ARIZONA STATE BOARD OF NURSING 4747 N. 7TH STREET, SUITE 200 PHOENIX ARIZONA 85014-3655

3

1

2

4

5

ISSUED TO:

Respondent.

TRUDY RUMANN HEIL,

6

7

8

10

11 12

13

14

15 16

17

18

19

20

21 22

23

24

25

26

FINDINGS OF PUBLIC EMERGENCY AND ORDER OF SUMMARY SUSPENSION

CASE NO. 1203035

On April 11, 2012, the Arizona State Board of Nursing ("Board") met at 4747 North 7th Street, Ste. 200, Phoenix, Arizona 85014-3655, to consider a complaint filed against Trudy

IN THE MATTER OF REGISTERED NURSE

LICENSE NO. RN056661 AND ADVANCED

PRACTICE CERTIFICATE NO. AP0213

Rumann Heil ("Respondent"), the holder of registered nurse license no. RN056661 and advanced practice certificate no. AP0213. Information was presented to the Board and, as a result, the Board made the following Preliminary Findings of Fact, Conclusions of Law and

Order.

PRELIMINARY FINDINGS OF FACT

1. In or about June, 2011, Heil diagnosed patient I.K., an 11 year old male, with Hypervitaminosis D and a thyroid disorder, despite the fact that lab work completed in or about June, 2011 negated these diagnoses. Notwithstanding the lab tests, in or about June and July, 2011, Heil prescribed thyroid replacement medications to patient I.K., as well as four to six times the recommended dose of Benicar, an angiotensin II receptor blocker (ARB), plus the antibiotics Minocycline and Clyndamycin, as part of an experimental treatment known as the "Marshall Protocol" (MP). Heil used the MP to treat patient I.K. for a condition described as "Th1 Spectrum Disorder," which is a diagnosis unrecognized in the accepted medical literature. According to the manufacturer of Benicar, Daiichi-Sankyo, Benicar is not approved by the FDA for the treatment of "Th1 Spectrum Disorder" or for use in the MP, and the maximum dosage of Benicar approved by the FDA is 40 mg daily.

- 2. On or about March 9, 2012, patient I.K.'s parents brought patient I.K. to the Emergency Department of Phoenix Children's Hospital (PCH). Upon arrival, patient I.K.'s lab results revealed that his potassium, creatinine, and BUN levels were critically high, indicating acute renal failure/acute kidney damage, which PCH physicians attributed to Benicar toxicity and dehydration. In addition, patient I.K. presented with elevated liver enzymes, which indicated possible liver damage secondary to Benicar toxicity.
- 3. On or about March 9, 2012, PCH physicians admitted patient I.K. to the PCH pediatric intensive care unit for acute renal failure/acute kidney injury, with orders to discontinue the Benicar to avoid raising patient I.K.'s potassium to "lethal levels." On or about the same date, however, Heil advised patient I.K.'s parents and PCH physicians to continue to administer Benicar to patient I.K., despite the serious risk of injury and/or death to patient I.K. Heil also requested a PCH nephrologist to give patient I.K. Diovan instead of Benicar, however the nephrologist refused and informed Heil that Diovan would be just as bad as the Benicar and that she could not give I.K. an ARB or "it would kill him." On or about March 9, 2012, at Heil's instruction and against medical advice from the PCH physicians, patient I.K.'s parents administered a dose of Benicar to patient I.K. while patient I.K. was still in the Emergency Department. To prevent further administration of Benicar to patient I.K., PCH assigned a sitter to watch over patient I.K. while hospitalized and reported the incident to Child Protective Services and the City of Phoenix Police.
- 4. During patient I.K.'s hospitalization at PCH, the physicians also noted that patient I.K.'s thyroid studies indicated overtreatment. A pediatric physician at PCH questioned whether Heil erroneously diagnosed and treated patient I.K. for a thyroid condition (Hypothyroidism) because patient I.K.'s T4 level was normal and his Thyroid Stimulating Hormone (TSH) was suppressed.
- 5. On or about March 14, 2012, prior to discharging patient I.K., PCH physicians advised patient I.K's parents that it was "imperative" that patient I.K. not resume Benicar, and

discharged patient I.K. into his parents' custody with instructions to follow up with a pediatric endocrinologist and a gastrointestinal physician. The day after discharge, on or about March 15, 2012, Heil prescribed Diovan 40 mg every eight hours to patient I.K. Diovan is an ARB medication similar to Benicar. On or about March 16, 2012, the pharmacy refused to fill Heil's Diovan prescription and Heil filed an appeal stating that the use of Diovan at 40 mg every eight hours was needed "in lieu of Benicar use" to avoid damage to patient I.K.'s vital organs pursuant to the "Marshall Protocol emergency guidelines." Also on or about March 16, 2012, Heil continued to prescribe thyroid supplements to patient I.K., despite the fact that patient I.K.'s lab results were previously inconsistent with a diagnosis of Hypothyroidism.

- 6. On or about March 29, 2012, Child Protective Services removed patient I.K. from his parents' home after patient I.K.'s parents attempted to fill Heil's prescription for Diovan, which Heil prescribed despite knowing the risk of serious injury and/or death posed to patient I.K. by prescribing Diovan, and in doses higher than recommended/approved by the manufacturer/FDA.
- 7. Medical records of patient I.K. and additional MP patients treated by Heil (M.P., S.M., D.K. [I.K.'s father], T.A., D.D., C.W., A.S., P.S., C.S., R.S., and former M.P. patients L.K. [I.K.'s mother], E.G., M.M.) were reviewed and revealed that Heil treated these patients in a manner inconsistent with the standard of care, including but not limited to:
 - a. Heil prescribed the MP, an experimental treatment protocol that is not recognized in accepted medical literature, for Th1 spectrum disorder, a diagnosis that is not recognized in accepted medical literature;
 - b. Heil failed to document all of her care and treatment of patients in the medical record and she failed to list Th1 as a diagnosis or to document her treatment plan for said diagnosis;
 - c. Heil prescribed the MP for patients with documented medical conditions for which the MP does not meet the standard of care for treatment;
 - d. Heil diagnosed the MP patients with Hypervitaminosis D and Hypothyroidism, although their lab work was not consistent with these diagnoses;
 - e. MP Patients were treated for Hypothyroidism with thyroid replacement medications, although their lab work was not consistent with a diagnosis of Hypothyroidism, resulting in suppressed TSH indicating overtreatment;

- f. Multiple MP patients reported symptomatology/adverse reactions to Heil that Heil ascribed to "Immunopathology" (IP) without an assessment, and instructed patients to take more Benicar;
- g. MP Patients suffered physical, psychological, and financial harm as a result of Heil prescribing the MP, as evidenced by:
 - MP Patients suffered multiple adverse reactions for extended periods of time and had abnormal lab work, including elevated creatinine, BUN, liver function tests, etc., which Heil attributed to IP;
 - 2. MP Patients also were prescribed additional, otherwise unnecessary medications by Heil in order for them to tolerate the adverse reactions (IP), including anti-anxiety medications and narcotics;
 - 3. MP Patients required multiple visits and laboratory tests to monitor this experimental treatment, which were billed to the patients and/or their insurers (including Medicare Part B);
- h. All MP patients (including Medicare Part B patients) were billed for office visits and lab work, apparently fraudulently submitted by Heil under the diagnosis codes for Hypervitaminonis D and/or Hypothyroidism, although their lab work was not consistent with these diagnoses;
- i. All MP patients (including Medicare Part B patients) were billed using "extended visit" codes, although the visits appear related to the MP experimental research protocol and medical records do not reflect a comprehensive history & physical assessment (or any physical exam on many visits) or complex decision making, which are required to bill for an "extended visit."
- 8. Heil treated herself in accordance with the MP, and authorized prescriptions for herself, including prescriptions for Benicar, Clindamycin, Levothyroxine, Liothyronine, and Minocycline. Additionally, Heil ordered lab tests for herself, including, but not limited to, complete blood counts, chemistry panels, Vitamin D levels, and thyroid tests.

PRELIMINARY CONCLUSIONS OF LAW

- 1. The Arizona State Board of Nursing ("Board") has the authority to regulate and control the practice of nursing in the State of Arizona, pursuant to A.R.S. §§ 32-1606, 32-1663, 32-1664, and 41-1092.11(B). The Board also has the authority, pursuant to A.R.S. § 32-1663 and A.R.S. § 32-1664, to impose disciplinary sanctions against the holders of nursing licenses for violations of the Nurse Practice Act, A.R.S. §§ 32-1601 through 1669, and A.A.C. R4-19-101 to R4-19-815.
- 2. 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. §

1	32-166	53(D) as described in:
2	A.R.S.	§ 32-1601 (18) (d), (h) and (j) (effective September 30, 2009)
3	18.	"Unprofessional conduct" includes the following whether occurring in this state or
4		elsewhere:
	(d)	Any conduct or practice that is or might be harmful or dangerous to the health of a patient
5		or the public.
6	(h)	Committing an act that deceives, defrauds or harms the public.
7	(j)	Violating a rule that is adopted by the Board pursuant to this chapter, specifically:
8	A.A.C	. R4-19-403 (1), (2), (7), (8) (a), (12), (19), (30) and (31) (effective January 31, 2009)
9	For pu	rposes of A.R.S. § 32-1601(18)(d), any conduct or practice that is or might be harmful or
10	danger	ous to the health of a patient or the public includes one or more of the following:
11	1.	A pattern of failure to maintain minimum standards of acceptable and prevailing nursing practice;
12	2.	Intentionally or negligently causing physical or emotional injury;
13 14	7.	Failing to maintain for a patient record that accurately reflects the nursing assessment, care, treatment, and other nursing services provided to the patient;
15	8.	Falsifying or making a materially incorrect, inconsistent, or unintelligible entry in any record:
16		a. Regarding a patient, health care facility, school, institution, or other work place location;
17		
18	12.	Assuming patient care responsibilities that the nurse lacks the education to perform, for which the nurse has failed to maintain nursing competence, or that are outside the scope
of practice of the nurse;	of practice of the nurse;	
20	19.	Providing or administering any controlled substance or prescription-only drug for other than accepted therapeutic or research purposes;
21		
22	30.	For a registered nurse granted prescribing privileges, any act prohibited under R4-19-511(D);
23	31.	Practicing in any other manner that gives the Board reasonable cause to believe the health
24		of a patient or the public may be harmed.
25		

R4-19-511(D) (2) and (5) (effective January 31, 2009)

Prescribing and Dispensing Authority; Prohibited Acts

- D. In addition to acts listed under R4-19-403, for a nurse who prescribes or dispenses a drug or device, a practice that is or might be harmful to the health of a patient or the public, includes one or more of the following:
 - 2. Providing any controlled substance or prescription-only drug or device for other than accepted therapeutic purposes.
 - 5. Prescribing, dispensing, or furnishing a prescription drug or a prescription-only device to a person unless the nurse has examined the person and established a professional relationship, except when the nurse is engaging in one or more of the following:
 - a. Providing temporary patient care on behalf of the patient's regular treating and licensed health care professional;
 - b. Providing care in an emergency medical situation where immediate medical care or hospitalization is required by a person for the preservation or health, life, or limb; or
 - c. Furnishing a prescription drug to prepare a patient for a medical examination.

FINDING OF PUBLIC EMERGENCY AND ORDER

Based upon the facts and circumstances set forth in the Preliminary Findings of Fact and Preliminary Conclusions of Law, the Board finds that the public health, safety and welfare imperatively requires emergency action.

IT IS THEREFORE ORDERED, pursuant to A.R.S. § 41-1092.11(B) and effective immediately, that registered nurse license no. RN056661 and advanced practice certificate no. AP0213 held by Trudy Rumann Heil is **SUMMARILY SUSPENDED** pending proceedings for revocation and other action by the Board. A hearing in this matter shall be promptly instituted and determined.

1	Dated this 11 th day of April, 2012.
2	SEAL
3	
4	Joey Ridenour, R.N., M.N. Executive Director
5	
6	COPIES hand-delivered this 11 th day of April, 2012, to:
7 8	Trudy Rumann Heil 7153 N 7 th St
9	Scottsdale AZ 85258
10	Robert Chelle, Esq. HALL & CHELLE, LLC
11	7400 E Pinnacle Peak Rd, Suite 204 Scottsdale, AZ 85255
12	Kim Zack
13	Assistant Attorney General 1275 W Washington LES Section
14	Phoenix AZ 85007
15	
16	By: Susan Barber
17	
18	
19	
20	
21	
22	
23	
24	
25	
26	