EFFECTIVE

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NEW JERSEY STATE BOARD

OF MEDICAL EXAMINERS

STATE OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF MEDICAL EXAMINERS

In the Matter of:

STEVEN C. BRIGHAM, M.D.

ORDER IMPOSING TEMPORARY SUSPENSION OF LICENSE

Overview

This matter was opened before the Board upon the filing of a Verified Administrative Complaint on September 8, 2010, and thereafter a First Amended Verified Complaint on September 17, 2010, wherein the Attorney General alleged that cause existed to revoke the license of respondent Steven C. Brigham to practice medicine and surgery in the State of New Jersey, and that cause also existed to order that Dr. Brigham's license be temporarily suspended until all administrative proceedings are concluded.

Dr. Brigham is charged with having violated requirements of New Jersey law and with having provided grossly negligent care to five patients (identified by the initials D.B., S.D., N.C., J.P. and M.L.) who sought and secured late term abortions, with gestational ages ranging from 18.4 to 33 weeks. In each of the five cases, it is alleged that the individual patient was seen by Dr. Brigham in his Voorhees, New Jersey office, and that Dr. Brigham began the abortion process or procedure in Voorhees by

inserting laminaria and/or administering misoprostol to effect softening of the cervix, and/or, in three cases, injecting digoxin to cause fetal demise. It is further alleged that following initial treatment in Voorhees, four of the five women were transported in car "caravans" from Voorhees to Elkton, Maryland, where their dilation and evacuation procedures (hereinafter "D & E" procedures) were performed, either by Dr. Brigham alone, or by Dr. Nicola Riley (a physician employed by Dr. Brigham) with Dr. Brigham present. In the case of patient D.B., it is alleged that a uterine perforation occurred during the D & E, which required D.B. to be transported emergently for care first to Union Hospital in Elkton and later, following airlift, to Johns Hopkins Medical Center in Baltimore, Maryland.

Dr. Brigham is additionally charged with having performed approximately 50 termination of pregnancy procedures (all second or third trimester cases) in the Elkton, Maryland office of American Women's Service, between January and August 2010, without holding a license to practice in Maryland; with having created false patient records; and with having falsified information in a

In the case of patient J.P., it is alleged that although Dr. Brigham intended that her D & E procedure would be performed in Elkton, the night before that procedure was to be performed J.P. was admitted emergently to Virtua West Jersey Hospital in Voorhees. Hospital records suggest that she reported intense abdominal cramping and pain on arrival, that she was admitted to Labor and Delivery and that she delivered a demised fetus within one hour of admission. No complications are alleged to have occurred in the other three cases.

response he made to a Demand for Statement in Writing Under Oath that was served upon him in June 2010.

Respondent agreed, in exchange for additional time to prepare his defense, to the entry of an Order on September 10, 2010, which required that he cease and desist from practicing medicine in New Jersey on September 16, 2010, until the Board considered the Attorney General's temporary suspension application. A hearing on the application for the temporary suspension of Dr. Brigham's license was held before the Board on October 13, 2010. In the course of the more than nine hour hearing, over fifty exhibits were moved into the record, testimony was offered by two expert witnesses for Dr. Brigham (Drs. Gary Mucciolo and Renga Rajan) and from Dr. Brigham himself, and the Board entertained oral arguments from counsel.

For the reasons set forth in greater detail below, we herein conclude that the Attorney General has met her burden of demonstrating that Dr. Brigham's continued practice would present clear and imminent danger to the public health, safety and welfare, and that cause exists to order that Dr. Brigham's license to practice medicine and surgery in the State of New Jersey be temporarily suspended at this time. Succinctly stated, we find that Dr. Brigham has repeatedly provided treatment to patients who sought his services for second and third trimester abortions in his Voorhees, New Jersey office (specifically, for termination

procedures more than 20 weeks after the start of the patient's last menstrual period, referred to both in the Board's regulations and herein as "weeks LMP"). He has done so notwithstanding the fact that he could not legally perform any of the termination procedures in New Jersey, both because he does not possess the minimum credentials and qualifications that the Board requires a physician to hold to perform such procedures, and because the procedures were not performed in one of the two permissible settings where such procedures can be performed in New Jersey - either a hospital or a licensed ambulatory care facility ("LACF")².

While we are cognizant that Dr. Brigham maintains that all of the treatment he provided in New Jersey should be considered to be "prefatory" to an abortion - and that the Board should consider his "plan" to have patients shuttled to an out-of-state site for the performance of the D & E procedure to have been previously "approved" by the Board (either based on the dismissal of charges brought against him in a prior administrative action which concluded in 1996, or based on the Board's having taken the position, in a letter authored by then Executive Director Judith Gleason in November 1999, that laminaria could be inserted in an office setting without violating the Board's termination of pregnancy regulation) we reject those contentions.

Dr. Brigham in fact does not hold privileges at any hospital nor at any LACF in New Jersey.

Significantly, we conclude that, regardless whether Dr. Brigham reasonably believed he could insert laminaria in patients in his private medical office in New Jersey and then transport those patients out-of-state for a D & E, we find any asserted claim or belief that he could have injected digoxin - in order to cause fetal death - without thereby subjecting himself to the requirements of the Board's termination of pregnancy regulation to be patently specious. Rather, when Dr. Brigham injected digoxin to cause intra-uterine fetal demise in patients S.D., M.L. and J.P., he placed each patient at a point where they had no viable option other than to have an abortion procedure completed, and thereby committed those patients to abortions which he could not legally perform in New Jersey.

The evidence before the Board further demonstrates that Dr. Brigham sought to obscure and hide pertinent information from his own patients. Dr. Brigham has conceded that his patients were

In similar fashion, we reject Dr. Brigham's claims that he satisfied the requirements of Maryland law (and thereby could legally perform abortions in Maryland, without holding a medical license in the by "engaging in consultations" with Dr. George Shepard, an eighty-eight year old, partially disabled Maryland licensee who Dr. Brigham hired to serve as "Medical Director" of the Elkton clinic and who was driven round-trip from his home in Delaware to the clinic on dates that abortions were performed. We point out that Dr. Brigham's unpersuasive, if not implausible, claims regarding the legality of his conduct in Maryland are belied by the fact that the Maryland State Board acted swiftly and forcefully to preclude Dr. Brigham from continuing to engage in any medical practice in Maryland shortly after that Board learned that Dr. Brigham was practicing medicine in Maryland (that is, when Dr. Brigham's conduct was brought to their attention following the D.B. case). <u>See</u> further discussion infra.

not routinely advised where their termination procedures would in fact be performed. In instances where the procedures were performed by Dr. Riley, he did not advise the patients of that fact when securing consent for the procedure. No patient was advised that their procedures could not legally be performed in the State of New Jersey by Dr. Brigham.

In short, the evidence underpinning the Attorney General's application for temporary suspension supports a finding that Dr. Brigham has manifestly sought to evade the requirements of New Jersey law and, in doing so, has eviscerated the protections that the Board's regulations seek to extend to patients who elect to have D & E procedures performed post 14 weeks LMP. We unanimously find that such conduct presents clear and imminent danger and supports the temporary suspension of Dr. Brigham's license.

<u>Procedural History and Summary of Evidence</u> <u>Offered at Temporary Suspension Hearing</u>

As noted above, this matter was initiated by the Attorney General upon the filing of an Administrative Complaint and Order to Show Cause on August 25, 2010. Respondent thereafter sought additional time to file an answer and prepare his defense, and voluntarily agreed, within a non-disciplinary Order, to cease and desist his practice of medicine in New Jersey until the application for temporary suspension could be heard on October 13, 2010. The Attorney General filed an Amended Verified Complaint on September 17, 2010, and respondent filed an Answer to the Amended Verified Complaint dated September 24, 2010.

General alleged that Dr. Brigham's conduct constituted clear and imminent danger to the public and warranted the entry of an Order temporarily suspending his license to practice medicine and surgery in the State of New Jersey pursuant to N.J.S.A. 45:1-22. Four of the six counts of the complaint charge Dr. Brigham with misconduct related to five specific patients - namely, patients D.B. (Count 1), S.D. (Count 3), N.C. (Count 3), J.P. (Count 5) and M.L. (Count 6). In each case, it is alleged that Dr. Brigham treated patients who sought second or third trimester abortions in his Voorhees, New Jersey office, where he either inserted laminaria (patients D.B., S.D., J.P., and M.L.), injected digoxin (patients S.D., J.P., and M.L.) and/or administered misoprostol (patients D.B. and N.C.). In

four of the five cases (all except J.P.), it is alleged that the patients were required to drive from Dr. Brigham's Voorhees office to a facility in Elkton, Maryland, where the D & E procedure was performed.

In the case of patient M.L., who was 33 weeks by gestational age, Dr. Brigham alone performed the abortion. It is claimed that the abortion procedures performed on patients D.B., S.D. and N.C. were commenced by Dr. Brigham in New Jersey and then completed by Dr. Nicola Riley, who Dr. Brigham hired to perform abortions in the Elkton, Maryland facility. In the case of patient J.P., it is alleged that Dr. Brigham inserted laminaria and injected digoxin in his office on June 10, 2010, with the intent that J.P.'s termination of pregnancy would be completed in the out-of-state facility, but that plan never reached fruition because J.P. was admitted after midnight on June 11, 2010 to Virtua West Jersey Hospital in Voorhees, New Jersey.

It is further alleged, within Count 2 of the Complaint, that Dr. Brigham performed abortions in the Elkton, Maryland facility for a period from approximately September 2009 through August 2010, to include the performance of approximately 50 procedures between January and August 2010, the majority of which were second trimester cases but some of which were third trimester cases. In each case, it is alleged that the procedures were begun by Dr. Brigham in a location other than the Elkton, Maryland

clinic, and it further alleged that Dr. Brigham created or caused to be created false patient records to reflect that those procedures were performed either by Dr. George Shepard or by Dr. Kimberly Walker, an unlicensed medical graduate, when in fact all procedures were performed by Dr. Brigham alone.

In his Answer to the Complaint, respondent admitted having performed laminaria insertions, digoxin injections and misoprostol administrations in his Voorhees, New Jersey office on each of the five identified patients. Respondent also conceded that on or about August 25, 2010, the Maryland State Board of Physicians entered an Order requiring that he cease and desist from the unlicensed practice of medicine in Maryland. Respondent generally denied the remainder of the substantive allegations within the Complaint. He asserts that none of the conduct alleged in the Complaint should be found to constitute a violation of New Jersey statute or regulation, or found to be cause to support the entry of an Order temporarily suspending his license.

On October 13, 2010, Deputy Attorney General Jeri

Count 4 of the Complaint includes allegations that Dr. Brigham lied when responding to a Demand for Statement in Writing Under Oath, by falsely stating "we are not performing any abortions beyond 14 weeks in New Jersey," when in fact he was routinely commencing abortions upon patients beyond 14 weeks in his Voorhees office. While we note that the allegations in Count 4 suggest yet another action by Dr. Brigham to deflect attention from his activities, we have not found it necessary to consider those charges at this time, as we have concluded that a more than ample demonstration to support the temporary suspension of Dr. Brigham's license has been made based on the evidence presented related to other misconduct charged in the Complaint.

Warhaftig appeared for complainant Paula T. Dow, Attorney General of New Jersey. Joseph M. Gorrell, Esq. and Eric W. Gross, Esq., of Brach Eichler, L.L.C., appeared on behalf of respondent Steven C. Brigham. We initially considered two motions filed by respondent – first, a motion to dismiss Counts 1, 2, 3, 5 and 6 of the Amended Verified Complaint based on application of the doctrine of collateral estoppel, and thereafter a motion to disqualify Gary Brickner, M.D., from acting as the expert for the Attorney General in this case. Both motions were denied (see accompanying Orders denying motions).

Each party respectively moved over twenty exhibits into evidence (see Exhibit List appended hereto). While the Attorney General rested her application for temporary suspension solely on the documentary evidence, respondent's defense was predicated both on the documentary evidence and on testimony that was offered by two expert witnesses and by Dr. Brigham himself. Dr. Gary Mucciolo testified generally that he had reviewed the care provided in each of the five cases and found no deviations from the standard of care in any of the five cases. Dr. Renga Rajan also opined that Dr. Brigham met the standard of care in each of the five cases.

In addition to offering opinions on the standard of care, both experts suggested that the abortion procedure - namely, the evacuation of the uterus - was a procedure that could be distinguished from acts that are prefatory to the evacuation of the

uterus, to include insertion of laminaria, administration of misoprostol and injection of digoxin. Both experts further stated that a patient could travel following the insertion of laminaria or administration of misoprostol. Dr. Mucciolo opined that traveling did not present further risks to the patient, as sufficient time is needed afterwards to allow the cervix to soften for a safer abortive procedure. Dr. Rajan similarly testified that it was common practice to let a patient drive after insertion of laminaria, injection of digoxin or administration of misoprostol. Significantly, both Dr. Mucciolo and Dr. Rajan conceded, on crossexamination, that once fetal death is induced following an administration of digoxin, a patient has to proceed with an abortion.

Gary R. Brickner, M.D. the expert witness for the Attorney General, was not called to testify, but his two written reports are in evidence (Exhibits P-V and P-W). Dr. Brickner opines that Dr. Brigham repeatedly violated Board regulations in the performance of pregnancy terminations, thereby exposing his patients to considerable risk of harm. Dr. Brickner further opined that Dr. Brigham committed gross medical negligence in his care of the five identified patients, for reasons including his performing a termination of an extremely risky 33 week abortion on patient M.L. in a facility that did not have the capability of doing major surgery; by causing patients already at risk for sudden labor and/or hemorrhage by his treatment to travel by personal automobile a substantial distance to continue/complete their procedures, thereby risking medical emergencies remote from immediate care; by allowing Dr. Riley, who he knew was unqualified, to perform late second trimester D & Es on his patients; and by failing to have an arrangement in place with an accredited hospital for emergency care of patients.

In his supplemental report, Dr. Brickner opined that Dr. Brigham's actions in the treatment of his patients were intended to flout and circumvent the Board's safety regulations, and also suggested that Dr. Brigham's actions should be considered to be the first part of a multi-step abortion process that was not conducted in accordance with Board regulations.

Testifying in his own defense, Dr. Brigham stated that he initially became aware of the Board's regulations regarding abortion procedures in 1992, at which time he sought advice from Dr. Michael Burnhill (who he understood had been the consultant used by the Board when the regulation was drafted) whether inserting laminaria in an office setting was permissible. T181, 1-10 (references to the transcript from the hearing shall appear as "T"). After obtaining advice from Dr. Burnhill and an attorney, he started inserting laminaria in his office and then taking patients to New York for procedures. T182,4-9. Following the Board's investigation of his practice, he testified that he voluntarily stopped inserting laminaria in his office. T182,10-24. Brigham testified that he continued to refrain from inserting laminaria from 1992 through some time in 1999 (after his attorney, Mr. Phillips, received Ms. Gleason's November 1999 letter), T183,3 - 184,18. He further maintained that in all such cases (that is, all cases where he inserted laminaria in patients who were beyond 14 weeks LMP), the procedure itself was done somewhere other than Dr. Brigham's Voorhees office, either out-of-state or, if in New Jersey, in a licensed ambulatory care facility or hospital. T186,19 - 187,1.

Dr. Brigham testified that he was moved to open a facility in Elkton, Maryland where late term abortions would be performed following the murder of Dr. George Tiller. T189,21 -

190,15. In doing so, Dr. Brigham claims he was seeking to afford patients looking to secure late-term abortions an option other than having to go to Colorado or California to have the procedure performed. Dr. Brigham stated that he generally attempted not to publicize information about the Elkton clinic, in an effort to avoid unwanted attention and the possibility of having to deal with protesters outside the facility. He testified that even patients who asked directly were not told where they were going for similar reasons, although he stated that patients who insisted (generally so as to plug it into a GPS system when driving from Voorhees to Elkton) were provided with the address. T195, 16-22; 237,15 -238,25.

Dr. Brigham testified generally that he would see second trimester patients in his Voorhees office, and perform actions which he considered to be prefatory to the abortion in that office. Patients seeking third trimester abortions would be met initially in Dr. Brigham's Mount Laurel office. Dr. Brigham testified that those patients had to complete an application process, would be carefully screened, and that third trimester abortions would be performed only where there was something seriously wrong with the fetus (such as existed in M.L.'s case), to include "fetal problems" or "fetal anomalies." T 201,21 - 203,14; 253,1-5; 256,14 - 257,5.

Dr. Brigham additionally offered testimony about each of the five patients identified in the Administrative Complaint,

providing history and background regarding each patient's treatment and abortion procedure. With regard to all patients, Dr. Brigham generally suggested that he attempted to provide compassionate and medically sound care.

During his testimony, Dr. Brigham consistently maintained that he believed he did not need a medical license in Maryland because Maryland law allowed a physician licensed in another state to practice if he or she did so while engaging in consultation with a Maryland licensed physician. Dr. Brigham claimed that he satisfied the requirements of Maryland law by engaging in consultations with Dr. George Shepard, see, i.e., T 228,23 - 229, 3. At one point during his testimony, Dr. Brigham suggested that he may have been engaged in consultations with "another licensed Maryland doctor," T219, 9-13, but he thereafter never identified any consulting physician other than Dr. Shepard. Dr. Brigham hired Dr. Shepard to serve as the Medical Director of his clinics. Dr. Shepard also held the title Medical Director in Dr. Brigham's New Jersey office, but his involvement was primarily in Elkton. T232,22 - 233,4.

Dr. Brigham testified about the presenting condition of each of the five patients, and about the care that he provided in New Jersey and the abortion procedures that were performed in Maryland on patients M.L., D.B., S.C. and N.D. Dr. Brigham also testified about the circumstances which preceded patient J.P.'s hospital admission in New Jersey, to include his decision to go to her hotel room after midnight to remove laminaria, and the claimed hostile manner in which he was treated by police after he arrived at the hotel room.

Dr. Brigham testified that Dr. Shepard was present at the Elkton clinic when procedures were performed. When pressed about what a "consultation" would entail, Dr. Brigham testified:

Dr. Shepard would come in - I did the care. Dr. Shepard was not - he would come in and he would say hello to the patient, shake their hand ask if they have any questions. He would be in the room at the patient's bedside and he would talk to me and ask me questions, and I would talk to him and ask him questions, and conversations going back and forth with us. So we were engaging in medical conversation.

And the Maryland law says while engaging in consultation. So, it appears to be a two-way street. ... He would be - he would ask me questions. He would watch the patient. Sometimes he'd say: I think she needs more medication, Steve. He would watch the pulse ox. He would ask me questions. I would ask him questions.

T230,5 - 232,1.

Dr. Brigham conceded that he alone performed all of the abortions in Maryland (prior to the time that he hired Dr. Nicola Riley) and that Dr. Shepard did not perform or assist in the performance of any procedure. T272,5 - 273,22. He further acknowledged that Dr. Shepard had some impairment of his right hand or arm, T271,10-13, and that Dr. Shepard was in fact not physically capable of performing a D & E procedure because he lacked the required physical strength. Dr. Brigham conceded that he needed Dr. Shepard to be present for legal reasons alone, and not for medical reasons. T264,7 - 265,6. Dr. Brigham denied creating false records, and suggested that the logs that the Attorney General had submitted in evidence should not be taken as evidence

of who performed the procedures.

Dr. Brigham stated that he hired Dr. Nicola Riley after interviewing her in July 2010. He stated that Dr. Riley in fact performed the abortions on patients J.B., N.C. and S.D., and stated that he was present in a consulting role while she did so. Dr. Brigham testified that the decision to transport J.B. to Union Hospital in Elkton in her automobile (rather than to call for an ambulance) was made by Dr. Riley alone.

Dr. Brigham in closing asked the Board to consider that the abortion issue is emotional, and asked that the Board put aside any personal opinions that members may have on abortion. T 285,24 - 287, 16.

Findings of Fact

At this juncture of the proceeding, based on our review of the documents that were moved into evidence and testimony offered, we are able to make the following preliminary findings of fact that we find critical in our analysis whether Dr. Brigham's continued practice would present clear and imminent danger.

- 1. Dr. Brigham provided care to, and treated, each of the five patients identified in the complaint, each of whom sought the performance of an abortion and each of whom was post 20 weeks LMP. Specifically, D.B. was approximately 23.5 weeks LMP, S.D. 27 weeks LMP, N.C. 20.4 weeks LMP, M.L. 35 weeks LMP and J.P. 26 weeks LMP.
- 2. Dr. Brigham, in his Voorhees, New Jersey office, either inserted laminaria, administered digoxin, and/or administered misoprostol in advance of scheduled D & E procedures to each of the five patients. Specifically, with regard to patient:
- D.B., Dr. Brigham inserted laminaria on August 12, 2010, and administered misoprostol on August 13, 2010.

Within the complaint, the Attorney General has identified the number of weeks pregnant that each patient was, rather than referencing the number of weeks post LMP. As set forth in our regulation, the number of weeks LMP is generally recognized to be two weeks greater than gestational size (the regulation states "the stage of pregnancy 12 weeks' weeks from the first day of the last menstrual period). Accordingly, in order to calculate each patient's number of weeks LMP, we have added two weeks to the reported weeks pregnant or gestational ages.

- S.D., Dr. Brigham administered digoxin to cause fetal demise on August 11, 2010 and August 12, 2010, and inserted laminaria on August 11, 2010.
- N.C., Dr. Brigham administered misoprostol on August 13, 2010. $^{\text{g}}$
- M.L., Dr. Brigham injected digoxin to cause fetal demise on August 2, 2010, and inserted laminaria on August 2, 2010 and August 3, 2010.
- J.P., Dr. Brigham injected digoxin to cause fetal demise on June 9, 2010, and inserted laminaria on June 9, 2010 and June 10, 2010.
- 3. None of the five patients had D & E procedures performed in New Jersey. Rather, it was Dr. Brigham's plan and intent that each of the five patients would have the D & E procedure performed at a clinic that he owned in Elkton, Maryland. Four of the five patients traveled by automobile, on the morning that their procedure was to be performed, a distance of greater than fifty miles from Dr. Brigham's Voorhees office to the Elkton

The evidence suggests that N.C. also had laminaria inserted on August 12, 2010. It is unclear where that insertion was performed, as Dr. Brigham claims that the insertion was done in a Paramus, New Jersey office of American Women's Services by another physician, but information set forth in the Certification of Investigator Carreto (Exhibit P-X, under seal) suggests that N.C. has stated that the insertion was done in Voorhees by a nurse.

office of American Women's Services. Dr. Brigham alone performed the D & E procedure on patient M.L. in Elkton on August 4, 2010. D & E procedures were performed on patients D.B., S.D. and N.C. on August 13, 2010 by Dr. Nicola Riley, while Dr. Brigham was present, in Elkton. 16

4. Dr. Brigham did not routinely advise his patients, in advance of scheduled D & E procedures, that their procedures would

We cannot establish, on the record before us, whether the Elkton, Maryland office was named American Women's Service, American Medical Services, Grace Medical, or whether it had some other title or no name at all (we hereafter will reference it simply as the "Elkton" office, facility or clinic). It is clear, however, that the facility was owned by Dr. Brigham, that Dr. Brigham performed numerous abortions at that facility in 2010, and that the D & E procedures performed on patients M.L., J.B., S.C. and N.D. were all performed at the Elkton facility.

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It is not clear, on the record before us whether and, if so, how significantly, Dr. Brigham was involved in performing, or assisting in the performance of, any or all of the three termination procedures on patients D.B., S.C. and N.D. Dr. Riley stated, when interviewed by the Maryland Board, that she performed the procedures, with Dr. Brigham functioning as a consulting physician. See Exhibit P-I.

In her written sworn statement, D.B. states that she "met Dr. Rielly (sic) [in Elkton] who appeared to be doing the procedures. Dr. Brigham was telling her every step. I became concerned because it seemed that she was practicing on me." See Exhibit P-N.

Additionally, it is reported that N.C. stated, when interviewed by Enforcement Bureau investigator Carreto, that Dr. Brigham introduced himself as "the doctor who would be performing the procedure." Exhibit P-X (sealed). It is also reported that S.D. stated, when interviewed by Investigator Lizzano, that although she did not recall "who did what," she "was of the belief that Dr. Brigham performed her procedure." Exhibit P-X (sealed).

It is not in dispute, however, that Dr. Brigham was present in his Voorhees office on the morning of August 13, 2010, and then traveled to Elkton, Maryland in his personal automobile that morning. Nor is it in dispute that he was, at a minimum, present while D & E procedures were being performed on patients D.B., S.C. and N.D.

be performed in Elkton, Maryland. Rather, patients were generally told only that the procedure would be performed in another facility. Similarly, patients were not advised that Dr. Brigham could not legally perform their D & E procedures in New Jersey. In cases where the D & E was performed by Dr. Nicola Riley in Elkton, patients were not advised in advance who would be performing the procedure, and instead first met Dr. Riley when they arrived at the Elkton facility.

5. Dr. Nicola Riley entered into a "physician independent contractor agreement" on July 30, 2010, with entities owned by Dr. Steven Brigham, to perform abortions at the Elkton facility. At the time, Dr. Riley held licenses to practice medicine in Utah, Maryland and Wyoming. Dr. Riley holds board certification by the American Board of Family Medicine, but is neither certified nor eligible for certification by the American Board of Obstetrics - Gynecology or the American Osteopathic Board of Obstetrics-Gynecology. Dr. Riley is not presently, and has

D.B. asserts in her sworn statement that she had been led to think her procedure would be performed in Philadelphia, and was not told where she was going when asked to follow a nurse (in a car in front of her) to the facility where the abortion would be performed. Other evidence (offered under seal) suggests that M.L., N.C. and S.D. were likewise not told where they would be traveling to by Dr. Brigham. M.L.'s husband stated, when interviewed by Investigator Lizzano, that M.L. "was very uncomfortable as the labor pains were very intense." S.D.'s husband stated that S.D. "became concerned and frightened during the drive to Elkton, Maryland, as no one had told them they had to drive that far in heavy traffic until the last moment." He also is reported to have "described his wife as being in 'severe pain' the entire trip. And that it seemed like it would never end." Exhibit P-X (sealed).

never held, a license to practice medicine in New Jersey. Dr. Riley has offered testimony to investigators in Maryland that, in the five years preceding her employment by Dr. Brigham, she served as a medical director of a women's clinic in Utah where she performed "abortions up to 14-plus weeks." She also testified that before that time, she was trained "during [her] first year of training" at facilities where abortions up to twenty weeks were performed.

- 6. Dr. Brigham planned that patient J.P. would have her D & E procedure performed in the Elkton facility on or about June 11, 2010. The planned D & E did not occur, however, as J.P. instead was treated by Dr. Brigham in her hotel room shortly after midnight on June 11, 2010, where Dr. Brigham removed gauze that he had previously inserted so that J.P. could urinate. J.P. was thereafter admitted emergently to West Jersey Virtua Hospital. Within the discharge summary included in J.P.'s hospital chart, it is recorded that J.P. reported intense abdominal cramping and pain, was admitted to Labor and Delivery and delivered a demised fetus within one hour of admission.
- 7. During the course of D.B.'s D & E procedure on August 13, 2010, a uterine perforation and a small bowel injury occurred. The procedure was stopped after the perforation was recognized, and D.B. was transported, in her private automobile, to Union Hospital in Elkton for emergency treatment. Dr. Brigham drove D.B. to Union

Hospital. No transfer agreement existed between the Elkton facility and Union Hospital. D.B. was thereafter airlifted from Union Hospital to Johns Hopkins Health Center in Baltimore, Maryland for additional emergency treatment, to include completion of the termination of pregnancy procedure and surgical repair of the perforation.

- 8. In addition to the five specified patients, Dr. Brigham, operating alone, performed multiple second and third trimester procedures on patients in the Elkton facility (from the time that the facility was opened through, at a minimum, the time that Dr. Nicola Riley was hired). Those procedures were, in some or all cases, performed on patients who Dr. Brigham initially treated in New Jersey, presumably in a manner similar to the five identified cases (that is, through in-office insertion of laminaria, intrauterine injection of digoxin to cause fetal death, and/or with the administration of misoprostol).
- 9. Dr. Brigham has maintained, in these proceedings, that pursuant to Maryland statutes, §14-302(2), he could legally practice medicine in Maryland without a license provided that he did so "while engaging in consultation" with a Maryland licensed

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When testifying before the Board, Dr. Brigham stated that the Elkton facility had a back-up arrangement with Christiana Hospital, which Dr. Brigham testified is located approximately 12 miles from the Elkton facility. At this stage of the proceeding, no additional evidence has been submitted regarding that back-up arrangement.

physician."¹³ Dr. Brigham maintains that all of the procedures were performed while he "was engaging in consultation" with Dr. George Shepard, a Maryland licensed physician, who Dr. Brigham employed to serve as "Medical Director" of the Elkton facility and other facilities owned by Dr. Brigham. Dr. Brigham testified that Dr. Shepard would be present in the Elkton facility when Dr. Brigham performed abortions, and that the "consultation" would involve his asking questions of Dr. Shepard and Dr. Shepard asking questions of him. Dr. Shepard did not in fact perform any abortion procedure at the Elkton facility, and Dr. Brigham conceded when testifying that Dr. Shepard would not be physically able to perform a D & E procedure.

- 10. Dr. Brigham is neither certified nor eligible for certification by the American Board of Obstetrics Gynecology or the American Osteopathic Board of Obstetrics-Gynecology.
- 11. Dr. Brigham holds no hospital privileges that would allow him to perform a D & E procedure, or any other procedure to effect a termination of pregnancy, in any New Jersey licensed

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^{\$14-302} of Maryland Code, Health Occupations, states: Subject to the rules, regulations, and orders of the Board, the following individuals may practice medicine without a license:

[•]

⁽²⁾ A physician licensed by and residing in another jurisdiction, while engaging in consultation with a physician licensed in this State.

hospital.

- 12. None of the offices that Dr. Brigham practices out of in New Jersey, to include his Voorhees office, is a licensed ambulatory care facility. Dr. Brigham is not authorized to perform a D & E at any licensed ambulatory care facility in New Jersey.
- 13. Dr. Brigham has never sought permission from the Board, as would be required by N.J.A.C. 13:35-4.2(g), to perform a D & E procedure in an LACF after 20 weeks LMP.
- an investigation of practices at the Elkton clinic and/or of the physicians engaged in practice at the Elkton clinic. On August 25, 2010, the Maryland Board entered an Order requiring that Dr. Brigham immediately cease and desist from practicing medicine in Maryland without a license. Within that Order, it was stated that the Board had probable cause to believe, among other items, (1) that Dr. Brigham is not and had never been licensed to practice in Maryland; (2) that Dr. Brigham had performed surgical procedures in Elkton, Maryland on a regular basis and (3) that Dr. Brigham had "initiated" or "directed" a procedure on August 13, 2010 which had to be completed on an urgent The Maryland Board found that the health of Maryland patients was being endangered by Dr. Brigham's unlicensed practice of medicine in Maryland.
- 15. Digoxin is a drug that is inserted into the amniotic cavity to cause fetal demise. Dr. Brigham injections of digoxin

caused fetal death to occur in the cases of patients M.L., S.D. and J.P. S.D., who was carrying twins, was injected with digoxin on two occasions, as it was determined that one fetus may have survived the initial injection. Once a digoxin-induced fetal death occurs (in advance of a planned D & E), a patient must proceed with an abortion.

Legal Analysis

New Jersey law provides that, before we may order the temporary suspension of a medical license, the Attorney General must make a palpable demonstration that a licensee's continued practice in New Jersey would present clear and imminent danger to the public health, safety and welfare. Upon review and consideration of the evidence, we have concluded that the Attorney General has met her burden of proof, as the record before us demonstrates that Dr. Brigham has placed numerous New Jersey patients in imminent danger by engaging in an elaborate, multistate plot to evade the requirements of New Jersey law.

a. The Board's Termination of Pregnancy Regulation

The focus of our analysis is on N.J.A.C. 13:35-4.2, the Board's termination of pregnancy regulation (the full text of the regulation is appended hereto for reference). Initially, we note that the regulation does not prohibit the performance of abortions

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Specifically, N.J.S.A. 45:1-22 provides:

A board may, upon a duly verified application of the Attorney General that alleges an act or practice violating any provision of an act or regulation administered by such board, enter a temporary order suspending or limiting any license issued by the board pending plenary hearing on an administrative complaint; provided, however, no such temporary order shall be entered unless the application made to the board palpably demonstrates a clear and imminent danger to the public health, safety and welfare and notice of such application is given to the licensee affected by such order.

post 20 weeks LMP - rather, the regulation's intent is explicitly stated to be "to regulate the quality of medical care offered by licensed physicians for the protection of the public." N.J.A.C. 13:35-4.2(a). It is thus the case that all of the procedures which are the subject of this action could have legally been performed in New Jersey had they been performed by a physician appropriately qualified under the regulation, and had they been performed in a permissible setting.

In broad overview, our regulation does not address or in any way limit performance of "first-trimester" abortions. After a pregnancy progresses to 14 weeks LMP, however, the regulation requires that all termination procedures, other than the D & E procedure, must be performed in a licensed hospital. N.J.A.C. 13:35-4.2(d). D & E procedures may be performed either in a licensed hospital or a licensed ambulatory care facility ("LACF"). From 15 weeks through 18 weeks LMP, a D & E may be performed in a LACF, provided that the physician performing the procedure has been granted privileges by the LACF's Credentials Committee to perform the procedure. N.J.A.C. 13:35-4.2 (e).

From 19 weeks through 20 weeks LMP, a D& E may be performed in an LACF, provided that the Medical Director of the LACF files a certification with the Board attesting that the physician performing the procedure meets seven defined eligibility standards (some of which are physician specific and some of which

are facility specific). N.J.A.C. 13:35-4.2 (f). It is evident that all of the standards necessarily reflect the Board's recognition that the performance of a D & E procedure at this advanced stage of pregnancy presents increased risks to the patient. With regard to physician qualifications, the regulation provides that the physician performing a 19 through 20 week LMP procedure must be certified by, or eligible for certification by, the American Board of Obstetrics-Gynecology or the American Osteopathic Board of Obstetrics-Gynecology, N.J.A.C. 13:35-4.2 (f) (1), and must have admitting and surgical privileges at a nearby licensed hospital which has an operating room, blood bank, and an intensive care unit, within 20 minutes driving time from the LACF. N.J.A.C. 13:35-4.2 (f) (2).

Finally, beyond 20 weeks LMP, a physician seeking to perform a D & E in an LACF must secure permission to do so directly from the Board. N.J.A.C. 13:35-4.2 (g). The regulation requires that the physician must provide proof, to the satisfaction of the Board, of superior training and experience, and must provide proof of support staff and facilities adequate to accommodate the increased risk to the patient of such procedure. Id.

In overview, the termination of pregnancy regulation is structured in a manner which necessarily recognizes that risks attendant to abortion procedures become increasingly more pronounced as a pregnancy advances into the second trimester. See

also Planned Parenthood v. Verniero, 41 F. Supp. 2d 478, 483, fn1 (D.N.J. 1998), aff'd 220 F. 3d 127 (3rd Cir 2000) ("... the risk of death from abortion increased about thirty percent with each week of gestation from eight weeks lmp to twenty weeks lmp ... the risk of major medical complications increases about twenty percent with each week of gestation from seven weeks lmp to full term."). In order to ensure patient safety, the regulation provides that only physicians with superior training and skills can qualify to perform the most advanced, and the most risk-laden, procedures in an LACF, and requires that any physician seeking to perform procedures beyond 20 weeks LMP must secure specific permission from the Board to do so.

As set forth in our findings of fact, Dr. Brigham could not have qualified to perform D & E procedures post 18 weeks in an LACF, both because he lacked the required Board certification and because he did not have the required hospital admitting and surgical privileges. Lacking those credentials, had Dr. Brigham sought permission from the Board to do late term procedures, he would not have been granted that permission. Dr. Brigham in fact, however, never even sought the required permission.

It is thus the case that, in the cases of patients D.B., N.C., S.D., M.L. and J.P., Dr. Brigham was not qualified, under New Jersey law, to perform their D & E procedures. It is also apparent that Dr. Brigham could not have qualified under New Jersey law to

perform any of the approximately 50 D & E procedures (on non-specifically identified patients) which are the subject of Count 2 of the complaint (assuming that all of those procedures were performed on patients greater than 18 weeks LMP). Similarly, Dr. Nicola Riley could not have qualified under New Jersey law to perform abortions post 18 weeks LMP, as she too lacked the minimum requisite credentials.¹⁵

b. Analysis of Dr. Brigham's Defense Claims

In his defense, Dr. Brigham has maintained that he did not believe that his actions violated New Jersey law, because he believed that he could perform all steps "prefatory" to an abortion (to include not only laminaria insertion, but also digoxin

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There is insufficient evidence in the record to allow us to make a determination whether the Elkton facility, were it located in New Jersey, would be an acceptable facility at which D & E procedures could be performed. We note, though, that in addition to any requirements that may be imposed through statutory requirements or by Department of Health regulations, the Board's regulation also includes criteria regarding the LACF. For procedures after 18 weeks LMP and through 20 weeks LMP, the LACF must be "current and in good standing" and have a "written agreement with an ambulance service assuring immediate transportation of a patient at all times when a patient has been admitted for surgery and until the patient has been discharged from the recovery room," N.J.A.C. 13:35-4.2(f)(3), and must provide "adequate staff support and resources for the operative procedure as well as interim follow-up and post-operative N.J.A.C. 13:35-4.2 (f)(6). The facility also must have " a physician ... available and readily accessible 24 hours/day to respond to any postoperative problem." Id. The regulation further requires that statistics detailing the utilization and safety record of each stage procedure and of each surgeon be maintained and submitted to the Board, see N.J.A.C. 13:35-4.2(f)(7) and requires that procedures be performed only on patients who have been "examined and found to be within the eligibility criteria established for advanced D & E procedures in the LACF setting." N.J.A.C. 13:35-4.2(f)(5). The manifest intent in all of the regulation's requirements is to insure that adequate safeguards are in place to accommodate the increased risk to the patient when a D & E is performed outside of a hospital on a patient beyond 18 weeks LMP.

injection and misoprostol administration) in his office without running afoul of the Board's regulatory requirements. Dr. Brigham asserts he held that belief based on the Board's dismissal of the charges that were brought against him in 1993, and based on the text of a letter authored by Executive Director Gleason in November 1999. He further maintains that he could legally perform abortions in Maryland without holding a license in that state, provided that he was engaging in consultation with a Maryland licensed physician.

We reject Dr. Brigham's assertions. While it is unquestionably the case that we stated, in Executive Director Gleason's November 1999 letter, that laminaria could be inserted in an office setting without violating the Board's termination regulation, it is clear that the position was taken upon the explicit condition that the procedure itself was going to be done by a qualified New Jersey licensee in a permissible setting - that is, in full compliance with all other requirements of the Board's termination regulation. In no way can the 1999 letter be read to condone the insertion of laminaria by a practitioner who would otherwise not be qualified under the Board's regulation to perform the D & E, nor can it reasonably be read to condone that insertion in circumstances where the D & E procedure is contemplated to be performed in any setting other than a New Jersey hospital or LACF. 16

1.6

For reasons that are set forth in greater detail in the accompanying Order denying respondent's motion to dismiss Counts 1, 2, 4, 5 and 6, we are unconvinced that the issue whether inserting laminaria

Just as significantly, neither the 1999 letter nor the Board's 1996 order in any way address or consider the issue whether the administration of misoprostol or the injection of digoxin can be performed in an office setting and/or without otherwise complying with the requirements of the Board's regulation. Injection of digoxin, however, is clearly a very different act from insertion of laminaria. Digoxin, when used in advance of a planned D & E, has one purpose - to effect fetal death. Once the intended fetal death occurs, a patient has proceeded to a point where there can be no going back on the decision to abort her pregnancy. In that sense, while both insertion of laminaria and injection of digoxin may be acts that "precede" a planned D & E, a distinction must be drawn between the two acts because one does not absolutely

in an office setting in fact violates the requirements of the Board's termination regulation was ever resolved in the 1993 action. See Order Denying Motion to Dismiss (noting that the finding that was made in the 1993 action was limited to a finding that Dr. Brigham neither intentionally nor negligently violated the regulation, and that the finding was based on the recognition that Dr. Brigham had voluntarily stopped inserting laminaria in his office after becoming aware of the Board's concerns regarding his actions).

We also note that Dr. Brigham's claims regarding the innocuous nature of laminaria insertion, and his claims that it should be viewed as a reversible act, are belied by the statements that appear on the informed consent forms that he had his patients execute. Those forms include statements that the administration of laminaria is the commencement of the abortion, and that the patient and her fetus would be exposed to great risks were the patient to decide, after laminaria are inserted, not to proceed with the abortion.

Indeed, Dr. Brigham's own expert, Dr. Mucciolo, conceded in his testimony that once fetal death is induced following an administration of Digoxin, a patient has to be aborted. T114, 4-11; 119, 9-16. See also testimony of Dr. Rajan, T162,24 - 163,9.

commit the patient to abort her pregnancy, whereas the other does.

Indeed, we find Dr. Brigham's claims that digoxin injection should be lumped together with other "prefatory" acts to be directly contradicted by both the testimony he offered in his defense in the 1993 action, and by the statements his attorney made to the Board in writing in 1999. When testifying before the Office of Administrative Law in the prior action, it is apparent that Dr. Brigham himself drew a distinction between acts such as insertion of laminaria, which do not necessarily terminate a pregnancy, and acts which terminate a pregnancy, including both killing and evacuating the fetus:

It was the opinion of respondent Brigham that insertion of laminaria does not constitute performance of an abortion. He offered several reasons. First, insertion of laminaria does not terminate the pregnancy; it neither kills nor evacuates the fetus. It is possible to remove the laminaria and have the patient go on to deliver a healthy baby. ... so, Dr. Brigham testified, he had every reason to believe that in New Jersey insertion of laminaria would not be deemed performance of an abortion.

Initial Decision in the Matter of Steven Brigham, Exhibit R-3 in evidence, p. 77 [emphasis added].

In a similar fashion, when soliciting an opinion from the Board whether laminaria could be inserted in an office setting, respondent's counsel pointedly drew a distinction between laminaria insertion and acts which would kill a fetus or evacuate the uterus. Mr. Phillips maintained that a patient could still change her mind about an abortion after laminaria are inserted without compromising the pregnancy, and provided copies of medical studies to support

his claim:

My client states that laminaria insertion involves only the cervix, not the uterus, and that it neither kills the fetus nor evacuates the uterus. Hence, laminaria insertion does not cause, and is not, an abortion. Patients have been known to change their minds after laminaria insertion, and for those patients the laminaria can be removed and the patient will go on to deliver a baby, with no ill effects from the laminaria. Indeed, this is well documented in the literature.

Letter dated January 26, 1999 from Stuart J. Phillips, Esq. to Judith I. Gleason, Executive Director of New Jersey State Board of Medical Examiners, R-10 in evidence, emphasis added.

We thus find respondent's present claim that he believed he could inject digoxin into patients in his Voorhees office, in advance of a scheduled D & E, without thereby being subject to the requirements of the Board's termination regulation, to be a claim that is directly contradicted by respondent's own prior statements. For him to now seek to disavow that recognition is both disingenuous and implausible.¹⁸

Finally, we find Dr. Brigham's assertion that he could secure a wholesale exemption from licensure requirements in

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We further conclude that neither the prior administrative action, nor the correspondence between Mr. Phillips and the Board, support respondent's assertion that the Board condoned his practice of administering misoprostol to patients in his office (in each case done immediately before that patient was asked to travel over fifty miles to another facility where a D & E would be performed). While the evidence does suggest that misoprostol is administered for a purpose similar to that sought when laminaria are inserted - namely to soften the cervix - own expert, Dr. Mucciolo, testified that he was unaware whether there was any literature addressing the question whether a patient could change her mind following the administration of misoprostol, but conceded that such a decision would be against medical advice. T 114,12-24.

Maryland - and thereby have carte blanche to perform second and third term surgical abortions in Maryland without a license - to be facially incredible and not worthy of serious consideration. It is instead a transparent fiction that Dr. Brigham created, to justify his performing procedures in Maryland (on patients that he treated in New Jersey) that he knew he could not legally perform in New Jersey.

We find nothing in the record (beyond Dr. Brigham's own self-serving statements) to support Dr. Brigham's claim that he engaged in meaningful or real consultation with Dr. Shepard, on each patient upon whom he performed an abortion in Elkton. Most significantly, Dr. Brigham's claims are contradicted by the statements that Dr. George Shepard gave when interviewed in Maryland.¹⁹

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We find the following statements offered by Dr. Shepard in response to inquiries made by Christine Farrelly (Compliance Analyst with the Maryland Board of Physicians) during an interview conducted on August 19, 2010 (in evidence at Exhibit P-F and P-U) illustrate the patent disingenuousness of Dr. Brigham's claim:

Q: Okay. So, then, when the patient came down to Elkton the next day to finish the abortion, what happens on the second day? What medically happens?

A. Well, I know they take - I think there's some gauze that keeps the Laminaria in place. So, they take out the gauze and then the Laminaria, they dilate the cervix and I think they put some (inaudible) or Pitocin in the cervix and use forceps to extract any fetal tissue that needs to come out.

Q: Okay. Yeah, I mean, I'm just trying to understand, you know, kind of how it works because I'm not a doctor. So, I mean, does the - when does the fetus die? How does that work out?

- A: Now you got me. I have no clue to any of that. All I know is when they get there, there's no fetal monitor or anything. If you're talking about, you know, after when does the heartbeat start.
- Q. On, no, no, I'm sorry. I'm not I'm just trying to figure out like does the I forget the does the Laminaria, does that opening of the cervix cause the fetal heart rate to stop?
- A. That's a good question. I haven't done that, so I'm not quite sure how that works.

. . .

- Q. Okay, gotcha. So, now, do you provide any training up there?
- A. No, I do not.
- Q. Okay, okay. Are you practicing medicine anywhere else right now?
- A. No. I'm not.
- Q. No? Okay.
- A. Like I said, I'm sort of handicapped, so it makes it difficult for me to do that. I get tired just using my arm sometimes to write. So, you know, I'm not doing very much.

Transcript of interview with George Shepard, Jr., M.D., held on August 19, 2010. p. 22-24.

Dr. Shepard was then interviewed a second time by Ms. Farrelly and Carol Palmer on August 30, 2010. His responses to questions regarding the extent of his responsibilities at the clinic, and about why Dr. Brigham needed Dr. Shepard to be present when abortions were being performed, again demonstrate the very limited role that Dr. Shepard had at the Elkton facility:

- Q. Dr. Shepard, could you tell us now, I understand that a car picks you up in Delaware, brings you to Elkton two days a week, if necessary, if there are any procedures to be done, correct?
- A. Correct.
- Q. Okay. Now, can you just walk us through exactly what you

The documents in evidence establish that Dr. Shepard is an 88 year old physician, who is picked up two days a week from his home in Delaware and driven to the Elkton facility. While he is

do once you arrive at the clinic in Elkton.

A. I walk around and I inspect the facility to see if the workers that are supposed to be working there are doing their job. And then I go and check the temperature of the refrigerator and all the places where biologicals are kept. And then I look in the patient area to see if all the instruments, the blood pressure and whatnot, are there and they're functioning, and that there are blankets there for the patients. And that's about the extent of what I do.

. . .

- Q. Okay. And now, you were saying that you go two days a week and that Dr. Brigham was performing, you know, two to three abortions Wednesdays and then two to three on Fridays for about a year by himself. Is that still correct.
- A. When you say "by himself," I'm not sure what you mean.
- Q. Well, is he the one performing the abortions.
- A. Yes.
- Q. Okay. And you also told me that you don't do abortions anymore.
- A. No, I haven't done any for about ten years now.
- Q. Okay. So, now, I guess I'm just trying to figure out why does Dr. Brigham need you to be there while he's performing abortions.
- A. Well, he knows that that I was an obstetrician for about 30,40 years and that you know, if there were any problems, I might be able to give him some idea of what should be done.

Transcript of interview with George Shepard, Jr., M.D., held on August 30, 2010. p. 6, 8-9.

the titular "Medical Director" of the facility, his responsibilities are exceedingly limited. Dr. Shepard has not performed any abortions at the Elkton facility, and Dr. Brigham has conceded in his testimony that Dr. Shepard is present for legal reasons alone. While Dr. Shepard orders medications in his name that are used for pregnancy termination, he could not recall when interviewed the name of any medication he in fact ordered. significantly, there is no suggestion whatsoever in Dr. Shepard's statements that he had any responsibility for care provided to any patient in Elkton, or that he was giving Dr. Brigham the direction, guidance, and information that one would expect to find in a bona fide consultative arrangement.20

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Respondent has offered into evidence two certifications, one from Kimberly Walker, M.D., dated October 7, 2010 (R-20 in evidence) and a second from George Shepard, M.D., dated October 8, 2010 (R-21 in evidence) which include statements suggesting that Dr. Shepard would work "in consultation with Dr. Brigham for services rendered in the Elkton office." Both have described the claimed consultations in very amorphous terms. Ms. Walker states that "Dr. Brigham and Dr. Shepard would engage in medical conversation, ask each other questions and discussion about patient care." Walker Certification, ¶5. She states that Dr. Brigham was "consulting with Dr. Shepard or another Maryland licensed physician at all times while any care was being delivered at the Elkton office." Id., In a statement that is also striking in its absence of any meaningful detail, and seemingly contradicts the statements that Dr. Shepard made when interviewed by a representative of the Maryland Board, Dr. Shepard asserted that "I would consult with Dr. Brigham for all care rendered at the Elkton office, as it was being delivered. Dr. Brigham and I would engage in medical conversation and discussion about patient care." Shepard Certification, ¶ 5.

Given the observations noted above, we are skeptical and unconvinced that any bona fide consultative arrangement existed between Dr. Shepard and Dr. Brigham. We also find Dr. Brigham's claims that any "consultation" that may have occurred would have authorized Dr. Brigham, under Maryland law, to perform second and third trimester abortions without holding a Maryland license, to be incredible.

c. <u>Conclusion</u>

We unanimously conclude that the Attorney General has met her burden of demonstrating that Dr. Brigham's continued practice would present clear and imminent danger to the public health, safety and welfare. The record before the Board demonstrates that Dr. Brigham has consistently and repetitively engaged in manipulative and deceptive behavior designed to circumvent the requirements of the Board's termination of pregnancy regulation. By ignoring the Board's mandates, Dr. Brigham has evidenced a willingness to substitute his judgment for that of the Board on issues related to the health, safety and welfare of women seeking abortions, and has clearly exposed his patients to substantial and real risk of harm.

We find that the very lengths that Dr. Brigham has gone to conceal and "justify" his scheme provide additional support for the conclusion that his continued practice would present clear and imminent danger, and militate against our entry of anything less

Nonetheless, we herein emphasize that we are not seeking to interpret Maryland law - rather, we leave that task to the Maryland Board alone. We stand ready to revisit our decision herein, in part or in full, in the event the Maryland Board concludes that Dr. Brigham's practice in Maryland was lawful, and/or that any consultations that may have occurred between Dr. Brigham and Dr. Shepard were adequate to trigger the exemption for unlicensed practice in Maryland. We are aware that respondent has filed a notice of appeal of the Maryland Order. See Exhibit R-6. We point out, however, that the observations and determinations we have made herein find full support in the swift actions that have thus far been taken by the Maryland Board (following their commencement of an investigation of practices at the Elkton clinic after D.B.'s case came to their attention), to include the Maryland Board's issuance of an Order requiring Dr. Brigham to cease and desist from the unlicensed practice of medicine in that State.

than the full temporary suspension of his license. Dr. Brigham has invented a series of convenient, but simply unbelievable, fictions to support his acts. Those fictions include his present selfserving claims, made in direct contradiction to his prior statements and representations to the Board, that suggest that the injection of digoxin should not be considered to be an act that can only be performed in compliance with the Board's regulatory requirements. They also encompass his claims that he could practice without being licensed in Maryland by engaging in "consultations" with Dr. Shepard, who in turn was unable to recall the names of drugs that were ordered in his name for abortion procedures or to answer a question regarding the effect that the insertion of laminaria would have on a fetus. Dr. Brigham's deceptions extend even to his patients, who are kept uninformed of information as basic as where their procedure would be performed and even, in some instances, the identity of the physician who would be performing the procedure.

Taken together, it is clear that Dr. Brigham has constructed an elaborate sham to allow him to do an end-run around New Jersey's regulatory requirements, and to continue to perform abortions on patients treated in New Jersey without affording those patients the protections that this Board has concluded are necessary. His willingness to do so, and the lengths to which he has gone to further his scheme, manifestly support a conclusion

that his continued practice would present clear and imminent danger.

WHEREFORE, it is on this 4TH day of November, 2010 ORDERED, nunc pro tunc October 13, 2010

The license of respondent Steven Chase Brigham to practice medicine and surgery in the State of New Jersey is temporarily suspended pending the completion of all administrative proceedings in this matter.

NEW JERSEY STATE BOARD OF MEDICAL EXAMINERS

By:

Paul T. Jordan, M.D. Board President

EXHIBIT LIST

Complainant's Exhibits

- P-A Transcript of Interview of D.B., conducted by Christine Farrelly, August 18, 2010.
- P-B Medical Record of D.B., produced by Nicola Riley, M.D. with attached two page note of Dr. Riley addressed "to whom it may concern," dated August 22, 2010.
- P-C Medical Record for patient D.B., produced by Nicola Riley, M.D. on August 23, 2010, in response to request made by Maryland Board of Physicians by letter dated August 20, 2010.
- P-D Medical Record of D.B.'s August 13, 2010 admission to Johns Hopkins Hospital, Baltimore, Maryland.
- P-E Medical Record of D.B.'s August 13, 2010 admission to Union Hospital, Elkton, Maryland.
- P-F Transcript of Interview of George Shepard, Jr., M.D., conducted by Christine Farrelly, August 19, 2010.
- P-G Transcript of Interview of Kimberly Walker, M.D., under oath, conducted by Christine Farrelly, August 23, 2010.
- P-H "Daily Tissue and Regulated medical Waste Log" for Elkton office, July 13, 2010 August 13, 2010; and "Recovery Room Log" for Elkton office, June 23, 2010 August 4, 2010.
- P-I Transcript of Interview of Nicola Riley, M.D., under oath, conducted by Christine Farrelly, August 24, 2010.
- P-J Transcript of Interview of C.B. (mother of D.B.), conducted by Christine Farrelly, August 21, 2010.
- P-K Letter dated September 1, 2010 from Nicola Riley to Jeri Warhaftig, D.A.G., to include Exhibit 1 (Dr. Nicola Riley's abortion log and three page procedure note addendum); Exhibit 2 (copy of D.B.'s medical chart) and Exhibit 3 (copy of Physician Independent Contractor Agreement between American Medical Associates, P.C., ... as well as Virginia Health Group, P.C. and Nicola Irene Riley, M.D., dated July 30, 2010).
- P-L Letter dated June 30, 2010 from Steve Brigham, M.D. to Siobhan B. Krier, D.A.G.

- P-M Cease and Desist Order in the Matter of Steven Chase Brigham, M.D., unlicensed, before the Maryland State Board of Physicians, case numbers 2007-0448, 2010-0304, and 2011-0117, dated August 25, 2010 [note: also in evidence as Exhibit R-5].
- P-N Sworn statement of D.B., dated September 9, 2010.
- P-O Medical Record for S.D., from "Grace Medical Care."
- P-P Medical Record for N.C., from American Medical Associates, P.C.
- P-Q Medical Record for J.P., from "Grace Medical Care."
- P-R Letter dated August 12, 2010 from Steven C. Brigham, M.D. to William Roeder, Executive Director, State Board of Medical Examiners.
- P-RA Undated letter (bearing "receipt stamp " dated November 8, 1999) from Judith I. Gleason, Executive Director of New Jersey State Board of Medical Examiners, to Stuart J. Phillips, Esq. (bearing caption: "Re: In-Office Insertion of Laminaria.") [note: also in evidence as Exhibit P-Z, R-11].
- P-S Medical Record for M.L., from "Grace Medical Care."
- P-T Medical Record of J.P.'s June 11, 2010 admission to Virtua West Jersey Health System, Voorhees, New Jersey.
- P-U Certification of George Shepard, Jr., M.D. dated October 6, 2010. (Exhibits to Certification include copy of transcript of interview of George Shepard, Jr., M.D., conducted by Christine Farrelly, August 19, 2010 [also in evidence as Exhibit P-F]; transcript of interview of George Shepard, Jr., M.D., conducted by Christine Farrelly, August 30, 2010, and information form submitted by Dr. Shepard to Maryland Board of Pharmacy on August 25, 2010.
- P-V Report of Gary R. Brickner, M.D., dated September 21, 2010 and curriculum vitae of Gary R. Brickner, M.D.
- P-W Supplemental Report of Gary R. Brickner, M.D., dated October 12, 2010.
- P-X ADMITTED UNDER SEAL: Two certifications of Investigator Richard J. Lizzano, both dated October 8, 2010, and certification of Investigator Yanis Carreto, dated

October 8, 2010.

- P-Y Letter dated September 29, 2010 from Joseph M. Gorrell, Esq. To Jeri Warhaftig, D.A.G.
- P-Z Letter dated January 26, 1999, from Stuart J. Phillips, Esq., to Judith I. Gleason, Executive Director of New Jersey State Board of Medical Examiners (bearing caption: "RE: Laminaria insertion in the office.").

Letter dated October 21, 1999 from Stuart J. Phillips, Esq., to Judith I. Gleason, Executive Director of New Jersey State Board of Medical Examiners (bearing caption: "RE: 'In Office' Insertion of Laminaria.") [note: also in evidence as Exhibit R-10].

Undated letter (bearing "receipt stamp " dated November 8, 1999) from Judith I. Gleason, Executive Director of New Jersey State Board of Medical Examiners, to Stuart J. Phillips, Esq. (bearing caption: "Re: In-Office Insertion of Laminaria.") [note: also in evidence as Exhibit P-RA, R-11].

Respondent's Exhibits

- R-1 Verified Complaint in the Matter of Steven C. Brigham, filed on November 24, 1993.
- R-2 Order of the New Jersey State Board of Medical Examiners, in the Matter of Steven C. Brigham, filed August 28, 1996 (nunc pro tunc August 14, 1996), BDS 1303-94, 2468-95.
- R-3 Initial Decision of A.L.J. Joseph Fidler in the Matter of Steven C. Brigham, dated April 12, 1996, BDS 1303-94, 2468-95.
- R-4 Cease and Desist Order in the Matter of Steven C. Brigham, M.D., filed September 10, 2010.
- R-5 Cease and Desist Order in the Matter of Steven Chase Brigham, M.D., unlicensed, before the Maryland State Board of Physicians, case numbers 2007-0448, 2010-0304, and 2011-0117, dated August 25, 2010 [note: also in evidence as Exhibit P-M].
- R-6 Notice of Appeal and Request for Case Resolution Conference and Hearing in the Matter of Steven Chase Brigham, signed by Marc K. Cohen, Esq., before the Maryland State Board of Physicians, case number 2011-0017

(undated).

- R-7 Excerpts from Transcript of Trial before the Office of Administrative Law, in the Matter of Steven C. Brigham, dated November 17, 1994 (testimony of Nicholas Kotopoulos, M.D.).
- R-8 Google Maps Directions from 1 Alpha Avenue, Echelon, New Jersey 08043 to 126 East High Street, Elkton, MD 21921, printed 9/21/10.
- R-9 Google Maps Directions from 1 Alpha Avenue, Echelon, New Jersey 08043 to 6930 Austin Street #101, Flushing, New York 11375-4222, printed 9/21/10.
- R-10 Letter dated January 26, 1999, from Stuart J. Phillips, Esq., to Judith I. Gleason, Executive Director of New Jersey State Board of Medical Examiners (bearing caption: "RE: Laminaria insertion in the office.").
 - Letter dated October 21, 1999 from Stuart J. Phillips, Esq., to Judith I. Gleason, Executive Director of New Jersey State Board of Medical Examiners (bearing caption: "RE: 'In Office' Insertion of Laminaria."). [note: also in evidence as Exhibit P-Z].
- R-11 Undated letter (bearing "receipt stamp " dated November 8, 1999) from Judith I. Gleason, Executive Director of New Jersey State Board of Medical Examiners, to Stuart J. Phillips, Esq. (bearing caption: "Re: In-Office Insertion of Laminaria.") [note: also in evidence as Exhibit P-RA, P-Z].
- R-12 Article entitled "Cervical preparation for surgical abortion from 20 to 24 weeks' gestation," printed from http://www.contraceptionjounal.org/article/PIIS00107824 08000310/fulltext on 10/3/2010.
- R-13 Report of Gary L. Mucciolo, M.D., dated October 5, 2010 and curriculum vitae of Gary L. Mucciolo, M.D.
- R-14 Excerpt from Black's Law Dictionary, Seventh Edition (including definition of "abortion").
- R-15 Report of Renga Rajan, M.D. (undated) and curriculum vitae of Renga Rajan, M.D.
- R-16 Letter from Jeri Warhaftig, D.A.G. to Joseph M. Gorrell, dated September 29, 2010.

- R-17 Report of Thomas Westover, M.D., dated October 7, 2010 and curriculum vitae of Thomas Westover, M.D.
- R-18 Letter from Victoria McIntyre, Compliance Analyst for Maryland Board of Physicians, to Steven C. Brigham, dated July 1, 2009 (bearing caption "Re: Case No. 2007-0448).
 - Letter from Marc K. Cohen, Esq. (Maryland counsel for Dr. Brigham) to Victoria McIntyre, Compliance Analyst, dated August 5, 2009 (bearing caption: "Re: Stephen C. Brigham, M.D., Case Number: 2007-0448.").
- R-19 Article entitled "Adequacy and safety of buccal misoprostol for cervical preparation prior to termination of second-trimester pregnancy," printed from http://www.contraceptionjounal.org/article/PIIS00107824 0500421X/fulltext on 10/3/2010.
- R-20 Certification of Kimberly Walker, M.D., dated October 7, 2010.
- R-21 Certification of George Shepard, M.D., dated October 8, 2010.
- R-22 Maryland law 20-209
- R-23 Maryland law 14-302
- R-23 Diagram handdrawn by Renga Rajan, M.D., during testimony offered on October 13, 2010.

In (a)1, substituted "on the premises of the health care facility" for "in the operating suite" at the end; and rewrote (e).

Amended by R.2000 d.66, effective February 22, 2000.

See: 31 N.J.R. 252(a), 32 N.J.R. 710(a).

In (c), added the second through fourth sentences; and in (d) and (f), inserted references to duly qualified certified nurse midwives. Amended by R.2005 d.120, effective April 18, 2005.

See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).

Rewrote (a); in (c), inserted "or a licensed podiatric physician" preceding "may so act" in the first sentence.

Cross References

Physician assistant, assisting surgery, see N.J.A.C. 13:35-2B.1 et seq.

Case Notes

Validity of rule (dissenting opinion). Eatough v. Albano, 673 F.2d 671 (1982) certiorari denied 102 S.Ct. 2931, 457 U.S. 1119, 73 L.Ed.2d 1331.

License revocation for violation of Medical Practice Act upheld; no denial of due process; Board could only impose monetary penalty for each statutory provision violated; additional penalties for multiple violations of each provision improper where physicians had no prior convictions for such offenses. In re Suspension of License of Wolfe, 160 N.J.Super. 114, 388 A.2d 1316 (App.Div.1978) certification denied 78 N.J. 406, 396 A.2d 592 (1978).

Former N.J.A.C. 13:35-7.1 governing the conduct of major surgery upheld as not inconsistent with the Medical Practice Act and as neither arbitrary, capricious, unreasonable nor vague. Garden State Community Hospital v. State Bd. of Medical Examiners, 147 N.J.Super. 592, 371 A.2d 794 (App.Div.1977) certification denied 74 N.J. 283, 377 A.2d 688 (1977).

13:35-4.2 Termination of pregnancy

(a) This rule is intended to regulate the quality of medical care offered by licensed physicians for the protection of the public, and is not intended to affect rules of the Department of Health establishing institutional requirements. To the extent that rules of the two agencies may overlap, the Medical Board recognizes and relies upon the regulatory procedures of the Department of Health in establishing minimum acceptable standards for non-physician personnel, equipment and resources, the adequacy of the physical plant of the facility in which surgical procedures shall be performed, and the facility's interrelationship with

an adequate network of health care-related resources such as ambulance service, etc.

- (b) The termination of a pregnancy at any stage of gestation is a procedure which may be performed only by a physician licensed to practice medicine and surgery in the State of New Jersey.
- (c) Provisions of this rule referring to stage of pregnancy shall be in terms of weeks from start of last menstrual period or "weeks LMP." For example, the stage of pregnancy at 12 weeks' gestational size, as determined by a physician, is the equivalent of 14 weeks from the first day of the last menstrual period (LMP).
- (d) After 14 weeks LMP, any termination procedure other than dilatation and evacuation (D & E) shall be performed only in a licensed hospital.
- (e) Fifteen weeks through 18 weeks LMP: After 14 weeks LMP and through 18 weeks LMP, a D & E procedure may be performed either in a licensed hospital or in a licensed ambulatory care facility (referred to herein as LACF) authorized to perform surgical procedures by the Department of Health. The physician may perform the procedure in an LACF which shall have a Medical Director who shall chair a Credentials Committee. The Committee shall grant to operating physicians practice privileges relating to the complexity of the procedure and commensurate with an assessment of the training, experience and skills of each physician for the health, safety and welfare of the public. A list of the privileges of each physician shall contain the effective date of each privilege conferred, shall be reviewed at least biennially, and shall be preserved in the files of the LACF.
- (f) Nineteen weeks through 20 weeks LMP: A physician planning to perform a D & E procedure after 18 weeks LMP and through 20 weeks LMP in an LACF shall first file with the Board a certification signed by the Medical Director that the physician meets the eligibility standards set forth in (f)1 through 7 below and shall comply with its requirements.

- 1. The physician is certified or eligible for certification by the American Board of Obstetrics-Gynecology or the American Osteopathic Board of Obstetrics-Gynecology, and the physician satisfactorily completes at least 15 hours of Continuing Medical Education each year in obstetrics-gynecology.
- 2. The physician has admitting and surgical privileges at a nearby licensed hospital which has an operating room, blood bank, and an intensive care unit. The hospital shall be accessible within 20 minutes driving time during the usual hours of operation of the clinic.
- 3. The procedure shall be done in a location which is designated by the Department of Health as a licensed ambulatory care facility (LACF) authorized to perform surgical procedures as in subsection (e) above. The LACF shall be licensed by the Department of Health as an ambulatory care facility authorized to perform surgical procedures. The facility shall be in current and good standing at all times when surgical procedures are performed there. The LACF shall have a written agreement with an ambulance service assuring immediate transportation of a patient at all times when a patient has been admitted for surgery and until the patient has been discharged from the recovery room.
- 4. The procedure shall be done in an LACF which shall have a Medical Director and a Credentials Committee which have duly evaluated the training, experience and skill of the physician at continuous and successive levels of complexity of the D & E procedure in pregnancies advancing in stages from 18 weeks LMP through 19 weeks LMP through 20 weeks LMP, and the physician has been granted successive practice privileges consistent with management of the increased risk to the health and safety of the patient at that stage documented in the personnel file maintained for that physician. (Where the applicant physician is also the Medical Director, the physician shall submit a certificate from the Administrator or Chief of Department of a hospital or the Medical Director of an LACF where the applicant has been evaluated and credentialed in a comparable manner.) The physician new to the LACF shall have his or her operating technique evaluated initially and at least yearly by the Medical Director or his or her designee who shall possess appropriate experience with D & E procedures at least as advanced as those for which the applicant physician seeks approval. The applicant shall be evaluated during that number of procedures which shall be adequate to achieve a sufficient professional skill, and the evaluation procedure shall be documented in the personnel file maintained for that physician. The Medical Director shall agree to review the charts of all patients who suffer complications and in addition shall review charts at random, and shall calculate the complication rate of each physician.
- 5. The physician shall perform the procedure only on a patient who has been examined and found to be within

- the eligibility criteria established for advanced D & E procedures in the LACF setting.
- 6. The procedure shall be performed in an LACF providing adequate staff support and resources for the operative procedure as well as interim follow-up and post-operative care, and where a physician is available and readily accessible 24 hours/day to respond to any postoperative problem.
- 7. The physician shall cooperate with the Medical Director to maintain contemporaneous and cumulative statistical records demonstrating the utilization and safety record of each stage procedure and of each surgeon. Said records shall be available for inspection by the Board and copies shall be submitted to the Board semi-annually. These records shall include the following information and data shall be maintained in records compiled monthly, but individual patients comprising the lists shall be identified only by date and by initials and/or case number:
 - i. Number of patients who received termination procedures;
 - ii. Number of patients who received laminaria or osmotic cervical dilators who failed to return for completion of the procedure;
- iii. Number of patients who reported for postoperative visits;
- iv. Number of patients who needed repeat procedures;
 - v. Number of patients who received transfusions;
 - vi. Number of patients suspected of perforation;
- vii. Number of patients who developed pelvic inflammatory disease within two weeks;
- viii. Number of patients who were admitted to a hospital within two weeks of the procedure;
 - ix. Number of patients who died within 30 days.

Subparagraphs ii. through ix. above shall be summarized by number and percentage of monthly total for post-18 week procedures. The Board shall inspect such reports monthly for the first five months and at such further monthly intervals as it deems necessary.

- (g) After 20 weeks: A physician may request from the Board permission to perform D & E procedures in an LACF after 20 weeks LMP. Such request shall be accompanied by proof, to the satisfaction of the Board, of superior training and experience as well as proof of support staff and facilities adequate to accommodate the increased risk to the patient of such procedure.
- (h) The physician shall make suitable arrangements to insure that all tissues removed shall be properly disposed of by submission to a qualified physician for pathologic analysis or by incineration or by delivery to a person/entity licensed

to make biologic and/or tissue disposals in accordance with law including rules of the Department of Health applicable to an LACF.

As amended, R.1984 d.470, effective October 15, 1984. See: 16 N.J.R. 2064(a), 16 N.J.R. 2823(a). Section substantially amended.
Amended by R.1985 d.530, effective October 21, 1985. See: 17 N.J.R. 1865(a), 17 N.J.R. 2562(b), (e) recodified to (f) and new (e) added. New Rule, R.1986 d.25, effective February 3, 1986. See: 17 N.J.R. 2738(a), 18 N.J.R. 286(a), Old rule repealed and new rule added. Amended by R.1986 d.217, effective June 16, 1986. See: 18 N.J.R. 614(a), 18 N.J.R. 1306(b). Substantially amended.
Amended by R.1989 d.532, effective October 16, 1989. See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a). Deleted references to specific statutes and rules.

Case Notes

Preliminary injunction granted against regulation forbidding outpatient facility abortions after 18 weeks gestation or 20 weeks after last menstrual period; history of regulation; finding that plaintiffs likely to succeed in regulatory challenge due to regulation's possible result of causing women to forego their abortion rights if procedure medically acceptable on an outpatient hasis is restricted to hospitals only (citing former regulation and previous codification as N.J.A.C. 13:35-7.2). Pilgrim Medical Group v. New Jersey State Bd. of Medical Examiners, 613 F.Supp. 837 (D.N.J.1985).

Former termination of pregnancy rule N.J.A.C. 13:35–7.2 upheld as properly adopted and reasonably related to maternal health; State has a compelling interest in maternal health after the first trimester of pregnancy so as to validate rules that foster that health. Livingston v. New Jersey State Bd. of Medical Examiners, 168 N.J.Super. 259, 402 A.2d 967 (App.Div.1979) certification denied 81 N.J. 406, 408 A.2d 800 (1979).

Physician's conduct in performing second trimester abortions was found not to constitute gross negligence, malpractice and incompetence; however, charges that physician's advertisements for safe, painless abortions were misleading were upheld. In the Matter of Steven Chase Brigham, 96 N.J.A.R.2d (BDS) 35.

SUBCHAPTER 4A. SURGERY, SPECIAL PROCEDURES, AND ANESTHESIA SERVICES PERFORMED IN AN OFFICE SETTING

13:35-4A.1 Purpose

These rules are designed to promote the health, safety and welfare of the members of the general public who undergo surgery (other than minor surgery), special procedures and receive anesthesia services in an office setting.

13:35-4A.2 Scope

(a) This subchapter establishes policies and procedures and staffing and equipment requirements for practitioners and physicians who perform surgery (other than minor surgery), special procedures and administer anesthesia services in an office setting.

(b) For purposes of this subchapter, the standards set forth at N.J.A.C. 13:35-4A.6 do not apply to those performing non-invasive special procedures, such as non-invasive radiologic procedures. However, the standards set forth at N.J.A.C. 13:35-4A.7, including the privileging standards set forth at (a) above, do apply to the anesthesia services provided in connection with all special procedures, whether invasive or non-invasive.

Amended by R.2002 d.404, effective December 16, 2002. See: 33 N.J.R. 3870(a), 34 N.J.R. 4449(a). Rewrote the section.

Case Note

Regulation promulgated by Board of Medical Examiners regarding the administration of anesthesia in physicians' offices during non-minor surgeries and procedures, which regulation required nurse anesthetists to be supervised by an anesthesiologist, was not arbitrary, capricious, or unreasonable given that anesthesiologists receive more training than nurse anesthetists, even though there was no medical research comparing mortality rates between anesthesiologists and nurses in administering anesthesia in an office setting. New Jersey State Ass'n of Nurse Anesthetists, Inc. v. New Jersey State Bd. of Medical Examiners. 859

13:35-4A.3 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Advanced cardiac life support trained" means that a licensee has successfully completed an advanced cardiac life support course offered by a recognized accrediting organization appropriate to the licensee's field of practice. For example, for those licensees treating adult patients, training in advanced cardiac life support (ACLS) is appropriate; for those treating children, training in pediatric advanced life support (PALS) or advanced pediatric life support (ALPS) is appropriate.

"Anesthesia services" means administration of any anesthetic agent with the purpose of creating conscious sedation, regional anesthesia or general anesthesia. For the purposes of this subchapter, the administration of topical or local anesthesia, minor conduction blocks, pain management or pain medication shall not be deemed to be anesthesia services.

"Anesthesiologist" means a physician who has successfully completed a residency program in anesthesiology approved by the American Council of Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA), or who currently is a diplomate of either the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology, or who was made a Fellow of the American College of Anesthesiology before 1982.

"Anesthetic agent" means any drug or combination of drugs administered with the purpose of creating conscious sedation, regional anesthesia or general anesthesia.

DIRECTIVES APPLICABLE TO ANY MEDICAL BOARD LICENSEE WHO IS DISCIPLINED OR WHOSE SURRENDER OF LICENSURE HAS BEEN ACCEPTED

APPROVED BY THE BOARD ON MAY 10, 2000

All licensees who are the subject of a disciplinary order of the Board are required to provide the information required on the addendum to these directives. The information provided will be maintained separately and will not be part of the public document filed with the Board. Failure to provide the information required may result in further disciplinary action for failing to cooperate with the Board, as required by N.J.A.C. 13:45C-1 et seq. Paragraphs 1 through 4 below shall apply when a license is suspended or revoked or permanently surrendered, with or without prejudice. Paragraph 5 applies to licensees who are the subject of an order which, while permitting continued practice, contains a probation or monitoring requirement.

Document Return and Agency Notification

The licensee shall promptly forward to the Board office at Post Office Box 183, 140 East Front Street, 2nd floor, Trenton, New Jersey 08625-0183, the original license, current biennial registration and, if applicable, the original CDS registration. In addition, if the licensee holds a Drug Enforcement Agency (DEA) registration, he or she shall promptly advise the DEA of the licensure action. (With respect to suspensions of a finite term, at the conclusion of the term, the licensee may contact the Board office for the return of the documents previously surrendered to the Board. In addition, at the conclusion of the term, the licensee should contact the DEA to advise of the resumption of practice and to ascertain the impact of that change upon his/her DEA registration.)

2. Practice Cessation

The licensee shall cease and desist from engaging in the practice of medicine in this State. This prohibition not only bars a licensee from rendering professional services, but also from providing an opinion as to professional practice or its application, or representing him/herself as being eligible to practice. (Although the licensee need not affirmatively advise patients or others of the revocation, suspension or surrender, the licensee must truthfully disclose his/her licensure status in response to inquiry.) The disciplined licensee is also prohibited from occupying, sharing or using office space in which another licensee provides health care services. The disciplined licensee may contract for, accept payment from another licensee for or rent at fair market value office premises and/or equipment. In no case may the disciplined licensee authorize, allow or condone the—use of his/her provider number by any health care practice or any other licensee or health care provider. (In situations where the licensee has been suspended for less than one year, the licensee may accept payment from another professional who is using his/her office during the period that the licensee is suspended, for the payment of salaries for office staff employed at the time of the Board action.)

A licensee whose license has been revoked, suspended for one (1) year or more or permanently surrendered must remove signs and take affirmative action to stop advertisements by which his/her eligibility to practice is represented. The licensee must also take steps to remove his/her name from professional listings, telephone directories, professional stationery, or billings. If the licensee's name is utilized in a group practice title, it shall be deleted. Prescription pads bearing the licensee's name shall be destroyed. A destruction report form obtained from the Office of Drug Control (973-504-6558) must be filed. If no other licensee is providing services at the location, all medications must be removed and returned to the manufacturer, if possible, destroyed or safeguarded. (In situations where a license has been suspended for less than one year, prescription pads and medications need not be destroyed but must be secured in a locked place for safekeeping.)

3. Practice Income Prohibitions/Divestiture of Equity Interest in Professional Service Corporations and Limited Liability Companies

A licensee shall not charge, receive or share in any fee for professional services rendered by him/herself or others while barred from engaging in the professional practice. The licensee may be compensated for the reasonable value of services lawfully rendered and disbursements incurred on a patient's behalf prior to the effective date of the Board action.

A licensee who is a shareholder in a professional service corporation organized to engage in the professional practice, whose license is revoked, surrendered or suspended for a term of one (1) year or more shall be deemed to be disqualified from the practice within the meaning of the Professional Service Corporation Act. (N.J.S.A. 14A:17-11). A disqualified licensee shall divest him/herself of all financial interest in the professional service corporation pursuant to N.J.S.A. 14A:17-13(c). A licensee who is a member of a limited liability company organized pursuant to N.J.S.A. 42:1-44, shall divest him/herself of all financial interest. Such divestiture shall occur within 90 days following the the entry of the Order rendering the licensee disqualified to participate in the applicable form of ownership. Upon divestiture, a licensee shall forward to the Board a copy of documentation forwarded to the Secretary of State, Commercial Reporting Division, demonstrating that the interest has been terminated. If the licensee is the sole shareholder in a professional service corporation, the corporation must be dissolved within 90 days of the licensee's disqualification.

4. Medical Records

If, as a result of the Board's action, a practice is closed or transferred to another location, the licensee shall ensure that during the three (3) month period following the effective date of the disciplinary order, a message will be delivered to patients calling the former office premises, advising where records may be obtained. The message should inform patients of the names and telephone numbers of the licensee (or his/her attorney) assuming custody of the records. The same information shall also be disseminated by means of a notice to be published at least once per month for three (3) months in a newspaper of

general circulation in the geographic vicinity in which the practice was conducted. At the end of the three month period, the licensee shall file with the Board the name and telephone number of the contact person who will have access to medical records of former patients. Any change in that individual or his/her telephone number shall be promptly reported to the Board. When a patient or his/her representative requests a copy of his/her medical record or asks that record be forwarded to another health care provider, the licensee shall promptly provide the record without charge to the patient.

5. Probation/Monitoring Conditions

With respect to any licensee who is the subject of any Order imposing a probation or monitoring requirement or a stay of an active suspension, in whole or in part, which is conditioned upon compliance with a probation or monitoring requirement, the licensee shall fully cooperate with the Board and its designated representatives, including the Enforcement Bureau of the Division of Consumer Affairs, in ongoing monitoring of the licensee's status and practice. Such monitoring shall be at the expense of the disciplined practitioner.

- (a) Monitoring of practice conditions may include, but is not limited to, inspection of the professional premises and equipment, and Inspection and copying of patient records (confidentiality of patient identity shall be protected by the Board) to verify compliance with the Board Order and accepted standards of practice.
- (b) Monitoring of status conditions for an impaired practitioner may include, but is not limited to, practitioner cooperation in providing releases permitting unrestricted access to records and other information to the extent permitted by law from any treatment facility, other treating practitioner, support group or other individual/facility involved in the education, treatment, monitoring or oversight of the practitioner, or maintained by a rehabilitation program for impaired practitioners. If bodily substance monitoring has been ordered, the practitioner shall fully cooperate by responding to a demand for breath, blood, urine or other sample in a timely manner and providing the designated sample.

NOTICE OF REPORTING PRACTICES OF BOARD REGARDING DISCIPLINARY ACTIONS

Pursuant to N.J.S.A. 52:14B-3(3), all orders of the New Jersey State Board of Medical Examiners are available for public inspection. Should any inquiry be made concerning the status of a licensee, the inquirer will be informed of the existence of the order and a copy will be provided if requested. All evidentiary hearings, proceedings on motions or other applications which are conducted as public hearings and the record, including the transcript and documents marked in evidence, are available for

Pursuant to 45 CFR Subtitle A 60.8, the Board is obligated to report to the National Practitioners Data Bank any action relating to a physician which is based on reasons relating to professional competence (1)

- Which revokes or suspends (or otherwise restricts) a license, (2)
- Which censures, reprimands or places on probation,
- Under which a license is surrendered. (3)

Pursuant to 45 CFR Section 61.7, the Board is obligated to report to the Healthcare Integrity and Protection (HIP) Data Bank, any formal or official actions, such as revocation or suspension of a license(and the length of any such suspension), reprimand, censure or probation or any other loss of license or the right to apply for, or renew, a license of the provider, supplier, or practitioner, whether by operation of law, voluntary surrender, non-renewability, or otherwise, or any other negative action or finding by such Federal or State agency that is publicly available information.

Pursuant to N.J.S.A. 45:9-19.13, if the Board refuses to issue, suspends, revokes or otherwise places conditions on a license or permit, it is obligated to notify each licensed health care facility and health maintenance organization with which a licensee is affiliated and every other board licensee in this state with whom he or she is directly associated in private medical practice.

In accordance with an agreement with the Federation of State Medical Boards of the United States, a list of all disciplinary orders are provided to that organization on a monthly basis.

Within the month following entry of an order, a summary of the order will appear on the public agenda for the next monthly Board meeting and is forwarded to those members of the public requesting a copy. In addition, the same summary will appear in the minutes of that Board meeting, which are also made available to those requesting a copy.

Within the month following entry of an order, a summary of the order will appear in a Monthly Disciplinary Action Listing which is made available to those members of the public requesting a copy.

On a periodic basis the Board disseminates to its licensees a newsletter which includes a brief

From time to time, the Press Office of the Division of Consumer Affairs may issue releases including the summaries of the content of public orders.

Nothing herein is intended in any way to limit the Board, the Division or the Attorney General from