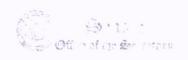
EIGHTEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
First Regular Session)



19 OCT -2 A11:27

SENATE

s. No. 1095

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Introduced by Senator Manuel "Lito" M. Lapid

AN ACT

STRENGTHENING THE REGULATION OF HEALTH FACILITIES AND SERVICES, AND APPROPRIATING FUNDS THEREFOR, REPEALING FOR THE PURPOSE REPUBLIC ACT NO. 4226, OTHERWISE KNOWN AS THE "HOSPITAL LICENSURE ACT"

EXPLANATORY NOTE

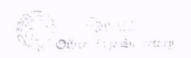
Evident developments and improvements have occurred in the field of health care which led to the emergence and development of new types of health care facilities such as diagnostic, therapeutic, and rehabilitative centers. Due to the changes in the structures and forms, several types of facilities no longer qualify for the regulation under the Republic Act No. 4226, otherwise known as "Hospital Licensure Act".

The bill seeks to expand and strengthen the regulation of health facilities in the Philippines through the renaming of the Health Facilities and Services Regulatory Bureau to the Bureau of Health Facilities and Services, with incorporation therein of additional responsibilities and duties in order to ensure the safety and quality of the health care facilities. Further, the Bureau is given the quasi-judicial powers over administrative cases against any health service establishment.

Thus, passage of this measure is earnestly requested.

MANUEL "LITO" M. LAPID

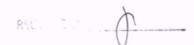
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1	Ве	e it enacted by the Senate and the House of Representatives in Congress
2	assemble	ed:
3		
4	SE	ECTION 1. Title This Act shall be known as the "Health Facilities Regulation
5	Act".	
6		
7	SE	ECTION 2. Definition of Terms For purposes of this Act, the following terms
8	are hereb	by defined as follows:
9		
10	a)	Health Facilities refer to institutions whether stationary or mobile, land
11		based or otherwise and other health related establishments which provide
12		diagnostic, therapeutic, rehabilitative, and other health care services except
13		hospital pharmacies;
14	b)	License refers to a formal authorization issued by the Department of Health
15		(DOH) to an individual, partnership, corporation or association to operate
16		health facilities or services. It is a prerequisite for accreditation of a hospital
17		and other health facilities by any accrediting body that is recognized by the
18		DOH;
19	c)	Licensee refers to the person, partnership, corporation, cooperative or

- association granted a license to operate and maintain a health facility or services according to an approved standard set by the Bureau;

 d) Department of Health Permit to Construct (DOH PTC) refers to a permit
- d) Department of Health Permit to Construct (DOH PTC) refers to a permit issued by DOH through Health Facilities and Services Regulatory Bureau to an applicant who will establish and operate a hospital or other health facility, upon compliance with required documents set forth in this Order prior to the actual construction of the said facility. A DOH-PTC is also required for hospitals and other health facilities with substantial alteration, expansion, renovation, increase in the number of beds or for additional services (addons) beyond their service capability. It is a prerequisite for License to Operate; and
- e) *Registration* refers to the act or process of entering information about a health facility into the records of the public health system.

SECTION 3. Bureau of Health Facilities and Services (BHFC). — The Health Facilities and Services Regulatory Bureau is hereby renamed as the Bureau of Health Facilities and Services (BHFS) herein referred to as the Bureau, which shall be created in the DOH. The Bureau shall be under the Office of the Secretary and shall have the following functions, powers and duties:

 a) To promulgate, establish and prescribe rules, regulations, standards, requirements and specifications in the construction and operation of health facilities and impose penalties for violations of such;

b) To inspect and monitor all health facilities and other related facilities to ensure their continued compliance with the rules and regulations in accordance with this Act and to make recommendations to directors or administrators of health facilities for the correction of deficiencies found during the inspections;

 To study and adopt a system of classifying health facilities and other related facilities in the Philippines;

 d) To review and approve construction designs and plans for all health facilities including renovation or expansion the same in accordance with the provisions of this Act;

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- e) To determine, levy, assess and collect, if applicable, the appropriate permit fee, registration fee, license fee and surcharges pertinent to the operation of facilities and services except in cases where charges or rates are established by international bodies or associations of which the Philippines is a participating member of by bodies organized by the Philippine government as the proper arbiter of such charges or rates;
- To coordinate and call the assistance of any department, office, agency or instrumentality of the national or local government and other entities concerned with any aspect involving health facilities for the effective implementation of this Act;
- g) To maintain a register of health facilities and other related facilities with licenses indicating the name of the facility, address or locations, classification, name of the director or administrator, ownership, number of authorized beds and such other pertinent data as may be necessary;
- h) To promulgate and implement the rules and regulations governing the registration, licensure and operations of health facilities and related facilities and to periodically review and amend the same, subject to the approval of the Secretary and in consultation with the sectors concerned; *Provided,* That such rules and regulations shall be in accordance with the provisions of this Act;
- To grant a certificate of a license for the operation and maintenance of health facilities and services, and to suspend or revoke the same in accordance with the provisions of this Act;
- j) To hire and train competent individuals and provide qualifications of personnel to be designated as regulatory officers;
- k) To submit yearly reports to the Secretary of Health, and the Chairpersons of the Committees on Health of both Houses of Congress; and
- To perform such other functions necessary to carry out the duties prescribed under this Act.

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SECTION 4. *Quasi-Judicial Powers.* — To carry out its tasks more effectively, the Bureau shall be vested with the following quasi-judicial powers:

- a) To investigate, hear and decide administrative cases initiated by the Bureau or filed by any person against a health facility or health service establishment violating any provision of this Act and its implementing rules and regulations and to impose appropriate administrative sanctions or penalties provided in this Act;
- b) To promulgate rules governing the conduct of administrative hearings: Provided, That in such proceedings, the Bureau shall not be bound by the technical rules of evidence of the Rules of Court: Provided, further, That the latter may be applied in a suppletory manner;
- c) To administer oaths and affirmations, and to issue subpoena duces tecum and ad testificandum, requiring the production of such books, contracts, correspondence, records, statement of accounts and other documents and the attendance and testimony of parties and witnesses, as may be material to the investigation being conducted by the Bureau;
- d) To exercise contempt powers and impose appropriate penalties;
- e) To cause the prosecution of all cases involving violations of this Act and its implementing rules and regulations;
- f) To summarily order the closure of health facilities and other related facilities operating without a license; and
- g) To preventively suspend health facilities found during inspection or monitoring to have committed gross violations of the standards or rules and regulations such as non-compliance to the approved construction design; any fraudulent, unscrupulous activities, false claims or misrepresentations; operating with unlicensed or unqualified health personnel; and the commission or omission of any act which may result to serious injury, permanent disability or loss of life of a patient or staff, or would compromise public safety.

SECTION 8. Minimum Qualifications for Appointment as Chief Executive Officer, Chief Operating Officer, or Administrative Officer. — The Chief Executive Officer, Chief Operating Officer, or Administrative Officer of a hospital or health facility who shall be responsible for the overall management and administration of the hospital; formulation of policies, plans, programs and strategies to ensure

SECTION 5. Mandatory Conciliation-Mediation. — The Bureau shall exert all efforts towards the amicable settlement of an administrative case within its jurisdiction on or before the first hearing. Towards this end, it shall have the power to ask the assistance of relevant government officials and qualified private individuals to act as a compulsory mediator on cases referred to it.

SECTION 6. Registration and License. — The Bureau shall facilitate the delivery of high-quality and cost-effective healthcare by promoting competition among health facilities. Towards this end, all hospitals and other health facilities, government or private, shall be registered and duly licensed by the Bureau before such facilities are allowed to operate or be opened to the public. Both public and private health facilities shall be required to apply for the permit to construct and license to operate.

SECTION 7. Organization. — The Director of the Bureau shall, subject to the approval of the Secretary of Health, organize its personnel in such divisions and units as will ensure efficiency and effectiveness:

The Bureau shall establish, operate and maintain a regional office in each of the administrative regions of the country to enforce regulatory policies and standards for the licensing, accreditation, and monitoring of health facilities to ensure quality health care.

In order to allow the Bureau to carry out its functions and responsibilities, the Secretary of Health shall hire additional personnel, as deemed necessary. The head of the Bureau shall make the necessary recommendations to the Secretary of Health regarding the number and competency of additional personnel to be hired.

implementation of health standards; and the day-to-day supervision of the functional

units shall possesses any of the following minimum qualifications: a) formal baccalaureate degree, preferably with a master's degree in hospital administration or related course; or b) at least five (5) year experience in a supervisory or managerial position.

SECTION 9. Classification of Hospitals and Other Health Facilities. — The existing classification of hospitals and other health facilities including the system, rules and regulations governing their classification shall be subject to automatic review by the Bureau, in consultation with relevant stakeholders, within three (3) years from the effectivity of this Act and thereafter as it may deem necessary. It shall take into consideration the findings and recommendations made by Congress, if any, and the actual situation in dealing with the existing classification of hospitals and other health facilities for the purpose of protecting and promoting the health of the public by ensuring a minimum quality of service rendered by hospitals and other regulated health facilities and to assure the safety of patients and personnel.

Classification of health facilities and other related facilities shall only be made upon the approval of the Secretary of Health after mandatory consultation with representatives from government and private hospital associations and patient organizations.

SECTION 10. Construction Design. — The Bureau shall review and approve the construction design and plans of health facilities or related facilities to be constructed or which shall undergo renovation or expansion.

An application for the construction design of a health facility or other related facility shall be submitted to the Bureau in a form prescribed by the latter and accompanied by a plan of the facility proposed to be constructed. The approved construction design and plan issued by the Bureau shall be a prerequisite for the issuance of a building permit by the official of the municipality or city where the facility is proposed to be constructed.

All level III government hospitals to be constructed shall include in its design the provision of generic word.

SECTION 11. Application, Inspection, and Issuance of License to Operate (LTO). — All health facilities shall be duly licensed by the Bureau, in accordance with Republic Act No. 11032 or the "Ease of Doing Business Act", before such facilities are allowed to operate or to be opened to the public.

An applicant of a health facility for the issuance of a License to Operate, including its medical ancillary services, shall be filed with the Bureau or its Regional Office using the prescribed forms.

The LTO shall be issued upon due compliance of the applicant with the rules and regulations prescribed by the Bureau pursuant to the provisions of this Act: *Provided,* That the Bureau has conducted a comprehensive on-site inspection and has certified that the applicant has satisfactorily compiled with the requisites prescribed in this Act and its implementing rules and regulations (IRR). *Provided further,* That an applicant shall get the approval of the Food and Drug Administration (FDA) for its pharmacy or Philippine Nuclear Research Institute (PNRI) for medical radiation facility.

The FDA, PNRI, Department of Environment and Natural Resources (DENR) and other agencies involved in the regulation of health facilities shall employ a One-Stop Shop strategy in the processing of applications through systems that are accessible to the public.

Upon issuance of the LTO, a health facility shall be included in the Bureau's registry and in the National Health Facility Registry upon the approval of the DOH.

All licensed health facilities shall be automatically allowed to participate in the National Health Insurance Program.

SECTION 12. Validity and Renewal of License. — The initial license to operate and maintain a health facility or other related facility shall be valid for a period of three (3) years from its date of issuance, and shall be renewed regularly, subject to the rules and regulations to be issued by the Bureau.

SECTION 13. Suspension and Revocation of License. — The Bureau, after conducting an administrative hearing, with due notice to the licensee, may suspend or revoke the license to operate and maintain a healthy facility or other related facility of any person, partnership, corporation or association for any of the following grounds:

(a) Violation by the license of any provision of this Act or any other existing law;

- (b) Violation of rules and regulations prescribed in the implementation of this Act; and
- (c) Failure to make necessary corrections or adjustments required by the Bureau in the improvement or maintenance of facilities and services.

SECTION 14. Appeal. — The orders, rulings or decisions of the Bureau shall be appealable to the Secretary of Health.

SECTION 15. Separate Licenses Required. — Separate licenses shall be required for health facilities or other related facilities or branches thereof maintained in separate premises even though they are operated under the same management: *Provided, however,* That separate licenses shall not be required for separate buildings in the same compound shall also be secured from the Bureau to determine compliance with standards and requirements herein authored.

SECTION 16. Non-Transferability of License. — A license for the operation of a health facility or other related facility shall not be transferable. The Bureau shall be notified of any change in ownership, change of name of the health facility or other related facility. Transfer of location of the facility shall require an application for a new license.

SECTION 17. *Penalties.* — Any person, partnership, association, or corporation who establishes, operates, conducts, manages or maintains a health facility or other related facility within the meaning of this Act without first obtaining a license, or violates any provision of this Act or its Implementing Rules and Regulations shall be liable to a fine of not less than Fifty Thousand Pesos (P50,000.00) but not to exceed One Hundred Thousand Pesos (P100,000.00) for the first offense, not less than One Hundred Thousand Pesos (P100,000.00) but not to exceed Five Hundred Thousand Pesos (P500,000.00), and not less than Five Hundred Thousand Pesos (P500,000.00) but not to exceed One Million Pesos (P1,000,000.00) for the third and

subsequent offenses. After the third offense, the license of the hospital shall be revoked. Each day that the health facility or other related facility operates after the first violation shall be considered a subsequent offense.

In addition to the penalties specified in the preceding paragraph, the Bureau may summarily order the closure of any health facility or other related facility found operating without a license, or revoke the license to operate of any health facility or other related facility after due process. Facilities may only re-apply for a new LTO one (1) year after revocation of its license.

SECTION 18. *Income Retention.* — To ensure that the Bureau shall have full authority to utilize its income and enhance its capacity to expand and to improve the quality of its services, it is hereby authorized to retain and utilize one hundred percent (100%) of its income generated from various fees and surcharges without remitting the same to the Bureau of Treasury.

In no case shall the retained income be used for the payment of salaries and other personnel benefits. The retained income shall be deposited in an authorized government depository bank recommended by the DOH, the DBM, and the Department of Finance.

SECTION 19. Appropriations. — The current appropriations of the DOH under the General Appropriations Act (GAA) shall be used to carry out the initial implementation of this Act. Thereafter, such sums as may be necessary for the continued implementation of this Act shall be included in the succeeding GAA.

SECTION 20. *Mandatory Review.* — Congress shall undertake a mandatory review of this Act at least once every five (5) years and as often as it may deem necessary, with the primary objective of overseeing the implementation of this Act and reviewing the accomplishments and the utilization of income of the Bureau.

SECTION 21. *Implementing Rules and Regulations.* — The Secretary of Health, upon the recommendation of the Bureau, FDA, PNRI, and other concerned agencies and after consultation with recognized health facilities, associations, patients'

1	organizations and other civil society organizations, shall issue the rules and regulations
2	implementing the provisions of this Act within ninety (90) days from its effectivity.
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4	SECTION 22. Separability Clause. — If any part or provision of this Act shall
5	be held unconstitutional or invalid, other provisions hereof which are not affected shall
6	continue to be in full force and effect.
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8	SECTION 23. Repealing Clause. — Republic Act no. 4226, otherwise known
9	as the "Hospital Licensure Act," is hereby repealed. Presidential decrees, executive
10	orders, rules and regulations and other issuances or parts thereof which are
11	inconsistent with the provisions of this Act are hereby repealed, amended or modified
12	accordingly.
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14	SECTION 24. Effectivity. — This Act shall take effect fifteen (15) days after
15	its publication in the Official Gazette or in any newspaper of general circulation.
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17	Approved,