OFFEL OF THE SECRETARY

FOURTEENTH CONGRESS OF THE REPUBLIC)
OF THE PHILIPPINES
)
First Regular Session
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SENATE S. No. <u>1734</u>

Introduced by Senator Miriam Defensor Santiago

EXPLANATORY NOTE

The movement of health care services away from traditional inpatient facilities to outpatient settings has escalated the volume of surgery and other invasive procedures being performed in the private offices and facilities. While the majority of these services are provided in a safe and effective manner, the complexity of services and procedures being performed in private practitioners' offices is increasing at unprecedented levels.

While surgery and other invasive and minor procedures performed in Philippine medical facilities, such as hospitals, diagnostic centers, and treatment centers, are regulated by the respective professional Boards (Board of Medicine, Board of Dentistry, etc.) to which the practitioner who performed the operation belongs, the same procedures performed in private medical or dental offices and clinics, cosmetic and facial care centers, spas, and other health facilities are not subject to similar regulatory standards, regardless of the scope or complexity of the procedure. The facility itself where the surgery is performed is not subject to the same regulation as hospitals, diagnostic centers, and treatment centers which must be licensed by the Department of Health.

This bill seeks to correct the unregulated performance of surgery and other invasive procedures and minor procedures in a location other than a hospital, diagnostic center, and treatment center. Thus, the performance of such procedures should be restricted only to licensed practitioners, and the location where such procedure is to be performed only to licensed facilities.*

MIRIAM DEFENSOR SANTIAGO

^{*} This bill was originally filed during the Thirteenth Congress, Second Regular Session.

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FOURTEENTH CONGRESS OF THE REPUBLIC) OF THE PHILIPPINES) First Regular Session)

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AN ACT TO REGULATE OFFICE-BASED INVASIVE PROCEDURES

Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled:

SECTION 1. Short Title. – This Act shall be known as the "Regulation of Office-Based Surgical Procedures Act of 2007."

SECTION 2. *Purpose*. – The purpose of this Act is to regulate the performance of surgery as well as cosmetic, dental and other invasive and minor procedures in private offices, clinics, and other cosmetic and facial care centers, spas, health facilities and other establishments.

SECTION 3. Definition of Terms. – For the purposes of this Act, the term:

- (A) "Office-based surgery" means surgical or other invasive procedure requiring anesthesia, analgesia or sedation including, but not limited to, cosmetic surgery including face lifts, nose lifts, chin lifts, tummy tucks, breast augmentation, and breast reduction; laser surgery; plastic and reconstructive surgery; and tumescent and high-volume liposuction on any part of the body, which is performed by a practitioner in a location other than a hospital, diagnostic center, and treatment center which results in a patient stay of less than twenty-four (24) consecutive hours.
- (B) "Minor procedures" are those that can be performed safely, requiring local or topical anesthesia with a minimum of discomfort, and where the likelihood of complications requiring hospitalization is minimal by current best practice experience. Such minor procedures include, but are not limited to, cosmetic tattooing, Clostridium botulinum

bacterium (Botox)	injections, collagen injections,	and the injection of any foreign
substance into any part of the body.		

- (C) "Practitioner' means either a physician, dentist, nurse or other health care practitioner licensed by the Professional Regulation Commission (PRC), who is engaged in the performance of office-based and minor procedures, either in a primary, contributing or assisting capacity, and whose professional practice is subject to review by their respective professional Boards.
- (D) "Unlicensed personnel" means the members of the staff and any other individuals employed by or affiliated with the practitioner, including contract.

SECTION 4. Who Can Perform Surgery and Other Invasive and Minor Procedures. – It shall be unlawful for any person who is not a licensed practitioner to perform any surgery or any invasive or minor procedure, or to contribute thereto by way of administering any anesthesia, analgesia, or in any way sedate the patient. It shall likewise be unlawful for any licensed practitioner to perform surgery or any invasive or minor procedure which he or she is not licensed to perform.

SECTION 5. Duties of Unlicensed Personnel. – It shall be unlawful for any person, being unlicensed personnel of the practitioner, to perform any duty, task or responsibility that requires a license to perform.

Duties that do not require professional licensure and are assigned to unlicensed personnel should be in accordance with their training, education and experience and under the direct supervision of a practitioner.

SECTION 6. Where the Surgery and Other Invasive and Minor Procedures Can Be Performed. – It shall be unlawful to perform any surgery or other invasive or minor procedure in an office, clinic, center, facility or other establishment that does not conform to all the following requirements:

(A) The premises in which the surgery is undertaken shall be licensed and registered under the Department of Health.

(B) All equipment in the said facility shall be properly maintained and calibrated.

- 2 (C) There shall be dated and documented procedures within the facility for the use of all surgical and clinical equipment. These must be reviewed annually.
 - (D) All staff using surgical and clinical equipment shall have completed a training program in the safe clinical use of the said equipment, and have demonstrated and documented competence to personnel licensed by the Department of Health to conduct such training programs.
 - (E) A backup power supply shall be available and readily accessible by the facility in case of power failure during a procedure.
 - SECTION 7. Information for Patients. There shall be made available to patients the following information:
 - (A) A price list of procedures and should be explicit about what is and is not included in the quoted fees. Such price list should also give details about payments of deposits, their refund, and any penalty which may be incurred by cancellation.
 - (B) A description of the procedure they wish to be performed on them which must be written in concise, plain non-technical language. Such information shall eligibility criteria for patients; treatment options including relative advantages and disadvantages; general and procedure-specific risks and complications associated with the procedure, their frequency, management course and possible outcomes; and statistical information regarding the probability of achieving the desired goal or probability of needing more than one procedure.
 - (C) The qualifications of the practitioners, including the specific office-based surgical or invasive procedures and anesthesia services which each practitioner is qualified and competent to perform, and the licensure, accreditation, training and experience relevant to the procedure to be performed. For medical practitioners, board certification or completion of a training program qualified to lead to board certification; for other practitioners, certification that is appropriate and applicable for

the practitioner. The practitioner should also include his or her professional misconduct and malpractice history.

SECTION 8. Follow-up Care. – The professional who performed the procedure shall be personally responsible for patient care. He or she must maintain an outpatient service, either at facility where procedure was undertaken, or elsewhere, such that the professional can provide appropriate follow-up care. The professional must ensure his or her availability for emergencies or arrange for appropriate cover if on leave.

SECTION 9. *Penalties.* – The performance of any surgery or any invasive or minor procedure by other than a licensed practitioner shall be punishable by a penalty of imprisonment ranging from *prision mayor* in its maximum term to *reclusion temporal* in its minimum term, or a fine ranging from Five Hundred Thousand Pesos (P500,000.00) to One Million Pesos (P1,000,000.00), or both, at the discretion of the court, taking into consideration all attending circumstances, and the cancellation of the license to practice his or her profession.

The performance of any surgery or any invasive or minor procedure by a licensed practitioner but who is not licensed to perform the procedure he or she did shall be punishable by a penalty of imprisonment ranging from *prision mayor* in its medium to *prision mayor* in its maximum term, or a fine ranging from Three Hundred Thousand Pesos (P300,000.00) to Five Hundred Thousand Pesos (P500,000.00), or both, at the discretion of the court, taking into consideration all attending circumstances, and the cancellation of the license to practice his or her procession.

The performance of any duty, task or responsibility other than any surgery or any invasive or minor procedure that requires a license to perform by any unlicensed person shall be punishable by a penalty of imprisonment ranging from *prision mayor* in its minimum term to *prision mayor* in its medium term, or a fine ranging from One Hundred Thousand Pesos (P100,000.00) to Three Hundred Thousand Pesos (P300,000.00), or both, at the discretion of the court, taking into consideration all attending circumstances.

The owner, proprietor, or operator of any office, clinic, center, facility or other location that does not conform to all requirements in section six of this Act be punished by a penalty of

- imprisonment ranging from prision mayor in its medium term to prision mayor in its maximum 1 term, or a fine ranging from Three Hundred Thousand Pesos (P300,000.00) to Five Hundred 2 Thousand Pesos (P500,000.00), or both, at the discretion of the court, taking into consideration 3 all attending circumstances, and the cancellation of the license to operation such an 4 establishment. If the owner, proprietor or operator of the establishment above is a corporation, 5 trust or firm, partnership, association or any other entity, the penalty of imprisonment shall be 6 imposed on the entity's responsible officers, including, but not limited to, the president, vice-7 president, chief executive officer, general manager, managing director or partner directly 8 responsible therefor. 9
- SECTION 10. Aggravating Circumstances. The penalties described in section eight shall be imposed in the maximum if the violation of this act results in the following circumstances:
- (A) death of the patient or the contraction of some incurable disease;
- (B) Insanity or psychological damage of the patient; and

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- 15 (C) Permanent physical disfigurement or permanent disability of the patient.
 - SECTION 11. Appropriations. To carry out the provisions of this Act, such sum as may be necessary is hereby authorized to be appropriated from the National Treasury. Thereafter, the sum necessary for the continuous operation of the program shall be included in the annual appropriation of the Department of Health.
- 20 SECTION 12 Separability Clause. If any provision or part hereof, is held invalid or 21 unconstitutional, the remainder of the law or the provision shall remain valid and subsisting.
- SECTION 13. Repealing Clause. Any law, presidential decree, issuance, executive order, letter of instruction, administrative order, rule or regulation contrary to or inconsistent with, the provisions of this Act is hereby repealed, modified or amended accordingly.

- SECTION 14. Effectivity Clause. This Act shall take effect fifteen (15) days after its
- 2 publication in at least two (2) newspapers of general circulation.
- 3 Approved,

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