IN THE MATTER OF	*	**BEFORE THE**
RALPH B. EPSTEIN, M.D.	*	**MARYLAND STATE**
Respondent	*	**BOARD OF PHYSICIANS**
License Number: D08249	*	**Case Number: 2014-0759B**

* * * * * * * * * * * *

CONSENT ORDER

PROCEDURAL BACKGROUND

On August 20, 2015, Disciplinary Panel B ("Panel B") of the Maryland State Board of Physicians (the "Board") charged **RALPH B. EPSTEIN, M.D.** (the "Respondent"), License Number D08249, with violating the probationary conditions imposed under the Consent Order, dated April 9, 2014/Order Terminating Suspension and Imposing Probation, dated May 19, 2014; and with violating the Maryland Medical Practice Act (the "Act"), Md. Code Ann., Health Occ. II ("Health Occ. II") §§ 14-101 *et seq.* (2009 and 2014 Repl. Vols.).

Specifically, Panel B charged the Respondent with violating the following probationary condition of the Consent Order, dated April 9, 2014 and the Order Terminating Suspension and Imposing Probation, dated May 19, 2014:

Condition No. 2

> The Respondent shall practice according to the Maryland Medical Practice Act, the Maryland Pharmacy Act and in accordance with all applicable laws, statutes, and regulations pertaining to the practice of medicine and pharmacy[.]

Panel B also charged the Respondent with violating the following provision of the Act under Health Occ. II § 14-404(a):

> (3) Is guilty of: (ii) unprofessional conduct in the practice of medicine[.]

On December 16, 2015, the Respondent appeared before Panel B. As a result of negotiations and presentations occurring before Panel B, the Respondent agreed to enter into the following Consent Order to resolve the above-stated charges.

FINDINGS OF FACT

Panel B makes the following Findings of Fact:

I. BACKGROUND/LICENSURE INFORMATION

1. At all times relevant hereto, the Respondent was licensed to practice medicine in the State of Maryland. The Respondent was originally licensed to practice medicine in Maryland on August 3, 1970, under License Number D08249.

2. The Respondent entered into a Consent Order with the Board, dated April 9, 2014, in which it suspended his license for 30 days, commencing on or about April 19, 2014. *See* ¶ 29-31, *infra*. Pursuant to an Order Terminating Suspension and Imposing Probation, dated May 19, 2014, the Board lifted the suspension of his license and placed him on probation for a minimum period of three years, subject to a series of probationary conditions. *See* ¶ 32, *infra*. The Respondent's license is currently active through September 30, 2016.

3. The Respondent is board-certified in obstetrics and gynecology.

4. At all times relevant hereto, the Respondent maintained medical offices at the following locations: 23 Crossroads Drive, Suite 215, Owings Mills, Maryland 21117; and 9110 Philadelphia Road, Suite 108, Rosedale, Maryland 21237.

II. PRIOR DISCIPLINARY HISTORY

CONSENT ORDER, DATED OCTOBER 1, 2007

5. In or around May 2005, a Baltimore-area hospital notified the Board that it suspended the Respondent's medical staff privileges and imposed other restrictions on his hospital privileges after its investigation concluded that he performed a surgical procedure (a panniculectomy, commonly referred to as a "tummy tuck") on a patient that he was not credentialed to perform; accepted payment from the patient with foreknowledge that the procedure he intended to perform was rejected by the insurer for coverage; failed to name the procedure when posting the patient for surgery; failed to obtain proper informed consent; deliberately failed to dictate the procedure into the operative note; and allowed the hospital to bill the insurer for operative time for the non-covered procedure, thereby potentially exposing the hospital to the charge of insurance fraud.

6. The Board investigated this matter and the Respondent's involvement in additional instances of similar misconduct on or about May 10, 2007. As a result, the Board charged him under Board Case Number 2005-0861 with violating provisions of the Act.

7. The Respondent resolved these charges by entering into a Consent Order with the Board, dated October 1, 2007, in which the Board found that the Respondent violated the following provisions of the Act: Is guilty of unprofessional conduct in the practice of medicine, in violation of Health Occ. § 14-404(a)(3)(ii); Fails to meet appropriate standards as determined by appropriate peer review for the delivery of quality medical and surgical care, in violation of Health Occ. § 14-404(a)(22); and Fails

to keep adequate medical records as determined by appropriate peer review, in violation of Health Occ. § 14-404(a)(40).

8. The Board reprimanded the Respondent and placed him on probation for two years, subject to several probationary conditions, including requiring training in medical ethics.

9. In addition, the Board imposed the following conditions in the Consent Order:

> **ORDERED** that the Respondent shall comply with all laws governing the practice of medicine under the Maryland Medical Practice Act and all rules and regulations promulgated thereunder;
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> * * *
>
> **ORDERED** that if the Respondent violates any of the terms of this Order including an unsatisfactory peer review or chart review, the Board may, after notice and an opportunity for a hearing, impose any sanction that the Board may have imposed in this case including probation, a reprimand, suspension, revocation and/or a monetary fine[.]

Consent Order, dated October 1, 2007, pp. 22-23.

10. The Respondent did not petition the Board for termination of his probation after the conclusion of his two year probationary period. As a result, the Respondent remained on probation with the Board.

CONSENT ORDER, DATED NOVEMBER 14, 2012

11. The Board initiated an investigation of the Respondent based on a complaint from several former employees who alleged that he engaged in various unethical practices, including, *inter alia*, ordering non-FDA approved intrauterine devices ("IUDs") through the Internet from Canada but billing for FDA-approved IUDs at a higher rate of reimbursement than the actual purchase price for these non-FDA approved IUDs.

12. As part of its investigation, the Board requested that Permedion, Inc. ("Permedion") perform a peer review of the Respondent's practice. This review determined that the Respondent failed to meet appropriate standards for the delivery of quality medical and surgical standards in one case and failed to keep adequate medical records in three cases.

13. The Board's investigation concerning the Respondent's use of non-FDA approved IUDs in fifteen patients determined that beginning in or around early 2009, he directed his office staff to order non-FDA approved IUD devices through the Internet from Canada. The Respondent's office staff placed him on notice that the devices in question were not FDA-approved. Despite being placed on notice that the IUDs were not FDA-approved, the Respondent instructed his staff to order them anyway.

14. The Respondent then inserted these non-FDA approved IUDs in at least 15 patients from February through July 2009, without informing them at the time of implantation that the devices were not FDA-approved.

15. The Respondent submitted billings to the patients' insurance companies in which he represented that he implanted FDA-approved IUDs, and billed for implanting FDA-approved devices at a level of reimbursement that was consistent with the cost of FDA-approved devices, even though he purchased the devices for a cost that was significantly lower than for what was billed.

16. On or about May 28, 2010, the Respondent reimbursed his patients' insurance companies for "overpayment to Dr. Ralph Epstein for services rendered for the insertion of an IUD which was later determined to be a non-FDA approved IUD." Board investigation determined that the Respondent was aware that he had inserted

non-FDA approved IUDs in patients and had billed the patients' insurance companies for implanting FDA-approved IUDs, but did not reimburse the insurance companies for at least one year afterwards.

17. The Board found that the Respondent inappropriately implanted non-FDA approved IUDs in patients; misrepresented in his patients' medical records that he implanted FDA-approved IUDs when in fact, he implanted non-FDA approved IUDs; misrepresented to his patients' insurance companies that he implanted FDA-approved IUDs when in fact, he implanted non-FDA approved IUDs; inappropriately billed his patients' insurance companies for implanting FDA-approved IUDs when in fact, he implanted non-FDA approved IUDs; failed to notify his patients in a timely manner that he implanted non-FDA approved IUDs; failed to develop an appropriate and timely plan to notify his patients that he implanted non-FDA approved IUDs; failed to develop and implement an appropriate plan to address his implantation of non-FDA approved IUDs in his patients; and failed to provide timely reimbursement to his patients' insurance companies after billing them and receiving reimbursement for implanting FDA-approved IUDs when in fact, he implanted non-FDA approved IUDs.

18. On or about May 9, 2012, the Board charged the Respondent under Case Numbers 2005-0861, 2009-0661 and 2010-0635 with violating the Consent Order, dated October 1, 2007, and for violating disciplinary provisions of the Act.

19. The Respondent resolved these disciplinary charges by entering into a Consent Order with the Board, dated November 14, 2012.

20. Pursuant to the Consent Order, the Board found as a matter of law that the Respondent's actions constituted a violation of the following provisions of the Act: Is

guilty of unprofessional conduct in the practice of medicine, in violation of Health Occ. § 14-404(a)(3)(ii); Willfully makes or files a false report or record in the practice of medicine, in violation of Health Occ. § 14-404(a)(11); and Willfully submits false statements to collect fees for which services are not provided, in violation of Health Occ. § 14-404(a)(23).

21. The Board also found as a matter of law that the Respondent violated the terms and conditions of the Consent Order, dated October 1, 2007. The Respondent violated the Consent Order by: (a) undergoing a peer review that yielded unsatisfactory findings, where it was determined that he failed to meet appropriate standards for the delivery of quality medical and surgical care and failed to keep adequate medical records; (b) by failing to comply with the laws governing the practice of medicine under the Act when he underwent a peer review that determined that he failed to meet appropriate standards for the delivery of quality medical and surgical care and failed to keep adequate medical records, in violation of the Act; and (c) by implanting non-FDA approved IUDs in patients.

22. The Respondent violated the terms and conditions of the Consent Order by violating the following provisions of the Act: Is guilty of unprofessional conduct in the practice of medicine, in violation of Health Occ. § 14-404(a)(3)(ii); Willfully makes or files a false report or record in the practice of medicine, in violation of Health Occ. § 14-404(a)(11); Fails to meet appropriate standards as determined by appropriate peer review for the delivery of quality medical and surgical care performed in an outpatient surgical facility, office, hospital, or any other location in this State, in violation of Health Occ. § 14-404(a)(22); Willfully submits false statements to collect fees for which

services are not provided, in violation of Health Occ. § 14-404(a)(23); and Fails to keep adequate medical records as determined by appropriate peer review, in violation of Health Occ. § 14-404(a)(40).

23. Pursuant to the terms of the Consent Order, the Board reprimanded the Respondent and ordered him to remain on probation pursuant to Case Number 2005-0861 for a minimum period of two years, subject to a series of probationary conditions, including the following:

> 4. The Respondent shall practice according to the Maryland Medical Practice Act and in accordance with all applicable laws, statutes, and regulations pertaining to the practice of medicine;

Consent Order, dated November 14, 2012, p. 16.

Consent Order, dated April 9, 2014/Order Terminating Suspension and Imposing Probation, dated May 19, 2014

24. The Board initiated an investigation of the Respondent after receiving a complaint, dated May 14, 2013, from a former employee who alleged that the Respondent acted improperly when placing an IUD in a patient on May 14, 2013.

25. Board investigation determined that on May 14, 2013, the Respondent: implanted a non-FDA approved Mirena IUD in the patient, without her knowledge or consent; failed to inform her that he implanted a non-FDA approved IUD; billed her insurance company for implanting an intrauterine copper device that was not approved for use in the United States; altered her medical record by removing the Mirena IUD sticker and replacing it with a NovaSure sticker; and willfully made material misrepresentations in her chart regarding the IUD he implanted. Board investigation

also determined that the Respondent did not place the correct serial number for the IUD he implanted in the patient.

26. While investigating the above allegations, Board staff investigated the Respondent's medication dispensing practices and administration of medications to patients.

27. Board investigation determined that the Respondent provided bariatric treatment to patients at his Owings Mills and Rosedale offices from in or around 2010 onward, during which time he dispensed the drug phentermine without a valid dispensing permit and violated State and federal laws and regulations when dispensing phentermine and administering other medications, including diazepam, for in-office procedures.

28. On or about December 12, 2013, the Board charged the Respondent with violating disciplinary charges under the Act and with violating the probationary conditions imposed under the Consent Orders, dated October 1, 2007, and November 14, 2012.

29. The Respondent resolved these charges by entering into a Consent Order with the Board, dated April 9, 2014. Pursuant to the Consent Order, the Board found as a matter of law that the Respondent violated the following provisions of the Act: Fraudulently or deceptively uses a license, in violation of Health Occ. § 14-404(a)(2); Is guilty of: (ii) Unprofessional conduct in the practice of medicine, in violation of Health Occ. § 14-404(a)(3)(ii); Willfully makes or files a false report or record in the practice of medicine, in violation of Health Occ. § 14-404(a)(11); Willfully fails to file or record any medical report as required under law, willfully impedes or obstructs the filing or

recording of the report, or induces another to fail to file or record the report, in violation of Health Occ. § 14-404(a)(12); Makes a willful misrepresentation in treatment, in violation of Health Occ. § 14-404(a)(17); Willfully submits false statements to collect fees for which services are not provided, in violation of Health Occ. § 14-404(a)(23); and Fails to comply with the provisions of § 12-102 of this article, in violation of Health Occ. § 14-404(a)(28).

30. The Board also found that the Respondent's actions constituted a violation of probationary conditions set forth in the Consent Order, dated October 1, 2007, and November 14, 2012.

31. Pursuant to the Consent Order, the Board suspended the Respondent's medical license for thirty (30) days, to commence ten days after the date the Board executed the Consent Order (April 9, 2014), after which it placed him on probation for a minimum period of three years, subject to a series of probationary conditions, which included but were not limited to the following:

> Condition No. Two (2)
>
> The Respondent shall practice according to the Maryland Medical Practice Act, the Maryland Pharmacy Act and in accordance with all applicable laws, statutes, and regulations pertaining to the practice of medicine and pharmacy[.]

32. Pursuant to an Order Terminating Suspension and Imposing Probation dated May 19, 2014, the Board terminated the suspension imposed above and placed the Respondent on probation for a minimum period of three years, subject to a series of probationary conditions that were set forth in the Consent Order referenced in ¶ 29-31 above, including Condition No. Two (2) above.

V. BOARD INVESTIGATIVE FINDINGS

33. The Board initiated an investigation of the Respondent under Board Case Number 2014-0759B after receiving a complaint on April 2, 2014, from a former employee (the "Complainant")[1] of the Respondent. The Complainant worked in the Respondent's office from in or around May 2013 until in or around March 2014. The Complainant reported concerns about the Respondent, whom she stated was not practicing proper hand hygiene or appropriately maintaining/storing patient records. The Complainant stated that she observed that the Respondent performed some pelvic/vaginal examinations without using gloves. The Complainant also stated that in some instances, the Respondent did not wash his hands before or after performing examinations on patients. The Complainant also reported that the Respondent had his former office manager store his patient records in an off-site location, the basement of her personal residence.

34. Board investigators interviewed a series of the Respondent's employees who worked for him at various times from 2007 through 2014. These employees included medical assistants, chaperones and other office personnel. The Respondent's former office personnel reported numerous instances where he: failed to use gloves during his performance of pelvic/vaginal examinations; failed to wash his hands before or after examining patients and otherwise failed to employ appropriate hand hygiene methods or protocols; and failed to undertake appropriate decontamination of office surfaces.

[1] To ensure confidentiality, the names of complainants, patients or other individuals have not been disclosed in this document. The Respondent is aware of the identity of all complainants, patients and individuals referenced herein.

35. Board investigators also interviewed the Respondent, who denied engaging in improper hand hygiene practices. The Respondent stated that although during certain pelvic examinations he used only one glove, he stated that the second, ungloved hand did not come in contact with bodily fluids.

36. Based on this information received, the Board's investigation determined that the Respondent is guilty of unprofessional conduct in the practice of medicine, in violation of Health Occ. II § 14-404(a)(3)(ii), in that: he failed to wear gloves during pelvic examinations or used only one glove during such examinations; he performed pelvic/vaginal examinations using an ungloved hand; when performing pelvic/vaginal examinations without proper use of gloves, he contaminated his instrument drawer by reaching into the drawer to take out instruments; he performed pelvic/vaginal examinations during which time he failed to undertake proper decontamination efforts after his patients' bodily fluids contaminated the instrument drawer; he inserted one or more intrauterine devices ("IUDs") without using gloves or without the proper use of gloves; before and after some patient examinations, which included pelvic/vaginal examinations, he failed to wash his hands; he examined patients without employing proper hand hygiene; and he otherwise failed to use proper hand hygiene when examining patients or performing procedures on patients.

37. The Board retained an expert physician to evaluate the Respondent's hand hygiene and record storage practices. With respect to the Respondent's hand hygiene practices, the Expert stated,

> I believe the Respondent was engaged in unprofessional conduct in the practice of medicine in violation of Health Occ. 14-404 by failing to use hand hygiene to protect against infections.

> The witnessed details and specifics of lack of hand hygiene and appropriate glove use is overwhelming from the Respondent's former longtime employee dating back to 2010/11 to recent medical assistants during routine exams and minor in office procedures. I believe the use of one gloved hand, as the Respondent admits to using in his practice, presents a challenge in completely examining the external female genitalia and placing a speculum to visualize internal tissues. It is nearly impossible to maintain good hygiene when only one gloved hand is used during pelvic examinations. The fact that the Respondent's patients noticed him not wash his hands, make comments as to whether or not he wore gloves during an exam, and questioned odors from his hands further points to violations in his practice of medicine.

38. Board investigators also interviewed the Respondent's office manager, who reported that the Respondent stored approximately 30 boxes of patient records, each containing 30 to 50 patient records, in her basement from in or around 2012 to in or around 2014. These records primarily involved patient charts from prior to 2008. The office manager reported that the area of her house where the Respondent stored the records, her basement, was not a secured location, and that other individuals had access to such records. Board investigators personally observed the Respondent's records at his office manager's house.

39. In an interview with Board investigators, the Respondent confirmed that he did store patient medical records at his office manager's house in her basement. The Respondent further stated that in his belief, his storage of his records under these circumstances was secure.

40. The Board's investigation determined that the Respondent is guilty of unprofessional conduct in the practice of medicine, in violation of Health Occ. II § 14-404(a)(3)(ii), in that he inappropriately stored medical records at an off-site location,

failed to verify their confidentiality and security, and otherwise failed to maintain appropriate security for the medical records stored.

41. With respect to the Respondent's maintenance of medical records, the Board's expert stated,

> In the matter of maintaining medical records in a secure and confidential manner, the Respondent had charts from 2008 and prior stored in his basement and that of a former employee. He could not verify if the storage area was locked and that no one else had access to the records in the employee's home. For records stored in this capacity, the security and confidentiality could not be verified and this practice presented a deviation in national standards to protect individuals' health information through HIPAA.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, Panel B finds as a matter of law that the Respondent violated the following provisions of the Act: Health Occ. II § 14-404(a)(3), Is guilty of: (ii) Unprofessional conduct in the practice of medicine; and the terms and conditions of probation of the Consent Order, dated April 9, 2014/Order Terminating Suspension and Imposing Probation, dated May 19, 2014.

ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law, it is, by a majority of the quorum of Panel B considering this case, hereby:

ORDERED that the Respondent is hereby **REPRIMANDED**; and it is further

ORDERED that the Respondent is placed on probation for a minimum period of **TWO (2) YEARS**,[2] and continuing until he successfully completes the following probationary terms and conditions:

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[2] The probationary periods ordered in previous orders that the Respondent had agreed to are superseded by the minimum two year period of probation ordered in this Consent Order. Additionally, this Consent Order goes into effect upon the signature of the Board's Executive Director.

1. Within six (6) months, the Respondent shall pay a civil fine in the amount of **FIVE THOUSAND ($5000.00)**, by certified check or money order, payable to the Maryland Board of Physicians, P.O. Box 37217, Baltimore, Maryland 21297;

2. Within one (1) year, the Respondent, at his own expense, shall enroll in and successfully complete at least forty (40) hours of Panel B-approved coursework in Centers for Disease Control and Prevention guidelines on universal precautions and/or courses in appropriate professional office/personal hygiene practices. This coursework shall not be internet-based but shall involve personal didactic instruction, and shall consist of not less than thirty (30) hours of instruction. The Respondent shall submit written documentation to Panel B regarding the particular coursework he proposes to fulfill the condition. Panel B reserves the right to require the Respondent to provide further information regarding the coursework he proposes, and further reserves the right to reject his proposed coursework and require submission of an alternative proposal. Panel B will approve a coursework only if it deems the curriculum and the duration of the coursework adequate to satisfy its concerns. The Respondent shall be responsible for submitting written documentation to Panel B of his successful completion of the coursework. The Respondent understands and agrees that he may not use the coursework to fulfill any requirements mandated for licensure renewal. The Respondent shall be solely responsible for furnishing Panel B with adequate written verification that he has completed the coursework according to the terms set forth herein;

3. The Respondent shall follow and abide by all Centers for Disease Control and Prevention guidelines on universal precautions and all applicable guidelines on professional hygiene practices;

4. The Respondent shall maintain his medical records in a secure fashion, in compliance with all federal and State laws;

5. The Board reserves the right to conduct random or scheduled inspections of any practice locations or health care facilities where the Respondent practices medicine to determine if he is: (a) in compliance with all applicable Centers for Disease Control and Prevention standards on universal precautions and appropriate professional office/personal hygiene practices; and (b) maintaining his office records in a secure manner and in compliance with all applicable federal and State laws; and

6. The Respondent shall comply with the Maryland Medical Practice Act and all laws, statutes and regulations pertaining to the practice of medicine.

AND IT IS FURTHER ORDERED that after the conclusion of the entire two (2) year period of probation, the Respondent may file a written petition to the Board requesting termination of his probation. After consideration of his petition, the probation may be terminated through an order of Panel B or the Board. The Respondent may be required to appear before Panel B or the Board. Panel B, or the Board, will grant the termination if the Respondent has fully and satisfactorily complied with all of the probationary terms and conditions of this Consent Order, including the expiration of the two (2) year period of probation, and if there are no outstanding complaints related to the charges before Panel B; and it is further

ORDERED that if the Respondent violates any of the terms or conditions of this Consent Order or of probation, Panel B, or the Board, in its discretion, after notice and an opportunity for a hearing before an administrative law judge at the Office of Administrative Hearings if there is a genuine dispute as to the underlying material facts,

or an opportunity for a show cause hearing before Panel B, or the Board, may impose any other disciplinary sanctions a disciplinary panel or the Board may have imposed, including a reprimand, probation, suspension, revocation and/or a monetary fine, said violation being proven by a preponderance of the evidence; and it is further

ORDERED that the Respondent shall not apply for early termination of probation; and it is further

ORDERED that the Respondent shall be responsible for all costs incurred in fulfilling the terms and conditions of the Consent Order; and it is further

ORDERED that the Consent Order is considered a **PUBLIC DOCUMENT** pursuant to Md. Code Ann., General Provisions §§ 4-101 *et seq.* (2014).

01/21/2016
Date

Christine A. Farrelly
Christine A. Farrelly, Executive Director
Maryland State Board of Physicians

CONSENT

I, Ralph B. Epstein, M.D., acknowledge that I have had the opportunity to consult with counsel before signing this document. By this Consent, I agree and accept to be bound by this Consent Order and its conditions and restrictions. I waive any rights I may have had to contest the Findings of Fact, Conclusions of Law and Order.

I acknowledge the validity of this Consent Order as if entered into after the conclusion of a formal evidentiary hearing in which I would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on my own behalf, and to all other substantive and procedural protections as provided by law. I

acknowledge the legal authority and the jurisdiction of Disciplinary Panel B to initiate these proceedings and to issue and enforce this Consent Order. I also affirm that I am waiving my right to appeal any adverse ruling of Disciplinary Panel A that might have followed any such hearing.

I sign this Consent Order after having had an opportunity to consult with counsel, without reservation, and I fully understand and comprehend the language, meaning and terms of this Consent Order. I voluntarily sign this Order, and understand its meaning and effect.

1/14/2016.
Date

Ralph B. Epstein, M.D.
Respondent

Read and approved as to form:

Brian R. Bregman, Esquire
Counsel for Dr. Epstein

NOTARY

STATE OF Maryland

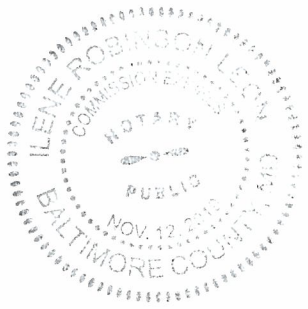
CITY/COUNTY OF: Baltimore

I HEREBY CERTIFY that on this 14th day of January, 2016, before me, a Notary Public of the State and County aforesaid, personally appeared **Ralph B. Epstein, M.D.**, and gave oath in due form of law that the foregoing Consent Order was his voluntary act and deed.

AS WITNESS, my hand and Notary Seal.

Ilene Robinson Leon

Notary Public



My commission expires: November 12, 2019