ("MP"). As part of this treatment, IK was given an angiotensin II receptor blocker ("ARB") olmesartan (Benicar). Benicar is approved by the Food and Drug Administration ("FDA") for the treatment of hypertension. Respondent asserts that Benicar was properly prescribed in an off-label manner using the FDA guidelines for off-label use. In addition, IK was treated with the antibiotic Minocycline as part of the MP. Respondent asserts that while under Respondent's care and treatment, IK's symptoms improved

4. Benicar is approved by the FDA for the treatment of hypertension. The maximum recommended adult dosage of Benicar for hypertension, approved by the FDA, is 40 mg once daily. According to its manufacturer, the dosage of Benicar should be individualized for pediatric patients, and the usual recommended starting dose is 20 mg once daily for pediatric patients who weigh over 77 lbs. Patient I.K., who was not being treated for hypertension weighed 104 lbs, and was receiving at-least 40 mg of Benicar every four to six hours for a total of 160 mg to 240mg a day.

5. Respondent diagnosed I.K. with Hypervitaminosis D and hypothyroidism prior to obtaining laboratory results confirming the diagnoses, and subsequent laboratory results that were obtained by Respondent did not support these diagnoses. Respondent asserts that lab tests were ordered by Respondent prior to confirming a diagnosis, which supported the findings of hypervitaminosis D and hypothyroidism. Respondent further asserts that she has been properly trained in both identifying and treating hypervitaminosis D and hypothyroidism.

6. On March 7, 2012, I.K. presented to Phoenix Children's Hospital ("PCH") Urgent Care complaining of vomiting and diarrhea that had been occurring for three days. I.K. was diagnosed at the time with gastroenteritis, and treated at the Urgent Care with Zofran (an anti-emetic) and a fluid challenge. Respondent asserts that she advised the parents of I.K. to take I.K. to an urgent

care for rehydration.as the three-day history of vomiting and diarrhea from gastroenteritis could cause dehydration. Respondent further asserts that she had provided I.K.'s parents with copies of a document titled, "Notice to Emergency Personnel" that would have informed the Urgent Care doctor regarding the dosage and frequency of Benicar that I.K. was taking, as well as her phone number. However, the Urgent Care doctor testified at hearing that he was not provided with this document nor was he informed that I.K. was taking Benicar at any dose. The Urgent Care doctor testified that he was able to recall a letter given to him by I.K.'s Father that started with, "To the Provider" and informed him that if any steroids or antibiotics were to be given to I.K., to call a phone number which was printed at the bottom of the letter. The Urgent Care doctor testified that he did not call the phone number because he was prescribing neither steroids nor antibiotics.

7. On March 9, 2012, I.K. was transported to PCH Emergency Room via ambulance. IK presented to the Emergency Department with a history of vomiting and diarrhea for one week and was diagnosed with dehydration. In addition, IK's parents informed the ED physician that IK had not urinated for three days. I.K.'s lab results revealed critically elevated potassium, creatinine, and BUN (Blood urea nitrogen) and elevated transaminases. I.K. was admitted for treatment, which consisted of rehydration with IV fluids. After a consultation with PCH Nephrology, I.K. was diagnosed with acute kidney injury secondary to a combination of intravascular volume depletion. PCH doctors concluded that Benicar administration had a toxic effect and delayed the resolution of the acute kidney injury. Respondent asserts that Benicar was neither toxic nor affected the resolution of the acute kidney injury to IK.

8. According to the medical records and testimony of the treating PCH Emergency Room resident "Physician A" who treated I.K., Physician A had two conversations with Respondent. On March 9, 2012, Respondent was consulted at 11:00 a.m. with recommendations

to Physician A to give fluids and continue home medications. Physician A called Respondent in follow up at 2:45 p.m. and informed Respondent of the creatinine and potassium lab values. Respondent discussed continuing to give fluids and felt that Benicar was renal protective, and not to stop without calling. According to the medical record, the attending physician discussed IK with Physician A, examined IK and agreed with Physician A's note as written. After speaking to Respondent, Physician A consulted with PCH Nephrology Department, and it was recommended to keep IK well hydrated. According to testimony of a PCH nephrologist "Physician B" who treated I.K. on March 9, 2012, Physician B advised I.K.'s parents that the Benicar must be stopped immediately based on I.K.'s kidney function labs. According to Physician B, IK's parents requested Physician B call Respondent to discuss Diovan. According to Physician B's testimony, Physician B informed Respondent during a phone conversation, that Diovan has a similar profile of indications, side effects and cautions as Benicar and that Physician B could not give I.K. an ARB because it could potentially threaten I.K.'s life. Respondent asserts that she did not have a phone conversation with Physician B at any time. Against the medical advice of PCH Physicians, on March 9, 2012 at 4:00 p.m. I.K.'s mother administered a dose of Benicar to I.K. At 5:00 p.m. on March 9, 2012, Respondent attended a conference with PCH physicians and IK's parents. Respondent asserts that she first learned during this treatment conference at 5:00 p.m. on March 9, 2012, that the PCH physicians did not want either the Diovan or Benicar continued as part of the treatment plan. Three days later, during an investigation, Mother claimed that Respondent recommended that the 4:00 p.m. dose of Benicar be given on March 9, 2012. Respondent denies instructing IK'S Parents to administer Benicar against the advice of the PCH physicians and specifically denies advising the parents to give the 4 pm dose on March 9, 2012.

9. I.K. was discharged from PCH on March 14, 2012. His discharge diagnosis included hyperkalemia with acute kidney injury, - resolved, and hepatitis with elevated transaminases - resolving. The chief nephrologist (Physician C) concluded that Benicar exacerbated I.K.'s presentation, and delayed I.K.'s renal response and the resolution of the acute kidney injury. Respondent asserts that Benicar did not delay or have a toxic effect on the resolution of the acute kidney injury, but never the less, did defer to the chief nephrologist's orders. Further, PCH physicians felt that IK's thyroid levels did not suggest that IK had hypothyroidism. Respondent asserts that IK had hypothyroidism confirmed by initial presentation, and symptoms, and a therapeutic probe of thyroid to the patient. I.K. was referred to an endocrinologist for further evaluation and to follow up with PCH Gastroenterology within 2 weeks. I.K.'s parents were advised that I.K. was not to resume the Benicar treatment. Respondent alleges that she was not aware of or provided a copy of I.K.'s discharge instructions, which are routinely provided as a courtesy to the treating provider. There is no record that Respondent requested the discharge instructions from PCH.

10. Respondent's first examination of I.K. after his hospitalization occurred on March 20, 2012. On March 15, 2012, Respondent wrote a prescription for I.K. for Diovan, at 40 mg every 8 hours. Diovan is approved by the FDA for the treatment of hypertension. On March 16, 2012, the insurance company refused to pay for Respondent's Diovan prescription for patient I.K. and Respondent filed an appeal with the insurance company stating that the use of Diovan at 40 mg every eight hours was needed "in lieu of Benicar use" to safely exit IK from the MP and avoid damage to patient I.K.'s vital organs pursuant to the "Marshall Protocol emergency guidelines." Also on or about March 16, 2012, Respondent continued to prescribe thyroid supplements to

patient I.K. Respondent asserts that this was due to returning symptomatology and confirmation of hypothyroidism by timed labs.

11. Patients S.M., D.K., T.A., D.D., C.W., A.S., C.S., R.S., L.K, E.G. and M.M. were also treated by Respondent utilizing the Marshall Protocol (“MP Patients”). A review of these records revealed that Respondent treated these patients in a manner inconsistent with the standard of care because:

- a. Respondent prescribed the MP, an unapproved experimental treatment protocol that is not recognized in accepted medical literature, for various diagnoses; Respondent asserts that components of the MP are recognized in accepted medical literature for treatment of inflammatory conditions and she treated these patients in a manner consistent with the standard of care.
- b. Respondent failed to document all of her care and treatment of patients in the medical record and she failed to properly document her treatment plan for said patients; Respondent asserts that her documentation was appropriate for her specialty bio-identical hormone and wellness practice.
- c. Respondent diagnosed and treated the MP patients with Hypervitaminosis D and hypothyroidism, although their lab work was not consistent with these diagnoses. Respondent asserts that she appropriately diagnosed these patients based on levels for Vitamin D 25 and Vitamin D 1,25 T3 and T4, as well as patients’ reported symptoms, and that she monitored treatment and assessed for clinical improvement.
- d. Multiple MP patients reported symptomatology/adverse reactions to Respondent that Respondent ascribed to “Immunopathology” (IP) (defined by the MP) without an assessment, and for which Respondent instructed patients to take more Benicar Respondent asserts that her MP care included informed consent of anticipated limited side effects, and included patient communication, clinical presentation, laboratory values, with adjustments to Benicar on those basis, Respondent denies that's she breached the standard of care.

12. On April 11, 2012 the Board summarily suspended Respondent’s licenses.

13. On April 17, 2013 Respondent surrendered her federal DEA prescribing authority.

14. On January 30, 2015 Respondent requests to voluntarily surrender her dispensing and prescribing authority.

CONCLUSIONS OF LAW

Pursuant to A.R.S. §§ 32-1606, 32-1663 and 32-1664, the Board has subject matter and personal jurisdiction in this matter.

The conduct and circumstances described in the Preliminary Findings of Fact constitute unprofessional conduct and grounds to take disciplinary action pursuant to A.R.S. § 32-1663(D) as described in:

A.R.S. § 32-1601 (18) (j) (effective September 30, 2009)

18. “Unprofessional conduct” includes the following whether occurring in this state or elsewhere:

(j) Violating a rule that is adopted by the Board pursuant to this chapter, specifically:

A.A.C. R4-19-403 (1), (7), (8) (a), and (31) (effective January 31, 2009)

For purposes of A.R.S. § 32-1601(18) (d), any conduct or practice that is or might be harmful or dangerous to the health of a patient or the public includes one or more of the following:

1. A pattern of failure to maintain minimum standards of acceptable and prevailing nursing practice;
7. Failing to maintain for a patient record that accurately reflects the nursing assessment, care, treatment, and other nursing services provided to the patient;
8. Falsifying or making a materially incorrect, inconsistent, or unintelligible entry in any record:
 - a. Regarding a patient, health care facility, school, institution, or other work place location;
31. Practicing in any other manner that gives the Board reasonable cause to believe the health of a patient or the public may be harmed.

The conduct and circumstances described in the Findings of Fact constitute sufficient cause pursuant to A.R.S. § 32-1664(N) to revoke, suspend or take other disciplinary action against Respondent’s license to practice as a registered nurse in the State of Arizona.

Respondent admits the Board's Findings of Fact and Conclusions of Law. All admissions herein, consistent with Rule 408, Arizona Rules of Evidence regarding the settlement of this disputed matter, are for the sole and limited purpose of the Board's disposition regarding Respondent's registered nurse license and advanced practice certificate and are not admissions, agreements, inferences or self-incriminations for any other purpose in law, except that this agreement may be used by other regulatory boards in the event that Respondent applies for licensure thereto.

In lieu of a formal hearing on these issues, Respondent agrees to issuance of the attached Order and waives all rights to a hearing, rehearing, appeal or judicial review relating to this matter. Respondent further waives any and all claims or causes of action, whether known or unknown, that Respondent may have against the State of Arizona, the Board, its members, offices, and/or employees arising out of this matter.

Respondent understands that all investigative materials prepared or received by the Board concerning these violations and all notices and pleadings relating thereto may be retained in the Board's file concerning this matter.

Respondent understands that the admissions in the Findings of Fact are conclusive evidence of a violation of the Nurse Practice Act and may be used for purposes of determining sanctions in any future disciplinary matter. The admissions in the Findings of Fact are not intended to be utilized for establishing any criminal liability.

Respondent understands the right to consult legal counsel prior to entering into this Consent Agreement and such consultation has either been obtained or is waived.

Respondent understands that this Consent Agreement is effective upon its acceptance by the Board or its Designee and by Respondent as evidenced by the respective signatures thereto.

Respondent's signature obtained via facsimile shall have the same effect as an original signature. Once signed by Respondent, the Agreement cannot be withdrawn without the Board's approval or by stipulation between Respondent and the Board's designee. The effective date of this Order is the date the Consent Agreement is signed by Respondent and accepted by the Board or its Designee.

Board Date: January 30, 2015

Shirley J. Remann Head
Respondent

Dated: 1/28/15
Joey Ridenour R.N., M.N., F.A.A.N.

Joey Ridenour, R.N., M.N., F.A.A.N.
Executive Director
ARIZONA STATE BOARD OF NURSING

Acceptance Date: January 30, 2015

ARIZONA STATE BOARD OF NURSING

ORDER

In view of the above findings of Fact, Conclusions of Law and the consent of Respondent, the Board hereby issues the following Order:

- A. Respondent's consent to the terms and conditions of the Order and waiver of public hearing regarding this matter (Order No. 1203033) is accepted.
- B. The Board hereby accepts the VOLUNTARY SURRENDER of Respondent's Prescribing and Dispensing certificate. This Order of Voluntary Surrender hereby entered shall be filed with the Board and shall be made public upon the effective date of this Consent Agreement.

- C. The suspension in effect for Respondent's RN license number RN056661 and Respondent's AP Certificate No, AP0213 is lifted. Respondent's RN license and AP Certificate are placed on probation for a minimum of 24 months pursuant to the terms and conditions stated herein.
- D. This Order becomes effective upon the Board and Respondent's acceptance of the Consent Agreement. The effective date of this Order is the date the Consent Agreement is signed by Respondent and accepted by the Board or its designee. If the Consent agreement is signed on different dates, the later is the effective date. Probation is to commence the effective date of this Order.
- E. While this Order is in effect and/or Respondent's license is subject to discipline as outlined in the terms and conditions identified below, up to and including revocation or voluntary surrender. Respondent is not eligible to renew any other expired license or certificate previously held by Respondent.
- F. If Respondent is noncompliant with any of the terms of the Order, Respondent's RN license, Respondent's RN license shall be immediately revoked. Respondent waives any and all rights to a hearing, rehearing or judicial review of any revocation imposed pursuant to this paragraph.
- G. If Respondent is convicted of or pleads guilty to a felony, Respondent's license shall be automatically revoked for a period of five years. Respondent waives any and all rights to a hearing, rehearing or judicial review of any revocation imposed pursuant to this paragraph.
- H. Probation is subject to the following terms and conditions:

TERMS OF PROBATION

1. Stamping of License

Within seven days of the effective date of this Order, Respondent shall submit her license to be stamped with “PROBATION- LIMITED LICENSURE AND VALID IN AZ ONLY.” While this Order is in effect, if the Board issues any certificates or licenses authorized by statute to Respondent, except a nursing assistant certificate, such certificate or license shall also be stamped “PROBATION- LIMITED LICENSURE AND VALID IN AZ ONLY.” Respondent is not eligible for a multistate “Compact” license.

2. Limited License

Upon Respondent’s signature on this Consent Agreement and the acceptance by this Board, Respondent’s RN license and AP certificate is are limited to practicing in non-patient care settings only as set forth in this agreement. Respondent shall not provide any direct patient care in the State of Arizona during the duration of this probation. Respondent shall work in the capacity of an independent, self-employed legal nurse consultant or nurse paralegal (which is defined as any position where Respondent is providing medical record review services to a lawyer or law firm) in a non-patient care setting.

3. Notification of Practice Settings

Respondent shall work in the capacity of a self-employed legal nurse consultant or nurse paralegal. Respondent by her agreement will not be employed in a patient care setting. In the event Respondent accepts direct employment, which is defined as Respondent being an employee of a firm or company other than her own firm/corporation, and excluding employment as an independent contractor functioning as a legal nurse consultant or nurse paralegal, which involves the practice of nursing as allowed under Respondent’s limited licensure, Respondent shall

provide a copy of the entire Order on or before the date of hire. Within three days of Respondent's date of hire, Respondent shall cause her immediate supervisor to inform the Board, in writing and on employer letterhead, acknowledgment of the supervisor's receipt of a copy of this Consent Agreement and Order and the employer's ability to comply with the conditions of probation. The acknowledgment shall also include confirmation of Respondent's job description.

4. Quarterly Reports

Respondent shall within 7 days of each assigned quarterly reporting due date, cause every employer, defined above, Respondent has worked for during the quarter to provide to the Board, in writing, employer reports on the Board-approved form, which shall require the employer to certify that Respondent's duties do not include directing or providing patient care. The first report is due on the first assigned quarterly report due date after the effective date of the Order. Receipt of notice of an unsatisfactory employer evaluation, verbal or written warning, counseling or disciplinary action, or termination from a place of employment shall be considered as noncompliance with the terms of the Order. In the event Respondent is working as a self-employed legal nurse consultant or nurse paralegal, unemployed or employed in a capacity that does not require RN licensure, Respondent shall provide to the Board, in writing, a self-report describing other employment or activities on the Board-approved form. Failure to provide employer evaluations/or self-reports within 7 days of the reporting date shall be considered as noncompliance with the terms of the Order.

5. Practice Supervision

If Respondent is employed as a legal nurse consultant or nurse paralegal, then Respondent is not required to practice under supervision.

6. Acceptable Hours of Work

Respondent can work any shift.

7. Out-of-State Practice/Residence

Before any out-of-state practice or residence can be credited toward fulfillment of these terms and conditions, it must first be approved by the Board prior to leaving the state. If Respondent fails to receive such approval before leaving the state, none of the time spent out-of-state will be credited to the fulfillment of the terms and conditions of this Order.

8. Release of Information Forms

Respondent shall sign all release of information forms as required by the Board or its designee and return them to the Board within 10 days of the Board's written request. Failure to provide for the release of information, as required by this paragraph constitutes non-compliance with this Order.

9. Interview with the Board or Its Designee

Respondent shall appear in person or if residing out of state telephonically for interviews with the Board or its designee upon request at various intervals and with reasonable notice.

10. Renewal of License

Respondent's registered nurse license is scheduled to expire in April 2017. Respondent agrees that she will not renew or request reinstatement of her license or AP certificate. Upon termination of this Consent Agreement in accordance with paragraph 16 below, Respondent must request retirement and will not thereafter request reinstatement of her licensure.

11. Change of Employment/Personal Address/Telephone Number

Respondent shall notify the Board, in writing, within 7 days of any change in nursing employment, personal address or telephone number. Changes in nursing employment include the acceptance, resignation or termination or employment.

12. Obey All Laws

Respondent shall obey all laws/rules governing the practice of nursing in this state and obey all federal, state and local criminal laws. Respondent shall report to the Board, within 10 days, any misdemeanor or felony arrest or conviction.

13. Costs

Respondent shall bear all costs of complying with this Order.

14. Violation of Probation

If Respondent is noncompliant with this Order in any respect, Respondent's RN license and AP certificate **shall be automatically revoked** for a minimum period of five years.

15. Voluntary Surrender of License

Respondent may, at any time this Order is in effect, voluntarily request surrender of her RN license or AP certificate.

16. Completion of Probation

Respondent is not eligible for early termination of this Order. Upon successful completion of the terms of probation and submission of a request for retirement, Respondent shall request formal review by the Board, and after formal review by the Board, Respondent's nursing license and AP certificate may be fully restored by the appropriate Board action for the purpose of accepting Respondent's request for retirement of her RN license and AP certificate.

Board Date: January 30, 2015

SEAL

Joey Ridenour R.N.M. J.A.N.

Joey Ridenour, R.N., M.N., F.A.A.N.
Executive Director
ARIZONA STATE BOARD OF NURSING

Acceptance Date: January 30, 2015

COPY mailed this 30th day of January, 2015 by First Class Mail, to:

Signed in the ~~Board Office~~ this _____ day of _____, 5

Trudy Rumann Heil
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By: TRINA Smith
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