HEARING CONDUCTED BY THE TEXAS STATE OFFICE OF ADMINISTRATIVE HEARINGS SOAH DOCKET NO. 503-16- 5806 .MD TEXAS MEDICAL LICENSE NO. N-4270

IN THE MATTER OF THE

BEFORE THE

COMPLAINT AGAINST

GEORGE BACKARDJIEV, M.D.

TEXAS MEDICAL BOARD

COMPLAINT

TO THE HONORABLE TEXAS MEDICAL BOARD AND THE HONORABLE ADMINISTRATIVE LAW JUDGE TO BE ASSIGNED:

The Staff of the Texas Medical Board (the Board) files this Complaint against GEORGE BACKARDJIEV, M.D. (Respondent), for alleged violations of the Medical Practice Act (the Act), Title 3, Subtitle B, Texas Occupations Code, and would show the following:

I. SUMMARY OF FACTUAL ALLEGATIONS

Respondent violated the standard of care in the treatment of one obstetrics patient and her newborn. Specifically, Respondent's inappropriate use of forceps during delivery caused a depressed skull fracture, brain and spinal cord damage in the infant. The newborn died as a result of these injuries.

Respondent also violated the standard of care in performing deliveries for five additional obstetrics patients, resulting in birth injuries to the newborns. These cases lacked indication for operative delivery and the medical records for each case were inadequate.

Finally. Respondent's hospital privileges were temporarily suspended during a peer review investigation into the first of the aforementioned cases. Respondent permanently resigned his privileges in lieu of further disciplinary action.

II. LEGAL AUTHORITY AND JURISDICTION

1. Respondent is a Texas physician and holds Texas Medical License No. N-4270, which was originally issued by the Board on November 6, 2009. Respondent's license was in full force and effect at all times material and relevant to this Complaint.

- 2. Respondent received notice of one or more Informal Settlement Conferences (ISC). The Board complied with all procedural rules, including but not limited to, Board Rules 182 and 187, as applicable.
 - 3. No agreement to settle this matter has been reached by the parties.
 - 4. All jurisdictional requirements have been satisfied.
- 5. The filing of this Complaint and the relief requested are necessary to protect the health and public interest of the citizens of the State of Texas, as provided in Section 151.003 of the Act.

III. APPLICABLE STATUTES AND STATUTORY VIOLATIONS

The following Statutes, Rules, and Agency Policy are applicable to the procedures for conduct of the hearing this matter:

A. General Statutes and Rules:

- 1. Section 164.007(a) of the Act requires that the Board adopt procedures governing formal disposition of a contested case before the State Office of Administrative Hearings.
- 2. 22 TEX. ADMIN. CODE, CH.187 sets forth the procedures adopted by the Board under the requirement of Section 164.007(a) of the Act.
- 3. 22 Tex. Admin. Code, Ch. 190 sets forth aggravating factors that warrant more severe or restrictive action by the Board.
- 4. 1 TEX. ADMIN. CODE, CH. 155 sets forth the rules of procedure adopted by SOAII for contested case proceeding.
- 5. 1 TEX. ADMIN. CODE, CH. 155.507, requires the issuance of a Proposal for Decision ("PFD") containing Findings of Fact and Conclusions of Law.
- 6. Section 164.007(a) of the Act, Board Rule 187 et. seq. and Board Rule 190 et. seq., provide the Board with the sole and exclusive authority to determine the charges on the merits, to impose sanctions for violation of the Act or a Board rule, and to issue a Final Order.

B. Specific Violations Cited:

Respondent has violated one or more of the following provisions of the Act:

1. Section 164.051(a)(3) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's violation of a Board rule, specifically Board Rule 165.1, which requires the maintenance of adequate medical records.

- 2. Section 164.051(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's failure to practice medicine in an acceptable professional manner consistent with public health and welfare as defined by Board Rules: violation of a Board Rule, specifically Board Rules 190.8(1)(A), requiring a licensee to treat a patient according to the generally accepted standard of care; 190.8(1)(B), negligence in performing medical services; 190.8(1)(C), requiring a licensee to use proper diligence in one's professional practice; 190.8(1)(D), requiring a licensee to safeguard against potential complications; 190.8(1)(G), failure to disclose reasonably foreseeable side effects of a procedure or treatment; 190.(1)(H), requiring a licensee to disclose reasonable alternative treatments to a proposed procedure or treatment; and 190.8(1)(I), which requires a licensee to obtain informed consent from the patient or other person authorized by law to consent to treatment on the patient's behalf before performing tests, treatments, or procedures.
- 3. Section 164.051(a)(7) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent being removed, suspended, or subject to disciplinary action taken by the person's peers in a local, regional, state, or national professional medical association or society, or is disciplined by a licensed hospital or medical staff of a hospital, including removal, suspension, limitation of hospital privileges, or other disciplinary action, as defined by Board Rule 190.8(4), disciplinary actions by peer groups.
- 4. Section 164.052(a)(5) of the Act authorizes the Board to take disciplinary action against Respondent based on unprofessional or dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public, and further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient.
- 5. Section 164.053(a)(5) of the Act authorizes the Board to take disciplinary action against Respondent for prescribing or administering a drug or treatment that is non-therapeutic.

IV. FACTUAL ALLEGATIONS

Based on information and belief, Board Staff alleges:

A. <u>Standard of Care</u>: Respondent violated the acceptable standard of care with regard to the care and treatment of six obstetric patients and their infants. Respondent's repeated failure to meet the standard of care demonstrates a failure to recognize the presence and/or implications of fetal distress and/or to react appropriately in light of arising complications. The cases at issue are set out in detail below.

- Patients 1a and 1b¹: Respondent failed to the meet the standard of care in the labor and delivery of Patients 1a and 1b, respectively, and such failure resulted in harm to both patients, and resulting in Patient 1b's death.
 - a. On or about December 26, 2013, Respondent medicinally induced labor of Patient 1a.
 - b. Respondent improperly continued to increase induction medication despite arising and worsening complications, including abnormal and ominous fetal heart rate (FHR) tracing, fetal tachycardia, evidence of intra-amniotic infection, and labor dystocia (e.g. improper fetal placement, size, or position).
 - c. Respondent twice declined to initiate cesarean delivery and failed to offer the option to Patient 1a when increased and recurring complications indicated the procedure was appropriate.
 - d. Respondent improperly used forceps in the delivery of Patient 1b when not indicated.
 - e. Respondent incorrectly and repeatedly applied forceps, of a kind that were not appropriate for the attempted procedure, and despite multiple slips of the instrument from the infant's head.
 - f. Respondent's improper use of forceps caused significant injury to Patient 1b, including a depressed skull fracture and significant damage to the brain and spinal cord. These injuries contributed to the infant's death three days later when life support was removed.
 - g. Respondent failed to counsel Patient 1a as to delivery options and associated risks. Further, Respondent performed an operative vaginal delivery without obtaining proper informed consent.
- 2) Patients 2a and 2b: Respondent failed to the meet the standard of care in the labor and delivery of Patients 2a and 2b, respectively, and such failure resulted in harm to both patients.
 - a. On or about September 25, 2013, Patient 2a was admitted to the hospital under Respondent's care for presumed early labor at 38 6/7 weeks.

¹ Patients are referred to numerically and as "a" and "b" to indicate mother and fetus/infant, respectively. A list identifying each patient will be submitted confidentially and under seal in a separate filing.

- b. Despite exhibiting symptoms of natural labor, Patient 2b was treated with medications to induce labor.
- c. Patient 2b experienced several episodes of prolonged FHR decelerations, from which the fetus fully recovered.
- d. Respondent improperly used forceps in the delivery of Patient 2b.
- c. Respondent's improper use of forceps caused Patient 2a to suffer a third degree and bilateral labial lacerations.
- f. Respondent's improper use of forceps caused Patient 2b to suffer a 4 cm laceration and bruising to the left cheek.
- g. Respondent failed to offer Patient 2a a caesarian section when indicated.
- h. Respondent failed to counsel Patient 2a as to delivery options and associated risks. Further, Respondent performed an operative vaginal delivery without obtaining proper informed consent.
- 3) Patients 3a and 3b: Respondent failed to meet the standard of care in the labor and delivery of Patients 3a and 3b, respectively, and such failure resulted in harm to both patients.
 - a. On or about April 2, 2013, Respondent ordered, increased and repeatedly administered labor inducing medications to Patient 3a, who had experienced a complicated prenatal course.
 - b. Respondent improperly used forceps to deliver Patient 3b when not indicated.
 - c. Respondent's improper use of forceps resulted in bilateral labial lacerations and forceps laceration to Patient 3a.
 - d. Respondent's improper use of forceps resulted in marks and residual bruising to Patient 3b.
 - e. Respondent failed to counsel Patient 3a as to delivery options and associated risks. Further, Respondent performed an operative vaginal delivery without obtaining proper informed consent.
- 4) Patients 4a and 4b: Respondent failed to meet the standard of care in the labor and delivery of Patients 4a and 4b, respectively, and such failure resulted in harm to Patient 4b.

- a. Respondent improperly performed instrumental delivery when there was no maternal or fetal indication for the procedure.
- b. Respondent improperly used forceps to deliver Patient 4b, when not indicated.
- c. Respondent improperly utilized forceps in the delivery of Patient 4b, which caused deep abrasions, including an open laceration to the left ear above the neck and hemorrhage of blood between the skull and periosteum to Patient 4b.
- d. Respondent's improper use of forceps also caused left side facial paralysis and left ear bleeding in Patient 4b.
- e. Respondent failed to offer Patient 4a a cesarean delivery as was indicated, in part, by an eight minute prolonged FHR deceleration.
- f. Respondent performed an operative vaginal delivery when not indicated.
- g. Respondent failed to counsel Patient 4a as to delivery options and associated risks. Further, Respondent performed an operative vaginal delivery without obtaining proper informed consent.
- 5) Patients 5a and 5b: Respondent failed to counsel Patient 5a as to delivery options and associated risks. Further, Respondent performed an operative vaginal delivery without obtaining proper informed consent.
- 6) Patients 6a and 6b: Respondent failed to meet the standard of care in the labor and delivery of Patients 6a and 6b, respectively, and such failure resulted in harm to Patient 6b.
 - a. On or about September 6, 2011, Respondent improperly performed an elective induction of labor on Patient 6a, who was 38 weeks pregnant, when induction of labor is not indicated as an elective course of treatment at less than 39 weeks.
 - b. Respondent improperly used forceps in the delivery of Patient 6b; specifically, by prematurely applying the tool at the first indication of a brief period of decelerated FHR and absent sufficient indication.
 - c. Respondent's use of forceps caused a deep laceration behind Patient 6b's left ear that required suturing.

d. Respondent failed to counsel Patient 6a as to delivery options and associated risks. Further, Respondent performed an operative vaginal delivery without obtaining proper informed consent.

The foregoing actions and/or omissions constitute violations as follows:

Section 164.051(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent for failing to practice medicine in an acceptable professional manner consistent with public health and welfare as defined by the following Board Rules: 190.8(1)(A), failure to treat a patient according to the generally accepted standard of care; 190.8(1)(B), negligence in performing medical services; 190.8(1)(C), failure to use proper diligence in one's professional practice; 190.8(1)(D), failure to safeguard against potential complications; 190.8(1)(G), failure to disclose reasonably foreseeable side effects of a procedure or treatment; 190.8(1)(H), failure to disclose reasonable alternative treatments to a proposed procedure or treatment; and 190.8(1)(I), failure to obtain informed consent from the patient or other person authorized by law to consent to treatment on the patient's behalf before performing tests, treatments, or procedures;

Section 164.052(a)(5) of the Act authorizes the Board to take disciplinary action against Respondent for unprofessional or dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public, and further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient; and

Section 164.053(a)(5) of the Act authorizes the Board to take disciplinary action against Respondent for prescribing or administering a drug or treatment that is non-therapeutic.

- B. <u>Medical Recordkeeping</u> Respondent further violated the standard of care in that he failed to maintain adequate and, in some cases, accurate medical records in each of the six labor and delivery cases as set out below.
 - 1) Patients 1a through 6b: Respondent's documentation is inadequate in that the following information is lacking and/or the details provided are insufficient in cases of operative vaginal delivery:
 - a. patient medical history and physical examination:

- b. no mention of indication for induction of labor or mention of the use of misoprostol, the medicine used to induce labor;
- c. information as to the circumstances that indicated the use of forceps;
- d. no mention or description as to the type of forceps used, the number of attempts to apply forceps, or other details regarding the forceps;
- no details on the delivery via forceps including fetal station, type
 of instrument used, rotation, indications, risks, and/or
 complications during the procedure;
- f. details of labor course or details of operative delivery;
- g. no written informed consent; and
- h. no description of discussion or patient consultation as to treatment alternatives or risks.
- 2) Patient 3a and 3b In addition to the afore-detailed inadequacies, Respondent's documentation for the third case included inaccurate information, to wit, Respondent documented that "FHR not found for 2 minutes". However, this is contrary to readings generated from the electronic monitoring system, which recorded normal reassuring heart rate pattern.

Section 164.051(a)(3), of the Act authorizes the Board to take disciplinary action against Respondent for violation(s) of Board Rule 165.1(a) failure to maintain an adequate medical record.

C. <u>Unprofessional Conduct / Disciplinary Action By Peers:</u>

- 1) On or about January 6, 2014, Respondent's hospital privileges were temporarily suspended pending investigation into the death of patient 1b.
- On or about January 17, 2014, a peer review committee voted to revoke Respondent's privileges.
- 3) Respondent tendered his resignation in lieu of further disciplinary action by his peers is evidence that the peer review action was appropriate and reasonably supported by the evidence.

Section 164.051(a)(7) of the Act authorizes the Board to take disciplinary action against Respondent for having been subject to disciplinary action by a licensed hospital, including limitation of hospital privileges, or other disciplinary action as defined by Board Rule 190.8(4), disciplinary actions by peer groups; and

Section 164.052(a)(5) of the Act authorizes the Board to take disciplinary action against Respondent for unprofessional or dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public.

V. AGGRAVATING AND MITIGATING FACTORS

Board Rule 190.15 provides that the Board may consider aggravating factors that warrant more severe or restrictive disciplinary action. This case includes the following aggravating factors: 1) one or more violations that involve more than one patient; 2) increased potential for harm to the public; 3) intentional, premeditated, knowing, or grossly negligent act constituting a violation; 4) harm to one or more patient(s); and severity of patient harm.

Board staff is aware of no mitigating factors that apply and demands that Respondent submit proof to substantiate any alleged mitigating factors.

VI. NOTICE TO RESPONDENT

IF YOU DO NOT FILE A WRITTEN ANSWER TO THIS COMPLAINT WITH THE STATE OFFICE OF ADMINISTRATIVE HEARINGS WITHIN 20 DAYS AFTER THE DATE OF RECEIPT, A DEFAULT ORDER MAY BE ENTERED AGAINST YOU, WHICH MAY INCLUDE THE DENIAL OF LICENSURE OR ANY OR ALL OF THE REQUESTED SANCTIONS, INCLUDING THE REVOCATION OF YOUR LICENSE. A COPY OF ANY ANSWER YOU FILE WITH THE STATE OFFICE OF ADMINISTRATIVE HEARINGS SHALL ALSO BE PROVIDED TO THE HEARINGS COORDINATOR OF THE TEXAS MEDICAL BOARD.

VII. PRAYER

Board Staff requests that an administrative law judge employed by the State Office of Administrative Hearings conduct a contested case hearing on the merits of the Complaint, and issue a Proposal for Decision containing Findings of Fact and Conclusions of Law necessary to support a determination that Respondent violated the Act as set forth in this Complaint.

Respectfully submitted,

TEXAS MEDICAL BOARD

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THE STATE OF TEXAS

COUNTY OF TRAVIS

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SUBSCRIBED AND SWORN to before me by the said Heather Barham, J.D., on August 18th, 2016.

SAQUANDA JOHNSON Notary Public. State of Texas My Commission Expires August 06, 2017

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Filed with the Texas Medical Board on August 13, 2016.

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Executive Director

Texas Medical Board