| STATE C | DF NEBRASKA | FILED |
|---|-----------------------|---------------------|
| DEPARTMENT OF HEA | LTH AND HUMAN SERVICE | |
| STATE OF NEBRASKA ex rel. DOUGLAS J. PETERSON, Attorney General, |)) 17061 | 7 MD |
| Plaintiff, |)) ORDE | DHHS Hearing Office |
| VS. |) AGREED SE | TTLEMENT |
| HAYES, PAUL, | į | |
| Defendant. |) | |

A proposed Agreed Settlement was filed with the Department on May 2, 2017.

ORDER

- 1. The Agreed Settlement is adopted, attached hereto and incorporated by reference.
- 2. The facts as set out in the Petition are taken as true and adopted herein.
- 3. The parties shall comply with all of the terms of the Agreed Settlement.

| DATED this | U | day of | MAT | , 2017 |
|------------|---|--------|-----|--------|
| | | | | |

Thomas L. Williams, MD

Chief Medical Officer

Director, Division of Public Health

Department of Health and Human Services

Civil penalty, if imposed, should be mailed to: DHHS, Division of Public Health, Licensure Unit, ATTN: Diane Pearson, P.O. Box 94986, Lincoln, NE 68509.

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing ORDER ON AGREED SETTLEMENT was sent on the below date certified United States Mail, postage prepaid, return receipt requested, and/or electronically to the following:

PAUL HAYES
13911 GOLD CIR STE 310
OMAHA NE 68144
MINDY LESTER
ASSISTANT ATTORNEY GENERAL
AGO.HEALTH@NEBRASKA.GOV

7016 2140 0000 8087 3625

Date: <u>Mary 11, 2017</u>

Buch Bourdson DHHS Hearing Office

P.O. Box 95026

Lincoln, NE 68509-5026 P. (402) 471-4731 F. (402) 742-2374

dhhs.hearingoffice@nebraska.gov

STATE OF NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF PUBLIC HEALTH

| STATE OF NEBRASKA ex rel. DOUGLAS J. PETERSON, Attorney General, |)) } |
|--|-----------------------|
| Plaintiff, |)) AGREED SETTLEMENT |
| v. | į |
| PAUL L. HAYES, M.D., |) } |
| Defendant. |) |

The Plaintiff and Defendant, Paul L. Hayes, M.D., in consideration of the mutual covenants and agreements contained herein, agree as follows:

- 1. The Defendant, Paul L. Hayes, M.D., was issued a license (#19535) to practice as a physician by the Nebraska Department of Health and Human Services Division of Public Health ("Department").
- 2. The Defendant acknowledges receipt of a copy of the Petition for Disciplinary Action and waives the need for further services of the Petition upon him.
- 3. Before disciplinary measures may be taken against the Defendant's license, the Defendant is entitled to a hearing as provided by law. The Defendant waives the right to a hearing. The Defendant waives any right to judicial review of an order by the Department's Chief Medical Officer which approves the terms of this Agreed Settlement.
- 4. No coercion, threats, or promises, other than hose stated herein, were made to the Defendant to induce him to enter into this Agreed Settlement.

5. The Defendant acknowledges that he has read the Petition for Disciplinary Action filed by the Nebraska Attorney General's Office. The Defendant neither admits nor denies the allegations of the Petition for Disciplinary Action.

6. The Plaintiff and Defendant consent to the Chief Medical Officer entering a final disciplinary order which finds the allegations of the Petition for Disciplinary Action are true and orders the Defendant's license to practice medicine and surgery be limited in the following way:

a. The Defendant shall not provide treatment for female infertility.

7. The Attorney General has given notice of this Agreed Settlement to the Board of Medicine and Surgery and has received their input in accordance with Neb. Rev. Stat. § 38-190 (Reissue 2016).

8. If this Agreed Settlement is not approved by the Chief Medical Officer, this Agreed Settlement shall become null and void and will not be admissible for any purpose at any hearing that may be held on this matter.

AGREED TO:

BY:

Paul L. Hayes, M.D.

Defendant

State of Nebraska

) ss.

County of \/

Acknowledged before me by Paul L. Hayes, M.D., on this

day of

, 2017.

GENERAL NOTARY - State of Nebraska
MARY A JONES

Notary Public

may 7,2018

THE STATE OF NEBRASKA, ex rel. DOUGLAS J. PETERSON,

Attorney General, Plaintiff,

BY:

DOUGLAS J. PETERSON, #18146

Attorney General

BY:

Mindy/L. Lester #24421 Assistant Attorney General 2115 State Capitol

2115 State Capitol Lincoln, NE 68509 (402) 471-1815

Attorneys for the Plaintiff

44-351.1a-6



STATE OF NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF PUBLIC HEALTH

| STATE OF NEBRASKA ex rel. DOUGLAS J. PETERSON, Attorney General, |)) |
|--|-----------------------|
| Plaintiff, |) PETITION FOR |
| PAUL L. HAYES, M.D., |) DISCIPLINARY ACTION |
| PAUL L. HATES, WI.D., | , |
| Defendant. | j |

ALLEGATIONS COMMON TO ALL CAUSES OF ACTION

The Plaintiff alleges as follows:

- 1. Jurisdiction is based on Neb. Rev. Stat. §§ 38-176 (Reissue 2008) and 38-186 (2014 Cum. Supp.).
- 2. At all times relevant herein, the Defendant, Paul Lawrence Hayes, M.D. has been the holder of a license (#19535) to practice as a physician issued by the Department of Health and Human Services Division of Public Health ("Department").
- 3. The Department is the agency in the State of Nebraska authorized to enforce the provisions of the Uniform Credentialing Act regulating the practice of medicine and surgery.
- 4. The Nebraska Board of Medicine and Surgery considered the investigation of this matter and made a disciplinary recommendation to the Attorney General, which recommendation has been considered. Such matters are privileged pursuant to Neb. Rev. Stat. §§ 38-1,105 and 38-1,106 (Reissue 2008).

- 5. At all times relevant herein, the Defendant was employed at T.W.P., in Lincoln, Nebraska. The Defendant treated patients for gynecological issues including, but not limited to, infertility and pregnancy.
- 6. The Defendant provided care for Patient 1 from 2011 to 2013. In February, 2012. The Defendant provided infertility treatment to Patient 1, including injectable gonadotropins. Defendant failed to document in Patient 1's medical record any consultation or discussion with Patient 1 regarding the risk of pregnancy with multiple fetuses with the use of gonadotropins for ovulation induction.
 - a. In February 2016, C.D., MD, FACOG, a Board Certified Physician of Reproductive Endocrinology, reviewed the Defendant's medical and prescribing records for Patient 1, from 2011 through 2013, and opined the Defendant failed to document any discussion with the Patient of the risk of conception of multiple fetuses with Patient 1. Dr. C.D. concluded the Defendant failed to meet the standard of care in his treatment of Patient 1 in this manner.
- 7. The Defendant provided care for Patient 2 at various times in 2011 and 2012 for infertility. The Defendant performed surgery on Patient 2 in December, 2011, and again in May, 2012, related to infertility concerns.
 - a. In February 2016, C.D., MD, FACOG, a Board Certified Physician of Reproductive Endocrinology, reviewed the Defendant's medical records for Patient 2 and determined the Defendant failed to meet the standard of care for the treatment of Patient 2's infertility. C.D., M.D., determined

the Defendant failed to complete a proper infertility examination and medical work-up prior to subjecting Patient 2 to each surgery.

FIRST CAUSE OF ACTION

- 8. Paragraphs 1 through 7 are incorporated herein by this reference.
- 9. Neb. Rev. Stat. § 38-178(23) (2015 Supp.) provides that a professional license may be disciplined for unprofessional conduct as defined in section 38-179.
- 10. Neb. Rev. Stat. § 38-179 (2014 Cum. Supp.) defines unprofessional conduct as any departure from or failure to conform to the standards of acceptable and prevailing practice of a profession or the ethics of the profession, regardless of whether a person, consumer, or entity is injured, or conduct that is likely to deceive or defraud the public or is detrimental to the public interest, including but not limited to...(10) failure to keep and maintain adequate records of treatment or service.
- departure from or failure to conform to the standards of acceptable and prevailing practice of medicine and surgery or the ethics of the profession, regardless of whether a person, patient, or entity is injured, but does not include a single act of ordinary negligence. Unprofessional conduct also means conduct that is likely to deceive or defraud the public or is detrimental to the public interest. Unprofessional conduct includes but is not limited to... (10) failure to keep and maintain adequate records of treatment of service. Adequate records means legible medical records containing, at a minimum, sufficient information to identify the patient, support the diagnosis, justify the treatment, accurately document the results, indicate advice and cautionary warnings provided to the patient and provide sufficient information for another practitioner to assume continuity of the patient's care at

any point in the course of treatment, and, when investigative or unproven therapies are utilized, the records must include written informed patient consent.

12. The Defendant's failure to adequately document in Patient 1's record that he discussed the risks of conception of multiple fetuses constitutes unprofessional conduct and is grounds for discipline.

SECOND CAUSE OF ACTION

- 13. Paragraphs 1 through 12 are incorporated herein by this reference.
- 14. Neb. Rev. Stat. § 38-178(23) (2015 Supp.) provides that a professional license may be disciplined for unprofessional conduct as defined in section 38-179.
- 15. Neb. Rev. Stat. § 38-179 (Reissue 2008) defines unprofessional conduct as any departure from or failure to conform to the standards of acceptable and prevailing practice of a profession or the ethics of the profession, regardless of whether a person, consumer, or entity is injured, or conduct that is likely to deceive or defraud the public or is detrimental to the public interest....(15) such other acts as may be defined in rules and regulations.
- 16. 172 NAC 88-010.02 (20) (2013) defines unprofessional conduct as providing treatment or consultation recommendations, including issuing a prescription, via electronic or other means, unless the physician has obtained a history and physical evaluation of the patient adequate to establish diagnosis and identify underlying conditions and/or contraindications to the treatment recommended/provided and that arrangements exist to insure availability of the physician or physician coverage for follow-up patient care.

- 17. 172 NAC 88-010.02 (32) (2013) defines unprofessional conduct as conduct tor practice outside the normal standard of care in the State of Nebraska which is or might be harmful or dangerous to the health of the patient or the public, not to include a single act of ordinary negligence.
- 18. The Defendant's conduct above, in failing to complete a proper infertility examination and medical work-up prior to performing surgery on Patient 2 on two separate occasions is grounds for discipline.

THIRD CAUSE OF ACTION

- 19. Paragraphs 1 through 18 are incorporated herein by this reference.
- 20. Neb. Rev. Stat. § 38-178(6) (2015 Supp.) provides that a professional license may be disciplined for the practice of the profession ... (d) in a pattern of incompetent or negligent conduct.
- 21. The Defendant's failure to complete a proper infertility examination and medical work-up prior to each of Patient 2's surgeries, in 2011 and in 2012, constitutes the practice of the profession in a pattern of incompetent or negligent conduct and is grounds for discipline.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff prays that the Chief Medical Officer set this matter for hearing, order appropriate disciplinary action pursuant to Neb. Rev. Stat. § 38-196 (Reissue 2008) and tax the costs of this action to the Defendant.

STATE OF NEBRASKA ex rel. DOUGLAS J. PETERSON, Attorney General, Plaintiff,

By: DOUGLAS J. PETERSON,

#18146

Attorney General

By:

Mindy L. Lester, #24421 Assistant Attorney General

2115 State Capitol Lincoln, NE 68509 (402) 471-1815

Attorneys for the Plaintiff.

44-351.1-6

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE STATE OF NEBRASKA

CREDENTIALING DIVISION

JAN 0 8 2867

| IN THE MATTER OF |) RECEIVED |
|-------------------|-----------------------------|
| THE LICENSE OF |)) ASSURANCE OF COMPLIANCE |
| PAUL HAYES, M.D., |) ASSURANCE OF COMPLIANCE |

Paul Hayes, M.D. ("Dr. Hayes") and the Attorney General's Office for the State of Nebraska enter into this Assurance of Compliance by agreeing as follows:

- 1. Dr. Hayes is the holder of a license to practice medicine (#19535) which was issued by the Nebraska Department of Health and Human Services Regulation and Licensure ("Department").
- 2. It is alleged that Dr. Hayes prescribed domperidone for a patient and use of said drug is not approved by the U. S. Food and Drug Administration unless the physician has acquired an Investigational New Drug ("IND") Application.
- 3. It is alleged that Dr.Hayes did not have an IND number and was therefore prescribing and allowing his nurse practitioner to prescribe an illegal drug in the U. S.
- 4. Dr. Hayes agrees to obtain an IND number from the U. S. Food and Drug Administration in the future if he wishes to prescribe domperidone to his patients.
- 5. Neb. Rev. Stat. § 71-147(10) provides that a credential to practice as a medical doctor may be disciplined for unprofessional conduct.
- 6. Neb. Rev. Stat. Section 71-148 defines unprofessional conduct as any departure from or failure to conform to the standards of acceptable and prevailing practice of a profession ... regardless of whether a person, patient, or entity is injured.

- 7. Neb. Rev. Stat. Section 71-148(22) defines unprofessional conduct as such other acts as may be defined in rules and regulations adopted and promulgated by the board of examiners in the profession of the applicant, licensee, certificate holder, or registrant with the approval of the department.
- 8. Title 172 NAC 88-013.15 Regulations Governing the Practice of Medicine defines unprofessional conduct as the use of any therapy, drug or device in a manner inconsistent with the Federal Food, Drug and Cosmetic Act.
- 9. Unprofessional conduct is defined by Neb. Rev. Stat. Section 71-148(17) as violating an Assurance of Compliance.
- 10. Any violation of this Assurance of Compliance by Dr. Hayes shall constitute unprofessional conduct pursuant to Neb. Rev. Stat. Section 71-147(10) and 71-148(17) and will be grounds for discipline.
- 11. This Assurance of Compliance is not a disciplinary action against Dr. Hayes' license to practice medicine.
- 12. This Assurance of Compliance is entered into pursuant to Neb. Rev. Stat. § 71- 171.02 and shall become effective ten (10) days from the date it is signed by the Attorney General's Office.

Dated this 3rd day of January, 2007.

Dr. Paul L. Hayes, M.D.

| State of Nebraska |)) ss. | | | |
|--|-------------------|--|---------------------------------------|------|
| County of <u>Lancaster</u> |) ss. _) | | | |
| The above Assurance of | f Compliance | was acknowledged | before me by Dr. | Paul |
| Hayes, M.D., on this3_ | _day of _ <i></i> | unuary | , 2007. | |
| GENERAL NOTARY-State of Nebraska inta Tigeris Watson My Comm. Exp. Dec. 22, 2007 | Nota | uter Tuged ory Public Commission Expires | | |
| | | | | |
| Dated this <u>54k</u> day | of far | <u>way</u> , 200 | 7. | |
| | / BY: | JON BRUNING, Attorney Genera | · · · · · · · · · · · · · · · · · · · | |
| | BY: | Terri J. Nutzman Assistant Attorne | | |
| | | 2115 State Capi Lincoln, NE 6850 Tel: (402) 471-20 Fay: (402) 471-4 |)9-8920 682 | |

34-2410-14