

DOCKET NUMBER 507-20-0395

IN THE MATTER OF §

BEFORE THE STATE OFFICE

PERMANENT CERTIFICATE NUMBERS AP119548 & 642611,

§ OF

ISSUED TO

JAMI MAYORGA DICKSON § ADMINISTRATIVE HEARINGS

OPINION AND ORDER OF THE BOARD

TO: JAMI MAYORGA DICKSON

C/O MARC M. MEYER, ATTORNEY 525 WOODLAND SQUARE BLVD.

STE 250

CONROE, TX 77384

MEITRA FARHADI

ADMINISTRATIVE LAW JUDGE 300 WEST 15TH STREET

AUSTIN, TEXAS 78701

At the regularly scheduled public meeting on July 23, 2020, the Texas Board of Nursing (Board) considered the following items: the Proposal for Decision (PFD) regarding the above cited matter; Staff's exceptions to the PFD; Respondent's response to Staff's exceptions to the PFD; the ALJ's final letter ruling dated May 4, 2020; Staff's recommendation to the Board regarding the PFD and order; and Respondent's recommendation to the Board regarding the PFD and order, if any.

The Board finds that after proper and timely notice was given, the above styled case was heard by an Administrative Law Judge (ALJ) who made and filed a PFD containing the ALJ's findings of facts and conclusions of law. The PFD was properly served on all parties and all parties were given an opportunity to file exceptions and replies as part of the record herein. Staff filed exceptions to the PFD on March 27, 2020. Respondent filed a response to Staff's exceptions to the PFD on April 13, 2020. On May 4, 2020, the ALJ issued a final letter ruling in which she modified proposed Finding of Fact Number 22. However, the ALJ made no other changes to the PFD.

The Board, after review and due consideration of the PFD; Staff's exceptions to the PFD; Respondent's response to Staff's exceptions to the PFD; the ALJ's final letter ruling dated May 4, 2020; Staff's recommendations; and the recommendations made by the Respondent, if any, adopts all of the findings of fact and conclusions of law of the ALJ contained in the PFD, including modified Finding of Fact Number 22. All proposed findings of fact and conclusions of law filed by any party not specifically adopted herein are hereby denied.

I do hereby certify this to be a complete, accurate, and true copy of the document which is on file or is of record in the offices of the Texas Board of Nursing.

ASS Executive Director of the Board**

Executive Director of the Board

Recommendation for Sanction

Pursuant to Tex. Occ. Code. §301.459 (a-1), an Administrative Law Judge may make a recommendation regarding an appropriate action or sanction. The Board, however, has the sole authority and discretion to determine the appropriate action or sanction.

The Board agrees with the ALJ that the Respondent's conduct warrants a first tier, sanction level I sanction for her violations of §301.452(b)(10) and (13)¹. While the patient was vulnerable, there was a low risk of harm to the patient as a result of the Respondent's conduct². Further, Respondent has no history of previous violations or disciplinary action by the Board³.

Therefore, after carefully reviewing and considering the aggravating and mitigating factors identified by the ALJ in this case, the Board has determined, pursuant to the Board's Disciplinary Matrix and the Board's rules, including 22 Tex. Admin. Code §213.33(e)(10), that a Remedial Education Order with a Fine is the most appropriate sanction in this matter.

The Board agrees with the ALJ and finds that the Respondent should complete remedial education courses in nursing jurisprudence and ethics, critical thinking, APRN scope of practice, and documentation⁴. These courses are intended to inform the Respondent of the standards and requirements applicable to nursing practice in Texas and to prevent future violations from occurring.

IT IS THEREFORE ORDERED that RESPONDENT SHALL receive the sanction of **REMEDIAL EDUCATION WITH FINE** in accordance with the terms of this Order.

- A. This Order SHALL apply to any and all future licenses issued to RESPONDENT to practice nursing in the State of Texas.
- B. This Order SHALL be applicable to RESPONDENT'S nurse licensure compact privileges, if any, to practice nursing in the State of Texas.

¹ See pages 17 -18 of the PFD.

² See page 18 of the PFD and Conclusion of Law Number 8 of the PFD.

³ See adopted Finding of Fact Number 24 and Conclusion of Law Number 8 of the PFD.

⁴ 22 Tex. Admin. Code §213.33(f) requires every order issued by the Board to include participation in a program of education, which at a minimum, shall include a review course in nursing jurisprudence and ethics; see also 22 Tex. Admin. Code §213.33(e)(10).

C. As a result of this Order, RESPONDENT'S license(s) will be designated "single state" and RESPONDENT may not work outside the State of Texas in another nurse licensure compact party state.

I. COMPLIANCE WITH LAW

While under the terms of this Order, RESPONDENT shall comply in all respects with the Nursing Practice Act, Texas Occupations Code, §§301.001 et seq., the Rules and Regulations Relating to Nursing Education, Licensure and Practice, 22 TEX. ADMIN. CODE §§211.1 et seq., and this Order.

II. UNDERSTANDING BOARD ORDERS

Within thirty (30) days of entry of this Order, RESPONDENT must successfully complete the Board's online course, "Understanding Board Orders", which can be accessed on the Board's website from the "Discipline & Complaints" drop-down menu or directly at: http://www.bon.texas.gov/UnderstandingBoardOrders/index.asp. Upon successful completion, RESPONDENT must submit the course verification at the conclusion of the course, which automatically transmits the verification to the Board.

III. REMEDIAL EDUCATION COURSE(S)

In addition to any continuing education requirements the Board may require for licensure renewal, RESPONDENT SHALL successfully complete the following remedial education course(s) within one (1) year of the effective date of this Order, unless otherwise specifically indicated:

- A. A Board-approved course in Texas nursing jurisprudence and ethics that shall be a minimum of six (6) hours in length. The course's content shall include the Nursing Practice Act, standards of practice, documentation of care, principles of nursing ethics, confidentiality, professional boundaries, and the Board's Disciplinary Sanction Policies regarding: Sexual Misconduct; Fraud, Theft, and Deception; Nurses with Substance Abuse, Misuse, Substance Dependency, or other Substance Use Disorder; and Lying and Falsification. Courses focusing on malpractice issues will not be accepted. Home study and video programs will not be approved.
- B. Successfully completes the course "Determining APRN Scope of Practice," a 1.4 contact hour online program provided by the Texas Board of Nursing. Information about this course is available at https://www.bon.texas.gov/catalog/product/#bon-course-aprnscope or from the "CNE Workshops/Webinars" section of the Board's website under "News" menu
- C. <u>A Board-approved course in nursing documentation</u> that shall be a minimum of six (6) hours in length. The course's content shall include: nursing standards related to accurate and complete documentation; legal guidelines for recording; methods and processes of recording; methods of alternative record-keeping; and computerized documentation. Home study courses and video programs will not be approved.
- D. <u>The course "Sharpening Critical Thinking Skills,"</u> a 3.6 contact hour online program provided by the National Council of State Boards of Nursing (NCSBN) Learning Extension.

In order to receive credit for completion of this/these course(s), RESPONDENT SHALL CAUSE the instructor to submit a Verification of Course Completion form or SHALL submit the continuing education certificate, as applicable, to the attention of Monitoring at the Board's office. RESPONDENT SHALL first obtain Board approval of any course prior to enrollment if the course is <u>not</u> being offered by a pre-approved provider. Information about Board-approved courses and Verification of Course Completion forms are available from the Board at <u>www.bon.texas.gov/compliance</u>.

IV. MONETARY FINE

RESPONDENT SHALL pay a monetary fine in the amount of five hundred dollars (\$500.00) within forty-five (45) days of the effective date of

this Order. Payment is to be made directly to the Texas Board of Nursing in the form of cashier's check or U.S. money order. Partial payments will not be accepted.

V. RESTORATION OF UNENCUMBERED LICENSE(S)

Upon full compliance with the terms of this Order, all encumbrances will be removed from RESPONDENT'S license(s) to practice nursing in the State of Texas and, subject to meeting all existing eligibility requirements in Texas Occupations Code Chapter 304, Article III, RESPONDENT may be eligible for nurse licensure compact privileges, if any.

Entered this 23rd day of July, 2020.

TEXAS BOARD OF NURSING

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KATHERINE A. THOMAS, MN, RN, FAAN EXECUTIVE DIRECTOR FOR THE BOARD

Attachment: Proposal for Decision; Docket No. 507-20-0395 (March 13, 2020)

ACCEPTED 507-20-0395 03/13/2020 11:09 AM STATE OFFICE OF ADMINISTRATIVE HEARINGS Donnie Roland, CLERK



FILED 507-20-0395 3/13/2020 10:51 AM STATE OFFICE OF ADMINISTRATIVE HEARING Donnie Roland, CLERK

State Office of Administrative Hearings

Kristofer S. Monson Chief Administrative Law Judge

March 13, 2020

Katherine A. Thomas, M.N., R.N. Executive Director Texas Board of Nursing 333 Guadalupe, Tower III, Suite 460 Austin, Texas 78701

VIA E-FILE TEXAS

RE: Docket No. 507-20-0395; In the Matter of Permanent Certificate Number RN642611 & AP119548 Issued to Jami Mayorga Dickson, Respondent

Dear Ms. Thomas:

Please find below by Proposal for Decision in this case. It contains my recommendation and underlying rationale.

Exceptions and replies may be filed by any party in accordance with 1 Tex. Admin. Code § 155.507, a SOAH rule which may be found at www.soah.texas.gov.

Sincerely,

Meitra Farhadi

Administrative Law Judge

Mate Lanhade

MF/lc

Helen Kelly, Assistant General Counsel, Texas Board of Nursing, 333 Guadalupe, Tower III, Stc. 460, Austin, TX 78701 – VIA E-FILE TEXAS
 Elizabeth Tschudi, Legal Assistant Supervisor, Texas Board of Nursing, 333 Guadalupe, Tower III, Stc. 460, Austin, TX 78701 (with 1 CD via interagency mail) – VIA E-FILE TEXAS

Marc M. Meyer, Attorney at Law, 525 Woodland Square Blvd., Suite 250, Conroe, TX 77384-2212 - <u>VIA</u> <u>E-FILE TEXAS</u>

P.O. Box 13025 Austin, Texas 78711-3025 | 300 W. 15th Street Austin, Texas 78701 Phone: 512-475-4993 | Fax: 512-475-4994 www.soah.texas.gov

SOAH DOCKET NO. 507-20-0395

TEXAS BOARD OF NURSING,	§	BEFORE THE STATE OFFICE
Petitioner	§	
	§	
v.	§	OF
	§	
JAMI MAYORGA DICKSON, APRN	§	
Respondent	§	ADMINISTRATIVE HEARINGS

PROPOSAL FOR DECISION

The staff (Staff) of the Texas Board of Nursing (Board) seeks to sanction Jami Mayorga Dickson (Respondent), an advanced practice registered nurse (APRN), based on allegations that she violated the Texas Nursing Practice Act (Act)¹ and the Board rules.² Staff alleges that Respondent exceeded her scope of nursing practice in her treatment of a patient (Patient DD) by failing to collaborate, or document collaboration, with her supervising physician; and by prescribing off-label drugs resulting in harm to Patient DD. Staff seeks a one-year warning with stipulations and certain educational requirements. After considering the evidence and applicable law, the Administrative Law Judge (ALJ) finds Staff established some of the alleged violations and recommends a sanction of remedial education and a \$500 fine.

I. JURISDICTION, NOTICE, AND PROCEDURAL HISTORY

Notice and jurisdiction were undisputed and are therefore set out in the Findings of Fact and Conclusions of Law without further discussion. The hearing convened January 15, 2020, before ALJ Meitra Farhadi in the hearings facility of the State Office of Administrative Hearings (SOAH) in Austin, Texas. Staff was represented by Helen Kelley, Assistant General Counsel. Petitioner appeared and was represented by attorney Marc Meyer. The record closed on January 15, 2020.

¹ Tex. Occ. Code ch. 301.

² 22 Tex. Admin. Code ch. 217. All citations in this Proposal for Decision are to the substantive provisions in effect at the time of the underlying incident (August 18, 2016 to February 20, 2017).

II. STAFF'S FORMAL CHARGES

Staff's First Amended Formal Charges allege the following:

Charge I:

On or about August 18, 2016 through February 20, 2017, while employed as a psychiatric/mental health nurse practitioner with Total Mental Wellness, Respondent failed to collaborate, and/or document collaboration with her supervising physician regarding her management of Patient DD.

Charge II:

On or about February 9, 2017, while employed as a psychiatric/mental health nurse practitioner with Total Mental Wellness, Respondent inappropriately prescribed Saphris to Patient DD, a 5-year-old diagnosed with Attention Deficit Hyperactivity Disorder (ADHD) and Oppositional Defiant Disorder (ODD).

III. APPLICABLE LAW

In regard to Charge I, Staff asserted that Respondent should be disciplined for violating numerous provisions of the Board's rules,³ which are found in 22 Texas Administrative Code chapters 211-228. Specifically, Staff alleged violations of Board Rules 217.11(1)(A)-(B), (1)(D), (1)(P), (4)(A),and 217.12(1)(A)-(C) and (4). According to Staff, Respondent's violation of these rules subjects her to discipline by the Board pursuant to Texas Occupations Code (Code) § 301.452(b)(10) and (13).

In regard to Charge II, Staff asserted that Respondent should be disciplined pursuant to Code § 301.452(b)(10) and (13), for violating Board Rules 217.11(1)(A)-(B), (1)(M), (4)(A)-(B), and 217.12(1)(A), (1)(B), (4), and 222.4(e).

³ For ease of reference, a Board rule may be cited as "Board Rule ____."

The Board is authorized by the Act to discipline a nurse who violates the Act or a rule that is not inconsistent with the Act.⁴ More specifically, the Board may discipline a licensee who engaged in "unprofessional or dishonorable conduct that, in the [B]oard's opinion, is likely to deceive, defraud, or injure a patient or the public." Board rules define "unprofessional conduct" to include:

- Carelessly failing, repeatedly failing, or exhibiting an inability to perform vocational, registered, or advanced practice nursing in conformity with the standards of minimum acceptable level of nursing practice as set out in Board Rule 217.11;6
- Carelessly or repeatedly failing to conform to generally accepted nursing standards in applicable practice settings;⁷
- Improper management of client records;⁸ and
- Careless or repetitive conduct that may endanger a client's life, health or safety, without requiring a showing of actual injury.⁹

The Act also permits the Board to take disciplinary action against a nurse who has failed to "care adequately for a patient or to conform to the minimum standards of acceptable nursing practice in a manner that, in the [B]oard's opinion, exposes a patient or other person unnecessarily to risk of harm." The Board has enacted rules that define standards of nursing practice to require that every nurse must, among other things:

• Know and conform to the Act and the Board's rules and regulations as well as all federal, state, or local laws, rules, or regulations affecting the nurse's current area of nursing practice;¹¹

⁴ Code § 301.452(b)(1).

⁵ Code § 301.452(b)(10).

^{6 22} Tex. Admin. Code § 217.12(1)(A).

⁷ 22 Tex. Admin. Code § 217.12(1)(B).

^{8 22} Tex. Admin. Code § 217.12(1)(C).

⁹ 22 Tex. Admin. Code § 217.12(4).

¹⁰ Tex. Occ. Code § 301.452(b)(13).

^{11 22} Tex. Admin. Code § 217.11(1)(A).

- Implement measures to promote a safe environment for clients and others;¹²
- Accurately and completely report and document: the client's status including signs and symptoms; nursing care rendered; physician orders; administration of medications and treatments; client response(s); and contacts with other health care team members concerning significant events regarding the client's status;¹³
- Institute appropriate nursing interventions that might be required to stabilize a client's condition and/or prevent complications; ¹⁴ and
- Collaborate with the client, members of the health care team and, when appropriate, the client's significant other(s) in the interest of the client's health care. 15

Specific standards of nursing care apply to APRNs, as promulgated in Board rules. The Board requires that APRNs:

- Practice in an advanced nursing practice role and specialty in accordance with authorization granted under Board Rules Chapter 221 (relating to practicing in an APRN role) and standards set out in that chapter;¹⁶
- Prescribe medications in accordance with prescriptive authority granted under Board Rules Chapter 222 (relating to prescribing by APRNs), and standards set out in that chapter and in compliance with state and federal laws and regulations relating to prescription of dangerous drugs and controlled substances;¹⁷ and

^{12 22} Tex. Admin. Code § 217.11(1)(B).

^{13 22} Tex. Admin. Code § 217.11(1)(D).

¹⁴ 22 Tex. Admin. Code § 217.11(1)(M).

^{15 22} Tex. Admin. Code § 217.11(1)(P).

¹⁶ 22 Tex. Admin. Code § 217.11(4)(A).

^{17 22} Tex. Admin. Code § 217.11(4)(B). Controlled substances are medications defined by the Texas Controlled Substances Act, chapter 481 of the Texas Health and Safety Code. 22 Tex. Admin. Code § 222.1(6). The drugs are listed in five scheduled categories based on risk of abuse and addiction. Schedule I includes drugs that carry an extremely high risk of abuse and addiction and have no legitimate medical use, and Schedule V includes drugs that have the lowest abuse/addiction risk. Tex. Health & Safety Code § 481.035. Dangerous drugs are not included in chapter 481 but are unsafe for self-medication and require a prescription. Tex. Health & Safety Code § 483.001(2).

• Order or prescribe only those medications that are FDA¹⁸ approved unless done through protocol registration in a United States Institutional Review Board or Expanded Access authorized clinical trial. "Off label" use, or prescription of FDA-approved medications for uses other than that indicated by the FDA, is permitted when such practices are: (1) within the current standard of care for treatment of the disease or condition; and (2) supported by evidence-based research.

When a nurse has violated the Act or Board rules, the Board must impose a disciplinary sanction, which can range from remedial education to license revocation. Board Rule 213.33 includes a Disciplinary Matrix that the Board and SOAH are required to use in all disciplinary matters. The Disciplinary Matrix categorizes violations into tiers, and into sanction levels within tiers, based on the seriousness of the offense and risk of harm to patients or the public. The Disciplinary Matrix also lists certain aggravating and mitigating factors that must be considered. Board Rule 213.33 includes another list of factors that the Board and SOAH must consider in determining the appropriate disciplinary sanction, including evidence of actual or potential harm to patients or the public, evidence of practice history, evidence of present fitness to practice, previous disciplinary history, and the length of time the person has practiced. 22

IV. EVIDENCE

At the hearing, Staff offered 13 exhibits that were admitted into evidence, and presented testimony from two witnesses, Jolene Zych, RN, APRN, Ph.D. and Respondent. Respondent testified on her own behalf and called one witness, Dante R. Burgos, M.D.

¹⁸ FDA is the federal Food and Drug Administration.

^{19 22} Tex. Admin. Code § 222.4(e).

²⁰ Tex. Occ. Code § 301.453; 22 Tex. Admin. Code § 213.33(e).

²¹ 22 Tex. Admin. Code § 213.33(a)-(b).

²² 22 Tex. Admin. Code § 213.33(c).

A. Testimony of Jolene Zych, RN, APRN, Ph.D.

Dr. Zych was licensed as a Registered Nurse (RN) in 1989 and as a women's health nurse practitioner in 1993. She also holds a Ph.D. in public policy and administration. After working as a women's health nurse practitioner in Illinois for approximately six years, Dr. Zych began working for the Board in 1999, where she serves as a Nurse Consultant for Advanced Practice.²³ Dr. Zych was deemed qualified by the ALJ to give expert testimony on the statutes and Board rules that apply generally to nurses and specifically to APRNs. She does not have any advanced training or certification in psychiatric nursing, and has no expertise in psychiatric prescribing practices.

Concerning Charge I, failure to collaborate, Dr. Zych testified that all nurses are expected to collaborate with other members of the healthcare team, and that APRNs have the additional obligation to collaborate with doctors. She stated that there is no way to know if collaboration occurred if there is no documentation of the collaboration. Based on her review of the medical records, Dr. Zych testified that Respondent diagnosed Patient DD with ADHD and prescribed Vyvanse (a Schedule II drug). However, she found no corresponding documentation of any discussion with the delegating physician regarding treating Patient DD with Vyvanse. She explained that Vyvanse is a stimulant drug used to treat ADHD, but that the FDA label indicates that it is not known if it is safe and effective for children under 6 years of age. Respondent's practice was not in a hospital, and, according to Dr. Zych, APRNs cannot prescribe a Schedule II drug in an office-based setting. Dr. Zych testified that Respondent should have documented her communication with the delegating doctor and that the doctor should have been the person to issue the prescription.

²³ Staff Ex. 10,

²⁴ Staff Ex. 5 at 42-43.

²⁵ Staff Ex. 12.

Board rules limit an APRN to authorizing prescriptions for Schedule II drugs only in a hospital facility-based setting and subject to additional conditions. 22 Tex. Admin. Code § 222.8(c). However, Staff did not plead a violation of this rule; therefore, the ALJ does not address the allegation.

Regarding Charge II, inappropriately prescribing Saphris to Patient DD, Dr. Zych opined that if this charge is proven true, then Respondent exceeded the scope of her license by engaging in off-label prescribing. Dr. Zych stated that Saphris is an atypical anti-psychotic drug. The medical records indicate that Patient DD had two diagnoses, ADHD and ODD. Dr. Zych testified that based on her review of the FDA label for Saphris, neither of Patient DD's diagnoses is included in the indications listed for usage.²⁷

Reviewing Board Rule 222.4(e), Dr. Zych explained that APRNs can only prescribe drugs that are FDA-approved for the purpose for which they are prescribed. The exceptions to this limitation are if the APRN is working with patients in an approved clinical trial; or if the off-label use is within the standard of care and supported by evidence-based research. Dr. Zych testified that the standard of care is often set by professional nursing or medical organizations that address treatment of patients. She acknowledged that it can take years for clinical trials to be designed and executed; however, she explained that evidence-based research is not limited to FDA-approved clinical trials. It includes published studies performed by physicians and medical schools. In her opinion, anecdotal evidence from a few doctors would not meet the requirements as specified in the Board's rule. Dr. Zych explained that the term "evidence-based research" is not defined in the Board's rules and she has not heard of it used in any context outside of the Board's rules.

Dr. Zych testified that she did a brief search, and did not find any evidence-based research supporting the use of Saphris to treat ADHD in a minor. In her opinion, Respondent should have had a discussion with the delegating physician regarding the potential use of Saphris to treat Patient DD. The discussion should have been documented, and then if the delegating physician believed it was appropriate to prescribe Saphris, Respondent should have documented that the physician was ordering the drug. Dr. Zych did not see any such documentation in the medical records.

²⁷ Staff Ex. 11.

Dr. Zych also noted her concerns with the information in the medical records concerning the Saphris prescription itself. The records state "Saphris samples 2.5 mg BID." There is no information on how many samples were given to the patient, how long the patient should take the drug, how the medication was to be taken, etc. Dr. Zych explained that such information is required under Board Rule 222.4, and that it is important for other providers to know exactly what the patient was prescribed by reviewing the information. In this case, Patient DD presented at Children's Medical Center emergency room (ER) nine days later complaining of restlessness, finger movements, nose touching, and lip smacking. The ER notes indicate that Patient DD had been taking 5 mg of Saphris twice a day, but stopped taking it 3 days prior because of trouble sleeping. Dr. Zych testified that from Respondent's medical records, it is unclear if the samples given were 5 mg and the parent was supposed to split the tablets in half, or if the parent was doubling the dosage prescribed by Respondent.

Dr. Zych testified that her review of the medical records from the hospital revealed that Patient DD suffered from akathisia 30 as a result of taking Saphris. It was her understanding that akathisia often resolves once the medication is withdrawn, but that it can also be permanent. The hospital records also indicated that Patient DD had been seen in an urgent care facility for strep throat the day before, and had been prescribed Erythromycin, an antibiotic. In Dr. Zych admitted that it was possible that the side effects from Erythromycin could mimic the side effects of psychoactive medications. She also agreed that antibiotics could affect how other medications are metabolized.

From her review of the medical records, Dr. Zych testified that Patient DD was given the Saphris samples on February 9, 2017, and that on February 13, 2017, the patient's mother was instructed to stop the Saphris immediately in response to her concerns over Patient DD's reactions

²⁸ Staff Ex. 5 at 53. Dr. Zych stated that BID means twice per day.

²⁹ Staff Ex. 6 at 3.

³⁰ Dr. Zych testified that akathisia consists of uncontrolled movements, twitching, or tics.

³¹ Staff Ex. 6 at 3.

to the drug.³² Dr. Zych acknowledged that according to the FDA label for Saphris, the half-life³³ is approximately 24 hours.³⁴ Therefore, she stated, the Saphris should have cleared from Patient DD's system by the time he went to the ER on February 18, 2017; however, she noted that it is uncertain if the drug was actually cleared from Patient DD's system because the FDA label does not indicate the half-life for a 5-year-old—the drug is only approved for children 10 years and older.

Dr. Zych also testified as to her opinion on the appropriate sanction(s) in this case. Looking at the Board's Disciplinary Matrix, she stated that if the charges are proven true, under both Code § 301.452(b)(10) and (13) Respondent's conduct would be a Second Tier, Sanction Level I offense. Dr. Zych explained that this is based on the aggravating factors that Patient DD was a child and therefore a vulnerable patient, and that Patient DD suffered harm in the form of side effects from the medication and had to go to the ER. She did not identify any mitigating circumstances. In her opinion a one-year warning with stipulations would be most appropriate because it was a one-time event and Respondent has no disciplinary history, but the patient experienced side effects as a result of taking Saphris. Specifically, she testified that Respondent should be required to have monthly one-hour face-to-face meetings with her supervisor with documentation of what was discussed in the meetings; and documentation of chart review of 25% of Respondent's charts. That documentation should be sent to the Board quarterly for review. In addition, Dr. Zych stated that the following classes should be required for Respondent to take: jurisprudence and ethics; critical thinking; documentation; and a course on APRN scope of practice.

B. Testimony of Respondent

Respondent graduated from Texas Christian University with a Bachelor of Science in nursing in 1997, and became licensed as an RN shortly thereafter. She later took graduate level

³² Staff Ex. 5 at 52-53, 55-56.

³³ Dr. Zych testified that half-life refers to how long it takes a drug to clear the system.

³⁴ Staff Ex. 11.

classes from the University of Texas at Arlington, and was subsequently licensed as an APRN in 2010. Respondent is board certified as a psychiatric mental health nurse practitioner. She testified that her coursework for her master's degree included an emphasis on psychiatry, and that she has training in medication management and psychotherapy.

Respondent started her own practice at Total Mental Wellness in McKinney, Texas, in 2015. It is not a hospital-based practice. Dr. Burgos has been her supervising physician since 2015. His primary practice is approximately 40 minutes away, however, she meets with him in person or by phone at least once a week for about 20-30 minutes. In addition, she meets with Dr. Burgos once a month in person for chart reviews where they go over all cases with controlled medications as well as any cases with unique circumstances. Respondent testified that she regularly has conversation with Dr. Burgos regarding Vyvanse and Saphris. She explained that Vyvanse is one of the safer medications to use for children with ADHD, and that Saphris can be used for disruptive, explosive behaviors.

Patient DD was a 5-year-old child who came to Total Mental Wellness after having been treated by another provider for ADHD and ODD. The patient was being managed with Risperdal, an antipsychotic medication which is approved for behavioral disturbance in children. Patient DD was not responding to the medication. In addition, although Patient DD was not having side effects from Risperdal, Risperdal has an unfavorable side effect profile. Respondent testified that she discussed Patient DD's case with Dr. Burgos and came to a conclusion as to how his medications should be managed. She explained that because the assessment indicated more attention issues than behavioral, the treatment decision was made to add Vyvanse to improve focus for school and to try to replace the Risperdal with something else. She testified that the addition of Vyvanse appeared to stabilize Patient DD's condition, as documented by the lack of hyperactivity in the medical records. Respondent admitted that her conversation with Dr. Burgos concerning prescribing Vyvanse to Patient DD was not documented in the medical records.

After later observing Patient DD's behavioral issues, Respondent agreed with the ODD diagnosis and decided to try a drug to control his disruptive behaviors in school. Respondent

explained that because the FDA-approved medications had already been tried and were unsuccessful at controlling his behavioral outbursts, then it is her standard process to try something else in the same category of medications where there is evidence that it could work for that particular setting. She testified that she had a conversation with Dr. Burgos and the result was that she prescribed Saphris. Saphris is approved to treat schizophrenia in adults and bipolar I in children 10 to 17 years old. Saphris was chosen because of the ease of its mode of administration (orally dissolving tablet) and the speed at which it can calm behaviors. Respondent explained that it is frequently used in children for these reasons. Respondent testified that she is not aware of any published case studies, clinical trials, or peer-reviewed articles regarding the use of Saphris in 5-year-old children; however, she maintained that her off-label use of Saphris was within the standard of care. Respondent further stated that she prescribes according to evidence-based practice; which to her is the equivalent of evidence-based research. She explained that she has never seen the term "evidence-based research" outside of Board Rule 222.4(e).

Respondent prescribed 2.5 mg of Saphris twice-a-day at an appointment on February 9, 2017, and on February 13, 2017, Patient DD's mother called the clinic expressing concern with Patient DD's reaction to the Saphris. Respondent advised her to stop the Saphris and to bring Patient DD in if there was no improvement.³⁵ On February 20, 2017, Respondent received a voicemail from Patient DD's mother advising that Patient DD had presented at the ER over the weekend. The voicemail message was unclear as to the reason for the ER visit, and Respondent was never contacted by the ER. Respondent testified that at the prescribed dose, it would be very unlikely that the akathisia documented in the ER visit notes would have occurred, and if the medication were stopped when instructed, it would be even more unlikely that those symptoms were related to the Saphris. She explained that her understanding is based on her education and evidence on how Saphris is metabolized in 10-year-old children.

Respondent testified that if she had to do everything over again, her documentation would be different, but that she would make the same treatment decisions. She stated that her current

³⁵ Staff Ex. 5 at 55-56.

practice is to electronically send the medical record and request for the prescription to Dr. Burgos when she believes a scheduled drug should be prescribed to a patient, and then he is able to issue the prescription electronically.

C. Testimony of Dr. Burgos

Dr. Burgos is a licensed physician in Texas and Oklahoma and is board certified in child and adolescent psychiatry. Among other positions, he is currently the medical director for the children's program at Perimeter Hospital in Garland, Texas. He has worked with Respondent for at least two years, and he has known her for many years. They have a collaborative agreement which requires him to monitor the prescriptions that she writes (especially controlled substances), that they meet frequently (at least weekly) to address patient care, and he signs off on her charts that he reviews. In situations when Respondent suggests a prescription for a controlled substance, he reviews the medical records, speaks with Respondent, and monitors for any other prescriptions the patient has sought for scheduled substances.

Dr. Burgos is familiar with Patient DD. The patient had been under treatment with a different facility and transferred to Respondent for continuing care. The patient had been on an anti-psychotic mood stabilizer and was also on a stimulant medication. Dr. Burgos recalled having a conversation with Respondent regarding prescribing Saphris to Patient DD. He testified that Saphris is a newer mood-stabilizing medication that comes in a dissolvable form, and has a more favorable side effect profile than the older medications. In his conversation with Respondent, they discussed the benefits versus the risks of Saphris versus other treatment strategies. The side-effect profile for Saphris, as well as all the medications in the same class, includes sedation, headaches, muscular tension, and akathisia. Dr. Burgos is aware that Saphris is not labeled for use in a patient as young as 5 years old. However, he explained that it was used in this case because the FDA-approved medications that were tried previously were either not tolerated or not effective, and because Saphris is fast-acting and effective. Dr. Burgos testified that Respondent adequately consulted with him regarding Patient DD because they meet weekly to discuss patients and have

him review her charts. He stated that Respondent met his expectations and that there is nothing that she did with regard to the care of Patient DD that he would have done differently.

Dr. Burgos testified that the standard of care is the same for doctors and for APRNs. In his opinion, when the FDA-approved medications have been exhausted, the standard of care is to try a non-FDA-approved medication. In those cases, the only studies available are anecdotal. Dr. Burgos stated that it is important in those instances to draw upon the practitioner's own experience, the experiences of their patients, and the experiences of others in the provider community. In his opinion, Saphris is effective in children based on the results he has seen in adults. He expounded that it is extremely common practice to use a medication that is not FDA-approved for a particular age group. Dr. Burgos further stated that the key is to explain the risks and the benefits to the family when recommending a medication that is not FDA-approved for a particular age group.

V. ANALYSIS

A. Charge I: Failure to Collaborate and/or Document Collaboration

Under Charge I, Staff alleged that Respondent failed to collaborate, and/or document collaboration with her supervising physician regarding her management of Patient DD; resulting in violations of Board Rules 217.11(1)(A)-(B), (1)(D), (1)(P), (4)(A), and 217.12(1)(A)-(C) and (4). According to Staff, Respondent's violation of these rules subjects her to discipline by the Board pursuant to Code § 301.452(b)(10) and (13). Staff did not indicate how the factual allegations corresponded with any of the rules.

Respondent testified credibly, with corroboration from Dr. Burgos's testimony, that she collaborated with Dr. Burgos regarding Patient DD. Specifically, she testified that she discussed Patient DD's case with Dr. Burgos and they came to a conclusion as to how his medications should be managed, resulting in the addition of Vyvanse and the tapering and replacement of Risperdal with Saphris. Respondent admitted that her conversations with Dr. Burgos were not documented in the medical records. Respondent testified that she is familiar with the Act and Board rules, and

acknowledged that her documentation of collaboration was poor. The evidence shows that Respondent collaborated with her delegating physician; however, she failed to adequately document their collaboration.

Staff failed to establish that the failure to adequately document collaboration with Dr. Burgos could have potentially endangered Patient DD, or that Respondent failed to implement measures to promote a safe environment.

Therefore, the evidence was sufficient to prove that Respondent is subject to sanction under Code § 301.452(b)(13) for failing to meet minimum standards of nursing practice, specifically for failing to know and conform to the Act, Board rules, and other applicable law (Board Rule 217.11(1)(A)) by failing to accurately and completely report and document required information in the medical records (Board Rule 217.11(1)(D)). In addition, Respondent is subject to sanction under Code § 301.452(b)(10) for unprofessional conduct, specifically for failing to conform to generally accepted nursing standards in the applicable practice setting (Board Rule 217.12(1)(B)) by improperly managing client records (Board Rule 217.12(1)(C)). While the evidence supported that the Board is authorized to discipline Respondent's APRN license for violations of the rules listed above, the evidence does not clearly establish violations of other cited rules.

B. Charge II: Inappropriate Prescribing

Under Charge II, Staff alleged that Respondent inappropriately prescribed Saphris to Patient DD; resulting in violations of Board Rules 217.11(1)(A)-(B), (1)(M), (4)(A)-(B), and 217.12(1)(A), (1)(B), (4), and 222.4(e). According to Staff, Respondent's violation of these rules subjects her to discipline by the Board pursuant to Code § 301.452(b)(10) and (13). Staff did not indicate how the factual allegations corresponded with any of the rules beyond Board Rule 222.4(e).

The evidence established that Respondent collaborated with Dr. Burgos in the management of Patient DD's medication, and that the decision was made to taper the patient off of Risperdal

due to its lack of effectiveness and the poor side-effect profile. They decided to treat Patient DD's ODD with Saphris because Patient DD had already tried all of the FDA-approved medications for ODD in children, because of its ease of use, that it is fast-acting, and it has a more favorable side effect profile. It was undisputed that treating ODD in a 5-year-old child is an off-label use of Saphris.

Reviewing Board Rule 222.4(e), Dr. Zych explained that APRNs can only prescribe drugs that are FDA-approved for the purpose for which they are prescribed. The exceptions to this limitation are if the APRN is working with patients in an approved clinical trial, or if the off-label use is within the standard of care and supported by evidence-based research. Patient DD was not part of a clinical trial, so that leaves the requirement that any off-label prescription ordered by Respondent must be *both* within the standard of care for treatment of the patient's condition, *and* supported by evidence-based research. In Dr. Zych's opinion, the standard of care is often set by professional nursing or medical organizations that address treatment of patients. In her opinion, anecdotal evidence from a few doctors would not rise to the standard of care as specified in the Board's rule.

Dr. Burgos testified that when the FDA-approved medications have been exhausted, the standard of care is to try a non FDA-approved medication. Dr. Burgos stated that it is important in those instances to draw upon the practitioner's own experience, the experiences of their patients, and the experiences of others in the provider community. Although neither Respondent nor Dr. Burgos are aware of any published case studies, clinical trials, or peer-reviewed articles regarding the use of Saphris in 5-year-old children; in Dr. Burgos's opinion Saphris is effective in children based on the results he has seen in adults. He expounded that it is extremely common practice to use a medication that is not FDA-approved for a particular age group. Respondent also testified that Saphris is frequently used in children.

Dr. Zych does not have any advanced training or certification in psychiatric nursing, or any expertise in psychiatric prescribing practices; while Dr. Burgos is a physician board certified in child and adolescent psychiatry and Respondent is board certified as a psychiatric mental health

nurse practitioner. The evidence presented establishes that the use of Saphris in a 5-year-old child to treat ODD is within the standard of care when the FDA-approved medications have been exhausted.

Turning to whether the off-label use is supported by evidence-based research, Dr. Zych testified that she did a brief search, and did not find any evidence-based research supporting the use of Saphris in a minor for ADHD.³⁶ The term "evidence-based research" is not defined in the Board's rules and neither Dr. Zych nor Respondent have heard it used in any context outside of the Board's rules. Respondent testified that she believes evidence-based research to be the equivalent of evidence-based practice. In response, Staff argues that the ALJ should construe the term by its common meaning; and therefore the use must be supported by research not practice.

The ALJ agrees with Staff. The evidence presented by Staff was that no research existed to support this off-label use. Respondent did not offer any evidence to the contrary; and in fact, Respondent testified that she was not aware of any published case studies, clinical trials, or peer-reviewed articles regarding the off-label use in minors with ODD. Because Board Rule 222.4(e) prohibits an APRN from prescribing off-label unless the practice is both within the standard of care and supported by evidence-based research, Respondent's conduct constitutes a violation of Board Rule 222.4(e) for the simple fact that she ordered the prescription instead of Dr. Burgos. As noted by Dr. Zych, if the delegating physician believed it was appropriate to prescribe Saphris, Respondent should have documented that the physician was ordering the drug instead of herself.

Because Respondent failed to prescribe medications in accordance with APRN prescriptive authority (Board Rules 217.11(4)(B) and 222.4(e)) the evidence was sufficient to prove that Respondent is subject to sanction under Code § 301.452(b)(13) for failing to meet minimum standards of nursing practice, specifically for failing to know and conform to the Act, Board rules, and other applicable law (Board Rule 217.11(1)(A)). While the evidence supported that the Board

³⁶ The ALJ notes that Saphris was prescribed for ODD, not ADHD, but there was no evidence that any clinical studies for the use of Saphris in a minor with ODD exist either.

is authorized to discipline Respondent's APRN license for violations of the rules listed above, the evidence does not clearly establish violations of other cited rules.¹⁷

C. Sanctions

For the reasons set forth above, the ALJ finds that Staff established by a preponderance of the evidence that Respondent failed to document collaboration with her supervising physician regarding her management of Patient DD. The conduct constitutes violation of Board Rules 217.11(1)(A), (D), and 217.12(1)(B)-(C). The rule violations subject Respondent to discipline pursuant to Code § 301.452(b)(10) and (13).

Staff did not establish that Respondent's failure to adequately document her collaboration with Dr. Burgos involved any risk to patient safety. Therefore, according to the Board's Disciplinary Matrix in Board Rule 213.33(b), Respondent's conduct under both Code § 301.452(b)(10) and (13) was a First Tier offense at Sanction Level I, which would make the appropriate sanction remedial education and/or a \$250 fine for each incident.³⁸

The ALJ also finds that Staff established that Respondent inappropriately prescribed Saphris to Patient DD because it was an off-label prescription not supported by evidence-based research. This conduct violates Board Rules 217.11(1)(A), (4)(B) and 222.4(e), which subject Respondent to discipline pursuant to Code § 301.452(b)(13).

The medical records and Respondent's testimony establish that four days after Saphris was prescribed by Respondent, Patient DD's mother called the clinic expressing concern with

Although the ALJ finds a violation of Board Rules 217.11(1)(A) and (4)(B), the evidence did not establish a corresponding violation of Board Rule 217.12(1)(A) because Respondent's conduct was not shown to be careless or repeated or based on inability to perform nursing properly.

³⁸ A Second Tier offense under Code § 301.452(b)(10) involves serious risk to patient or public safety, and a Third Tier offense is conduct resulting in serious harm to the patient or public or repeated acts of unethical behavior. Similarly, a Second Tier offense under Code § 301.452(b)(13) involves patient harm or risk of patient harm, and a Third Tier offense involves a serious risk of harm or death. There was no showing of serious risk or actual harm; therefore, the First Tier is appropriate under either Code section.

Patient DD's reaction to the Saphris. The records reflect that she was advised to stop the Saphris and to bring Patient DD in if there was no improvement. Patient DD later went to the ER experiencing akathisia, wherein it was noted that Patient DD had been prescribed an antibiotic for strep throat the day before, and that the Saphris had been discontinued three days prior. The FDA label further shows that the half-life for Saphris is approximately 24 hours. Although the FDA label is only for use in children 10 years and older, Respondent testified that based on her education and evidence on how Saphris is metabolized in 10-year-old children, it would be unlikely for the Saphris to be the cause of akathisia by the time Patient DD presented at the ER. The preponderant evidence therefore establishes that there was a low risk of harm to Patient DD as a result of this violation. According to the Board's matrix in Board Rule 213.33(b), Respondent's conduct under Code § 301.453(b)(13) was a First Tier offense at Sanction Level I, which would make the appropriate sanction remedial education and/or a \$250 fine for each incident.³⁹

The ALJ recommends that the appropriate sanction for the violations established is remedial education as specified by the Board and a fine of \$500.

VI. FINDINGS OF FACT

- 1. Jami Mayorga Dickson (Respondent) holds two licenses issued by the Texas Board of Nursing (Board): Advanced Practice Registered Nurse License No. AP119548 and Registered Nurse License No. 642611.
- 2. Respondent has been a registered nurse (RN) since 1997 and an Advanced Practice Registered Nurse (APRN) since 2010. Respondent is board certified as a psychiatric mental health nurse practitioner.
- 3. Since 2015, Respondent has worked at Total Mental Wellness in McKinney, Texas, where her delegating physician is Dante R. Burgos, M.D. It is not a hospital-based practice.
- 4. The standard of care applicable to Respondent as an APRN is the same standard of care that governs a physician's practice in treating patients in a psychiatric practice.

³⁹ A First Tier offense under Code § 301.452(b)(13) involves practice below standard with a low risk of patient harm, a Second Tier offense involves patient harm or risk of patient harm, and a Third Tier offense involves a serious risk of harm or death. The evidence did not establish a serious risk or actual harm; therefore, the First Tier is appropriate.

- 5. APRNs have limits on their prescribing authority that do not apply to physicians.
- 6. Patient DD, a 5-year-old diagnosed with Attention Deficit Hyperactivity Disorder (ADHD) and Oppositional Defiant Disorder (ODD), came to Total Mental Wellness after having been treated by another provider for ADHD and ODD.
- 7. Patient DD was being managed with Risperdal, an antipsychotic medication which is approved for behavioral disturbance in children. Risperdal has an unfavorable side effect profile, and Patient DD was not responding to the medication.
- 8. Respondent prescribed Vyvanse to Patient DD to treat ADHD.
- 9. Vyvanse is approved by the Food and Drug Administration (FDA) to treat ADHD, but the FDA label indicates that it is not known if it is safe for children under 6 years of age.
- 10. Respondent collaborated with Dr. Burgos regarding Patient DD and which medications to prescribe.
- 11. Respondent failed to adequately document collaboration with a delegating physician in regard to Patient DD, but this documentation failure did not create any risk to patient safety.
- 12. Saphris is a newer mood-stabilizing medication that comes in a dissolvable form, and has a more favorable side effect profile than the older medications.
- 13. Saphris is approved by the FDA to treat schizophrenia in adults and bipolar I disorder in adults and pediatric patients between the ages of 10 and 17. Saphris is not FDA-approved for children under 10 years of age.
- 14. Patient DD was not part of a clinical trial.
- 15. The use of Saphris in a 5-year-old child to treat ODD is within the standard of care when the FDA-approved medications have been exhausted.
- 16. The use of Saphris in a 5-year-old child to treat ODD is not supported by evidence-based research.
- 17. The FDA-approved medications for use in children as young as 5 years old were not effective in Patient DD's treatment for ODD.
- 18. After collaborating with Dr. Burgos, Respondent prescribed Saphris to Patient DD on February 9, 2017.
- 19. On February 13, 2017, Patient DD's mother called the clinic expressing concern with Patient DD's reaction to the Saphris. Respondent advised her to stop the Saphris and to bring Patient DD in if there was no improvement.

- 20. On February 17, 2017, Patient DD went to urgent care and was diagnosed with strep throat. The patient was given the antibiotic Erythromycin.
- 21. On February 18, 2017, Patient DD presented at the emergency room with akathisia consisting of restlessness, finger movements, nose touching, and lip smacking. Saphris was stopped at least 3 days prior.
- 22. Saphris has a half-life of approximately 24 hours, according to FDA studies based on adults and children 10 years and older.
- 23. It is unlikely that the Saphris was the cause of akathisia by the time Patient DD presented at the ER.
- 24. Respondent has no history of previous violations or disciplinary action by the Board.
- 25. On October 7, 2019, the Staff of the Board issued its Notice of Hearing to Respondent, together with First Amended Formal Charges.
- 26. The Notice of Hearing and the First Amended Formal Charges contained a statement of the time, place, and nature of the hearing on the merits; a statement of the legal authority and jurisdiction under which the hearing on the merits was to be held; a reference to the particular sections of the statutes and rules involved; and a short, plain statement of the factual matters asserted.
- 27. The hearing on the merits convened January 15, 2020, before Administrative Law Judge (ALJ) Meitra Farhadi in the hearings facility of the State Office of Administrative Hearings (SOAH) in Austin, Texas. Staff was represented by Helen Kelley, Assistant General Counsel. Petitioner appeared and was represented by attorney Marc Meyer. The record closed on January 15, 2020.

VII. CONCLUSIONS OF LAW

- 1. The Board has jurisdiction over this matter. Tex. Occ. Code ch. 301.
- 2. SOAH has jurisdiction over the hearing in this proceeding, including the authority to issue a proposal for decision with findings of fact and conclusions of law. Tex. Gov't Code ch. 2003.
- 3. Respondent received proper notice of the hearing on the merits. Tex. Occ. Code § 301.454; Tex. Gov't Code §§ 2001.051-.052.
- 4. Staff had the burden of proof by a preponderance of the evidence. 1 Tex. Admin. Code § 155.427.

- 5. Respondent is subject to sanction because she failed to meet minimum standards of nursing practice, specifically for failing to know and conform to the Act, Board rules, and other applicable law by failing to accurately and completely report and document required information in the medical records, and by failing to prescribe medications in accordance with APRN prescriptive authority. Tex. Occ. Code § 301.452(b)(13); 22 Tex. Admin. Code §§ 217.11(1)(A), (D), (4)(B) and 222.4(e).
- 6. Respondent is also subject to sanction because she committed unprofessional conduct by failing to conform to generally accepted nursing standards in the applicable practice setting by improperly managing client records. Tex. Occ. Code § 301.452(b)(10); 22 Tex. Admin. Code § 217.12(1)(B)-(C).
- 7. The Board may impose a disciplinary sanction, which can range from remedial education to revocation of a nurse's license, and which may include assessment of a fine. Tex. Occ. Code § 301.453; 22 Tex. Admin. Code § 213.33(e).
- 8. To determine the appropriate disciplinary sanction to be imposed in this case, the Board must consider the factors set forth in 22 Texas Administrative Code § 213.33(c) and the Board's Disciplinary Matrix (22 Texas Administrative Code § 213.33(b)). In this case, the Board may consider the aggravating factor of the patient's vulnerability. The Board may also consider as mitigating factors the lack of evidence of actual harm to Patient DD and Respondent's practice history showing no other disciplinary actions.

VIII. RECOMMENDATION

Based on the above Findings of Fact and Conclusions of Law, the ALJ recommends that Respondent be required to complete remedial education as specified by the Board, including nursing jurisprudence and ethics, critical thinking, documentation, and APRN scope of practice, and be required to pay a fine of \$500.

SIGNED March 13, 2020.

MEITRA FARHADI

ADMINISTRATIVE LAW JUDGE

STATE OFFICE OF ADMINISTRATIVE HEARINGS

ACCEPTED 507-20-0395 03/30/2020 8:17 AM STATE OFFICE OF ADMINISTRATIVE HEARINGS Jodi Brown, CLERK



FILED 507-20-0395 3/27/2020 5:56 PM STATE OFFICE OF ADMINISTRATIVE HEARINGS Jodi Brown, CLERK

Katherine A. Thomas, MN, RN, FAAN Executive Director

March 27, 2020

The Honorable Meitra Farhadi, Administrative Law Judge State Office of Administrative Hearings P.O. Box 13025 Austin, Texas 78711-3025 Via Electronic Filing

Re:

In the Matter of Permanent Certificate Nos. RN 642611 & AP119548

Issued to: JAMI MAYORGA DICKSON

SOAH Docket No. 507-20-0395

Dear Judge Farhadi:

Enclosed is Staff's Exceptions to the Proposal for Decision.

Sincerely,

Helen Kelley

Assistant General Counsel

Helen Kelley

Electronically Signed as Authorized by Tex. Bus. & Comm. Code §322.007

HK:cll

Enclosure

cc: Marc M. Meyer, Attorney, Law Office of Marc Meyer, PLLC, 525 Woodland Square Blvd., STE 250, Conroe, TX 77384, via email

SOAH DOCKET NO. 507-20-0395

IN THE MATTER OF	Ş	BEFORE THE	
PERMANENT CERTIFICATE	§		
NOS, RN 642611 & AP119548	§	STATE OFFICE	
ISSUED TO	§		
JAMI MAYORGA DICKSON	8	ADMINISTRATIVE HEARINGS	S

STAFF'S EXCEPTIONS TO PROPOSAL FOR DECISION

COMES NOW, Staff of the Texas Board of Nursing (hereinafter "Staff" or "Board"), and respectfully files its exceptions to the Proposal for Decision ("PFD") issued in this matter on March 15, 2019, as follows:

Pursuant to Section 2001.062(d) of the Texas Government Code "[a] proposal for decision may be amended in response to exceptions, replies, or briefs submitted by the parties." Section 2001.141(c) of the Texas Government Code provides that "[f]indings of fact may be based only on the evidence and on matters that are officially noticed." Additionally, Section 2001.058(e) of the Texas Government Code provides that:

A state agency may change a finding of fact or conclusion of law made by the administrative law judge, or may vacate or modify an order issued by the administrative judge, only if the agency determines:

- (1) that the administrative law judge did not properly apply or interpret applicable law, agency rules, written policies provided under Subsection (c), or prior administrative decisions;
- (2) that a prior administrative decision on which the administrative law judge relied is incorrect or should be changed; or
- (3) that a technical error in a finding of fact should be changed.

The agency shall state in writing the specific reason and legal basis for a change made under this subsection.

In accordance with the bases provided for excepting to an administrative law judges' findings of fact in Sections 2001.141(c) and 2001.058(e)(3), Staff objects to Finding of Fact No. 22, which states, that "Saphris has a half-life of approximately 24 hours, according to FDA studies based on adults and children 10 years and older," as this statement is patently false.

The FDA label actually states and Staff's expert testified that "the *mean terminal half-life* is approximately 24 hours." Staff's Ex 11 at section 12.3 Pharmacokinetics; Hearing recording at 50:00-50:07. While, Respondent's attorney, Marc Meyer, incorrectly asserted that mean terminal half-life is the same as half-life by stating that "it lists that period of time for a half-life here as 24 hours," Staff's Expert, Dr. Jolene Zych immediately corrected him by countering that what was actually listed was "following an initial more rapid distribution phase the *mean terminal half-life* is approximately 24 hours." Hearing recording at 49:50-50:07.

Pursuant to Section 311.011(b) of the Texas Government Code, "[w]ords and phrases that have acquired a technical or particular meaning, whether by legislative definition or otherwise, shall be construed accordingly." Mean terminal half-life as used in the Saphris FDA label under the section "12 Clinical Pharmacology," and specifically subsection "12.3 Pharmacokinetics" clearly has a specialized technical meaning. See, Novartis Pharm. Corp. v. W.-Ward Pharm. Int'l Ltd., 287 F.Supp.3d 505 (D. Del. 2017) (differentiating between the terms half-life, elimination half-life, and terminal half-life), In re Neopharm, Inc. Sec. Litig., 705 F.Supp.2d 946 (N.D. Ill. 2010); See also, Toutain, P.L., Bousquet-Mélou, A. Plasma terminal half-life. J.vet. Pharmacol. Therap. 2004; 27, 427-439 ("The terminal half-life is the time required for plasma/blood concentration to decrease by 50% after pseudo-equilibrium of distribution has been reached. . . it is not the time necessary for the amount of the administered drug to fall by one half.") Accordingly, this finding, as currently written, is technically incorrect under 2001.058(e)(3) of the Texas Government Code.

Furthermore, it should not be included as a finding of fact given that, as Dr. Zych testified, "the pharmacokinetics in this document are based on approved uses, this [patient at issue] is a five year-old and this [drug] is for ten and up." Hearing recording at 55:34-55:50. Dr. Zych further

testified that we don't "have any evidence as to how Saphris would be cleared, absorbed, what the terminal half-life, etcetera would be for a [five-year-old] child." Hearing recording at 1:28:20-1:29:05. Additionally, no experts in Pharmacology testified at the hearing. Given the limits of the evidence before the court, any conclusion drawn from Mr. Meyer's erroneous conflating of the terms half-life and terminal half-life would be best termed a finding of pseudo-science, and not a finding of fact.

Similarly, Staff objects to Finding of Fact No. 23 as there is no legitimate reason under Section 2001.062(c) of the Texas Government Code by which this finding could be based given the lack of evidence as to how the drug affects pediatric patients under the age of ten. Additionally, it is contrary to the evidence in the record that the Emergency Room physicians attributed the patient's twitching or akathisia to the Saphris. Exhibit 6 at 7, ("Spoke to Dr. Riela with neuro over the phone. Discussed case, he agrees that symptoms ["lip smacking and finger movements"] are probably Akathisia likely due to Saphris which has been discontinued."); Hearing record at 1:36:20-1:36:35. Furthermore, of the prescriptions the minor was taking, only the Saphris FDA label lists Tardive dyskinesia or uncontrollable movements of the face, tongue, or other body parts as a side effect. Compare Staff's Exhibit 11 (Saphris), with Staff's Exhibit 12 (Vyvanse); Hearing record at 1:23:45-1:24:05; and Staff's Exhibit 13 (Drug Interaction Report for Erythromycin and Saphris); Hearing record at 1:26:00-1:27:15. Moreover, if one was to rely on anything from the Saphris FDA label, other than that it was not indicated for the patient due to his age and diagnoses, it should be Section 5 Warnings and Precautions, specifically subsection 5.4 Tardive Dyskinesia, which states that "[t]he syndrome can develop after a relatively brief treatment period, even at low doses [and] filt may also occur after discontinuation of treatment." Staff's Exhibit 11 at Section 5.4 Tardive Dyskinesia. Finally, the Emergency room discharge instructions to the minor patient

state that "you are having a muscular reaction to a medicine you have taken... The reaction can happen fairly quickly after taking the medicine [or] [i]t may occur after hours or even days, however.") Staff's Ex. 6 at 11. Accordingly this finding of fact should be modified to state that: Saphris was determined to be the cause of akathisia suffered by Patient DD when he presented at the ER.

Staff objects to Conclusion of Law No. 8 under Section 2001.058(e)(1) of the Texas Government Code which states that there is a "lack of evidence of actual harm to patient DD." Proposal for Decision at 21. Staff's expert testified that there was actual harm to the patient, specifically for the "period of time where they ended up in the emergency room and certainly a cost to the family for that emergency room visit." Hearing recording at 38:00-38:10. Staff's expert further testified that harm is an aggravating factor under the Board's Disciplinary Matrix. 1:35:55-1:36:00. Staff's expert also declined to conclude under either Section 301.452(b)(10) or 301.452(b)(13) that Respondent's conduct did not harm the patient. Hearing recording at 37:00-39:22. Specifically, Dr. Zych testified that "under [301.452](b)(10) [of the matrix], a first tier offense is an isolated failure to comply with the rules with no adverse patient effects. So I don't believe a first tier offense applies because we do have a patient who ended up in the emergency department with side effects." Hearing recording at 37:00-37:15. Dr. Zych further testified that "again, I believe it would be a second tier offense, looking at tier one under 301.452(b)(13) it talks about risk of harm, it doesn't talk about there being actual harm, so again I would put it at a second tier offense." Hearing recording at 39:05-39:22. Additionally, Finding of Fact Nos. 19 and 21 demonstrate that the patient suffered a negative reaction that caused his mother such concern that she called Respondent's office, and then later took him to the emergency room. While Staff is not aware of the minor patient's long term prognosis, to say that the patient didn't suffer any actual

physical or economic harm as contemplated by the Board's Disciplinary Matrix found in 22 Tex. Admin. Code §213.33(b) and the factors listed in 22 Tex. Admin. Code §2133.33(c), particularly subsections (1) and (8) is a misapplication of the agency's rules under 2001.058(e)(1).

Additionally, the administrative law judge seemed to mistakenly rely on the Respondent's testimony regarding the cause of the minor patient's akathisia over that of the Neurologist and other physicians who actually examined and diagnosed the minor patient in the Emergency Room in concluding that "there was a low risk of harm to Patient DD." Compare Proposal for Decision at 18, with Staff's Exhibit 6 at 1-8. Tardive dyskinesia is "potentially irreversible," 'it is not possible to predict which patients are likely to develop the syndrome," and "[t]here is no known treatment." Staff's Exhibit 11, Section 5.4. Consequently, the risk of harm to the patient was serious in that it could become permanent. Additionally, the risk of harm to the patient was known or should have been known to the Respondent. Accordingly, under Section 301.452(b)(13) of the Board's Disciplinary Matrix, Respondent's conduct could even be considered a Third Tier Offense. Thus, this conclusion of law's second and third sentences should be modified accordingly: In this case, the Board may consider as aggravating factors the patient's vulnerability and the actual harm suffered by the patient and his family. The Board may consider as a mitigating factor Respondent's lack of previous disciplinary action by the Board.

In conclusion, given these proposed modifications, Staff would urge the administrative law judge to reconsider the sanction previously recommended. While the administrative law judge's recommended sanction is not set out as a finding of fact or conclusion of law, Staff is, in addition to the reasons stated above, providing an additional legal basis for requesting a modification to the ALJs' recommended sanction in accordance with Texas Gov't Code § 2001.058(e)(1). Pursuant Section 301.4531 of the Texas Occupations Code, the Board has adopted a schedule of sanctions

or disciplinary matrix, located at 22 Tex. Admin. Code § 213.33(b). The preamble of the Board's

disciplinary matrix, like the statute that mandates the Board's adoption of a disciplinary matrix,

requires the Board to consider "whether the person is being disciplined for multiple violations of

either this chapter or a rule or order adopted under this chapter." Tex. Occ. Code §

301.4531(b)(1)(A). Section 301.4531 of the Texas Occupations Code and 22 Tex. Admin. Code §

213.33(b) further mandate that the Board consider "taking more severe disciplinary action," in the

case of a person who is being disciplined for multiple violations, than "would be taken for a single

violation." Tex. Occ. Code § 301.4531(c)(1). The administrative law judge incorrectly treated each

violation of the Texas Occupations Code as a separate "incident" before arriving at a sanction,

rather than considering the violations in total, as the Board's Disciplinary Matrix directs where

multiple violations have been established. Proposal for Decision at 17-18; Tex. Occ. Code §

301.4531(c)(1).

For these reasons, Staff Prays that the ALJ delete Finding of Fact No. 22 and amend

Finding of Fact No. 23, Conclusion of Law No. 8 and the recommended sanction.

Respectfully submitted,

TEXAS BOARD OF NURSING

Helen Kelley -

Helen Kelley, Assistant General Counsel

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JAMI MAYORGA DICKSON, SOAH Docket No. 507-20-0395

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing Staff's Exceptions to Proposal for

Decision was provided by electronic filing and email on this, the 27th day of March 2020, to:

State Office of Administrative Hearings

Filed electronically

And

Marc M. Meyer, Attorney Law Office of Marc Meyer, PLLC 525 Woodland Square Blvd., STE 250 Conroe, TX 77384 Via email

Helen Kelley -----

Helen Kelley, Assistant General Counsel

FILED 507-20-0395 4/13/2020 3:36 PM STATE OFFICE OF ADMINISTRATIVE HEARINGS Jessie Harbin, CLERK

DOCKET NO. 507-20-0395

ACCEPTED 507-20-0395 04/13/2020 3:59 PM STATE OFFICE OF ADMINISTRATIVE HEARINGS Jessie Harbin, CLERK

IN THE MATTER OF	§	
PERMANENT CERTIFICATE	§	BEFORE THE TEXAS STATE
Number RN 642611 & AP119548	§	
ISSUED TO JAMI MAYORGA DICKSON,	§	OFFICE OF ADMINISTRATIVE HEARINGS
RESPONDENT	§.	•

RESPONDENT'S RESPONSE TO STAFF'S EXCEPTIONS TO THE PROPOSAL FOR DECISION

TO THE HONORABLE JUDGE OF SAID COURT:

NOW COMES Respondent, Jami Mayorga Dickson, and files this response to Staff of the Texas Board of Nursing's ("Staff") exceptions to the Proposal for Decision:

Finding of Fact No. Twenty-two (22):

In this exception, Staff asserts that Finding of Fact No. Twenty-Two (22) is incorrect in asserting that the "half-life" of the drug is 24 hours. Instead, Staff asserts that the proper term is "mean terminal half-life", but that the Finding of Fact should be deleted as being "pseudo-science". Respondent does not disagree with Staff's assertion that the label "half-life" is incorrect, as it appears the literature does state the correct term is "mean terminal half-life". However, Respondent does not agree with Staff's contention that this finding of fact is "best termed a finding of pseudo-science". The meaning of the term, as laid out by Staff's own exceptions, is quite clear: "the terminal half-life is the time required for plasma/blood concentration to decrease by 50% after pseudo-equilibrium has been reached." Therefore, Respondent asserts that Finding of Fact No. Twenty-Two (22) should read as follows: "Saphris has a mean terminal half-life of approximately 24 hours, according to FDA studies based on adults and children 10 years and older."

Finding of Fact No. Twenty-three (23):

In this exception, Staff asserts that Finding of Fact No. Twenty-Two (22) is incorrect because it states that Saphris was unlikely the cause of the akathisia Patient DD exhibited in the emergency room. Staff asserts this because of the medical records from the ER physician at

¹ Staff's Exhibit 11, at section 12.3.

² Staff's Exceptions, at 2, citing Tountain, P.L., Bousquet-Melou, A., Plasma terminal half-life, J. Vet. Pharmacol. Therap. 2004: 27, 427 – 39.

Children's Medical Center Plano. However, the records indicate that the information that the ER physician was not properly informed of when Patient DD's mother had been told to discontinue the medication. Specifically, the records state that the mother advised the ER physician that Patient DD stopped taking Saphris three days prior to the ER visit, or on February 15th. However, Respondent testified, and documented, that she advised the mother of Patient DD to discontinue the medication on February 13th. In addition, in the interim, Patient DD was seen the day before for potential strep throat and prescribed Erythromycin, which also has a similar side effect, which was admitted as possible by Dr. Jolene Zych, Staff's nursing practice witness.⁵

Respondent also notes that the Neurologist who was consulted by the ER physician, Dr. Reila, never assessed the patient, and "Recommended not to do anything for (sic), and to discharge home," Further, neither the ER physician, nor the neurologist were called as witnesses or subjected to cross-examination on their records and the discrepancy in Patient DD mother's account of when the medication was stopped, nor was there any expert testimony from Staff as to the likelihood of the Saphris causing Patient DD's akathisia. In fact, Staff notes in their Exceptions that there was no expert testimony in pharmacology presented in the hearing, and more specifically there was no testimony from a pharmacology expert that would have tied Saphris specifically to Patient DD's symptoms. The only expert witness, Dr. Jolene Zych, was only deemed qualified to give expert testimony on the statutes and Board Rules that apply to APRN's, but it was specifically noted that Dr. Zych had no training or certifications in psychiatric nursing, and had no expertise in psychiatric prescribing practices. Therefore, Respondent asserts that Staff did not show by a preponderance of the evidence that Saphris was the cause the Patient DD's symptoms, and Finding of Fact No. Twenty-three should remain unchanged.

³ Staff's Exhibit 6, at 3. The ER visit occurred on February 18th, meaning that 3 days prior would be February 15th. Id.

⁴ Staff's Exhibit 5, at 56.

⁵ Proposal for Decision (PFD), at 8.

⁶ Staff's Exhibit 6. at 7.

⁷ Staff's Exceptions, at 3.

⁸ PFD, at 6.

Conclusion of Law No Eight (8):

In this exception, Staff except to Conclusion of Law No. Eight (8) because Staff asserts that they have shown that there was actual harm to patient DD.⁹ It appear that Staff is asserting this because Patient DD went to the ER on February 18th, but Staff leaves the assumption that it bases this exception on silent, namely that Staff's believes it has proved that Saphris caused the symptoms that sent Patient DD to the ER, as they have asserted in their exceptions to Finding of Fact No. Twenty-Three (23). However, as Respondent notes supra, Staff does not show by a preponderance of the evidence that Saphris was the cause of Patient DD's symptoms, and thus there is no reason to change Conclusion of Law No. Eight (8) as Staff has not show there was actual harm as a result of any of Respondent's actions.

Finally, Staff argues that because of the changes they have requested, the recommended sanction should change as well. However, Respondent notes that while she does not materially dispute the exception to Finding of Fact No. Twenty-Two (22), this is not a change that supports a change in either Finding of Fact No. Twenty-Three (23) or Conclusion of Law No. Eight (8). Thus, Respondent asserts that the recommended sanction in this matter is appropriate for the violations found by the Administrative Law Judge, and urges the sanctions be affirmed.

Respectfully submitted,

By: Marc M Meyer

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Attorney for Respondent Jami Mayorga Dickson

⁹ Staff's Exceptions, at 4.

CERTIFICATE OF SERVICE

This is to certify that on the 13th day of April, 2020, a true and correct copy of the above and foregoing document was served on the following individual(s) at the location(s) and in the manner indicated below:

Docketing Division
State Office of Administrative Hearings
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Helen Kelley, Assistant General Counsel Texas Board of Nursing 333 Guadalupe, Suite 3-460 Austin, TX 78701 VIA electronic filing manager

Marc M Meyer

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State Office of Administrative Hearings

ACCEPTED 507-20-0395 5/4/2020 9:54 AM STATE OFFICE OF ADMINISTRATIVE HEARINGS Donnie Roland, CLERK



FILED 507-20-0395 5/4/2020 8:51 AM STATE OFFICE OF ADMINISTRATIVE HEARING Donnie Roland, CLERK

Kristofer S. Monson Chief Administrative Law Judge

May 4, 2020

Katherine A. Thomas, M.N., R.N. Executive Director Texas Board of Nursing 333 Guadalupe, Tower III, Suite 460 Austin, TX 78701

VIA E-FILE TEXAS

RE: Docket No. 507-20-0395; Texas Board of Nursing v Jami Mayorga Dickson

Dear Ms. Thomas:

On March 13, 2020, I issued a Proposal for Decision (PFD) in this case. Staff filed timely exceptions in accordance with 1 Tex. Admin. Code § 155.507, and Respondent filed a response to Staff's exceptions but did not file exceptions.

Staff excepts to Finding of Fact No. 22, which states as follows:

Saphris has a half-life of approximately 24 hours, according to FDA studies based on adults and children 10 years and older.

Staff contends that the statement is false because the evidence actually states that "the mean terminal half-life is approximately 24 hours." Staff explains that the phrase "terminal half-life" is the time required for plasma/blood concentration to decrease by 50%; not the time for the amount of the drug to fall by one half. In addition, Staff asserts that the finding should be deleted in its entirety because the pharmokinetics of Saphris are based on children ten years and older. Respondent does not disagree that the evidence states "mean terminal half-life" and asserts that the finding should be modified to reflect that.

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I agree that the evidence reflects the phrase "mean terminal half-life" and therefore recommend that Finding of Fact No. 22 should be modified as follows:

Saphris has a <u>mean terminal</u> half-life of approximately 24 hours, according to FDA studies based on adults and children 10 years and older.

I believe Finding of Fact No. 22 is adequately supported by the evidence in this case, as detailed in the PFD.

Staff also excepts to Finding of Fact No. 23, which states as follows:

It is unlikely that the Saphris was the cause of akathisia by the time Patient DD presented at the ER.

Staff asserts that the evidence contradicts this finding and that the finding should be modified to state the opposite—that Saphris was determined to be the cause of Patient DD's akathisia. However, as discussed in the PFD, Staff did not show by a preponderance of the evidence that Saphris was the cause the Patient DD's symptoms, and this finding should not be changed.

In addition, Staff disagrees that there is a lack of evidence of actual harm to Patient DD, and excepts to Conclusion of Law No. 8, which states in part:

... The Board may also consider as mitigating factors the lack of evidence of actual harm to Patient DD . . .

I believe this Conclusion of Law is adequately supported by the findings in this case, as detailed in the evidence and analysis sections of the PFD.

Lastly, Staff requests I amend my sanction recommendation based on the changes requested to Findings of Fact Nos. 22 and 23 and Conclusion of Law No. 8, as well as the fact that Respondent is being disciplined for multiple violations. The Board's disciplinary matrix states:

If multiple violations of the Nursing Practice Act (NPA) and/or Board rules are present in a single case, the most severe sanction recommended by the Matrix for any one of the individual offenses should be considered by the Board and SOAH.

As discussed in the PFD, the most severe sanction recommended in the disciplinary matrix for each of the offenses was a \$250 fine and/or remedial education. Therefore, the sanction I recommended—remedial education and a fine of \$500—is in accordance with the disciplinary matrix.

¹ 22 Tex. Admin. Code § 213.33(b).

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Accordingly, other than the amendment to Finding of Fact No. 22 discussed above, the ALJ recommends no changes to the PFD based on Staff's exceptions; and the PFD is ready for consideration by the Board.

Sincerely,

Meitra Farhadi

Administrative Law Judge

MF/Ic

xc: Helen Kelly, Assistant General Counsel, Texas Board of Nursing, 333 Guadalupe, Tower III, Ste. 460, Austin, TX 78701 - <u>VIA E-FILE TEXAS</u>
 Marc M. Meyer, Attorney at Law, 525 Woodland Square Blvd., Suite 250, Conroe, TX 77384-2212 - <u>VIA E-FILE TEXAS</u>