

FOURTEENTH CONGRESS
REPUBLIC OF THE PHILIPPINES
Second Regular Session

OFFICE OF THE SECRETARY

9 JAN 26 P7:00

S E N A T E

S. No. 3016

RECEIVED BY



Introduced by Senator LOREN LEGARDA

EXPLANATORY NOTE

Health facilities have emerged and developed in a variety of forms and structures. As a result, a number of such types of facilities do not anymore qualify under the current regulatory mandate of the Department of Health (DOH) through the Bureau of Health Facilities and Services (BHFS). In other words, the mandate that subjects such types of facilities under the regulatory control of the Department is now outdated.

The new world order has opened up countries to a new level of competition. Trade borders are slowly disappearing alongside global development. This phenomenon has led industries, such as in the field of health facilities maintenance and health service provision, to grow, expand and evolve. As a consequence, the regulation of this field should also be enhanced in order to be responsive to such changes as it greatly affects the welfare of the people. Health regulations should be transformed in order to:

- a. Maintain its relevance; and,
- b. Expand its scope of authority and include the whole industry as well.

For years, the regulation of health facilities focused on the specific activities and objects that are to be regulated. This proposed measure introduces a paradigm shift from such traditional way of regulation by regulating the industry as opposed to mere regulation of individual and specific health facilities. As such, there shall be fewer opportunities for circumvention and the health cost becomes controlled. Also, with this measure, the quality of health facilities and services shall improve as well as the competitiveness, efficiency and productivity of the industry.

Through this bill, critical infrastructure and technical upgrading is provided to enable the DOH to cope with the challenges of globalization. Thus, aside from competitiveness, the high quality of health facilities and services are ensured. The creation of a Health Facilities Regulation Fund, which would be a new and innovative way of creating and disbursing resources in pursuit of a revitalized regulatory mandate, will facilitate access, productivity and efficiency. The creation and management of a system of benchmarking system would definitely improve quality and efficiency in health regulation and ensure accessibility with respect to necessary health facilities especially to the poor.

The bill also addresses another pressing issue in the field of health care, which is the increasing cost of health services. The increasing cost of health care, particularly hospital care, is a reality recognized by both the government and other stakeholders in the health sector. Because of the dichotomous health system and the way the health

system is organized in terms of health financing and health delivery, there is a lack of government control on the costs of health services being provided by the private health sector. This leads to escalating costs of health services, which erodes value of social health insurance in providing financial risk protection to the population. By regulating the costs of health services in health facilities especially through a strengthened Bureau of Health Facilities and Services, these services will be made more accessible financially to the population, especially those who belong to the lowest income group.

In essence, this bill would bring about improved mandate and available financial resources towards efficient and effective health regulation.

Support for the passage and approval of this bill is thus earnestly sought.



LOREN LEGARDA
Senator


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**AN ACT ENHANCING THE REGULATION OF HEALTH FACILITIES AND
APPROPRIATING FUNDS THEREOF.**

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

SECTION 1. Short title - "Health Facilities Regulation Act of 2009".

SEC 2. Declaration of Policy - Article XIII, Section 11 of the 1987 Philippine Constitution stipulates, among others that: "The State shall adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all the people at affordable cost." It is then the policy of the State to ensure the quality, safety, accessibility and affordability of health services and health facilities for each and every Filipino especially the poor. To attain these goals, the Department of Health, through the Bureau of Health Facilities and Services, must be provided the mandate and capability to regulate health facilities as they develop in time. Thus, to actualize this endeavor, the State shall enhance its regulatory capacity, capability, efficiency and coherence in order to regulate not only the health facilities but the industries that provide them as well.

SEC 3. Objectives - This Act shall adhere to the following objectives:

- (a) To enhance the administrative and technical capacity of government in health regulation;
- (b) To strengthen the government regulatory control powers in implementing health regulations;
- (c) To expand government's regulatory coverage over health facilities, and include the industries that provide them; and,
- (d) To provide coherence in the government's regulatory processes.

SEC 4. Definition of Terms - for purposes of this Act, the terms:

- (a) BFAD shall refer to the Bureau of Food and Drug;
- (b) BHDT shall refer to the Bureau of Health Devices and Technology;
- (c) BOQ shall refer to the Bureau of Quarantine;
- (d) BUREAU shall refer to the Bureau of Health Facilities and Services;
- (e) CHD shall refer to Center for Health Development of the DOH in different regions of the country tasked to implement regulatory functions therein;
- (f) COA shall refer to the Commission on Audit;
- (g) DOH shall refer to the Department of Health;
- (h) DFA shall refer to the Department of Foreign Affairs;
- (i) PHIC shall refer to the Philippine Health Insurance Corporation;

- (j) POEA shall refer to the Philippine Overseas Employment Administration; and
- (k) HEALTH FACILITIES shall refer to institutions that provide diagnostic, therapeutic, rehabilitative and other health care services.

SEC 5. Health Facilities Regulation Structure - The DOH, through the BHFS, has the primary role of regulating health facilities to ensure safety, quality, access and affordability thereof; *Provided*, that the CHDs shall be primarily tasked to enforce regulatory activities in their respective regions.

SEC 6. Powers and Functions - The DOH, through the BHFS shall have the following general powers and functions:

- (a) Prescribe measures to rationalize the establishment of health facilities all over the country in accordance with national health goals;
- (b) Prescribe measures to regulate the establishment, operation, maintenance, and use of health facilities;
- (c) Formulate, enforce and periodically review rules and regulations on the regulation of health facilities duly approved by the Secretary of Health;
- (d) Prescribe regulatory standards for health facilities and promulgate the necessary policy instruments and arrangements with other pertinent government agencies for the enforcement thereof;
- (e) Grant permits for the construction, renovation and expansion of health facilities;
- (f) Register, license, accredit or certify health facilities and suspend and revoke the license, accreditation or certification of the same in accordance with the provisions of this Act and its implementing rules and regulations;
- (g) Provide exemptions from registration, licensure, accreditation or certification with proper notice to the public;
- (h) Undertake inspections of health facilities to ensure compliance with this Act and its implementing rules and regulations;
- (i) Levy, assess and collect appropriate fees pursuant to its functions;
- (j) Publish an annual listing of all registered, licensed, accredited or certified health facilities;
- (k) Develop public-private partnerships towards quality assurance endeavors such as, but not limited to:
 - (i) Voluntary accreditation processes and mechanisms; and,
 - (ii) Adverse event reporting and monitoring;
- (l) Require all regulated health facilities to submit to the BHFS and CHDs any adverse event that caused or contributed to death, serious illness or serious injury to a patient;
- (m) Require all regulated health facilities to report notifiable diseases to the appropriate DOH office in accordance with national policies
- (n) Regulate and enforce standards on the management of health facility wastes;
- (o) Coordinate the regulation of health facilities with other government agencies involved directly or indirectly with health regulation;
- (p) Call on the assistance of any instrumentality of the government for the implementation of the provisions of this Act; and
- (q) Exercise such other powers and responsibilities that shall ultimately contribute to the better health status of the Filipino people as determined by the Secretary.

SEC 7. Validity of the Registration, License, Accreditation or Certification - The validity of the registration, license, accreditation or certification for health facilities and shall depend on the validity period to be prescribed by the BHFS.

SEC. 8. Regulation of the Price of Health Care Services - The President of the Philippines, upon recommendation of the Secretary of the Health, shall have the power to impose the maximum price over diagnostic, therapeutic, rehabilitative and other health care services rendered in health facilities.

The power to impose maximum prices over health care services shall be exercised within such period of time as the situation may warrant as determined by the President of the Philippines. No court, except the Supreme Court of the Philippines, shall issue any temporary restraining order or preliminary injunction or preliminary mandatory injunction that will prevent the immediate execution of the exercise of this power of the President of the Philippines.

The DOH, together with PHIC, in consultation with stakeholders, shall formulate the *implementing rules and regulations* for the provisions in Section 8 of this Act, within 120 days after the enactment of the same.

SEC. 9. Regulation Capability Strengthening - The DOH, through the BHFS, shall endeavor to strengthen its regulatory capabilities as well as those of the CHDs through process and systems reforms congruent with national health reforms such as, but not limited to, the establishment of a harmonized regulation system together with other DOH regulatory offices, namely, BFAD, BHDT and BOQ; *Provided*, that the CHDs shall enforce DOH regulatory mandates in the their respective regions.

SEC. 10. Information Technology - The DOH, through the BHFS, shall establish an information technology linkage with other health regulatory agencies within a year subsequent to the enactment of this Act. A web page dedicated to the compilation and maintenance of DOH regulation database shall be developed and maintained.

SEC. 11. Quality Seal - The DOH, through the BHFS, shall, in coordination with other DOH regulatory offices, implement a quality seals system for health facilities through the following activities:

- (a) Adoption of quality standards that would enable international competitiveness whenever applicable;
- (b) Critical capacity building of the BHFS and CHDs;
- (c) Enhancement of all necessary regulatory infrastructure; and,
- (d) Development of necessary requirements, such as but not limited to, sets of criteria, incentive packages, and advocacy scheme.

SEC 12. Cost Restructuring - The DOH, through the BHFS, is hereby mandated to restructure its fee schedule to a level commensurate to the cost of regulatory administration; *Provided*, that no increase in fees shall be implemented without proper consultation with necessary stakeholders.

SEC 13. Health Facilities Regulation Fund - A Health Facilities Regulation Fund is hereby established to institute an efficient, sustainable and cost-effective regulatory system for health facilities through incentives in the form of disbursements to BHFS and CHDs based on performance and compliance to Sections 9, 10, 11 and 12 of this Act and to implementing rules and regulations to be formulated by the DOH and subject to COA rules and regulations; *Provided*, that the same fund shall also be used to

upgrade the critical capacity and regulatory infrastructure of BHFS and CHDs; *Provided further*, that no amount thereof shall be used for payment of salaries and other allowances.

The fund shall be held in trust and derived from all receipts from registration, licensing, accreditation and certification fees, sale of publications and services, assessment, fines, penalties and other fees imposed by the BHFS and the CHDs, and may be augmented by grants, donations, endowments from various domestic or foreign sources, as allowed under the Administrative Code of 1987.

SEC. 14. Benchmarks - A system of benchmarks setting shall be institutionalized to provide yearly accomplishment targets for the stipulations under Section 8, 9 and 10 of this Act, which shall be one of the bases for performance evaluation and disbursement of the Health Facilities Regulation Fund to the BHFS and the CHDs.

SEC 15. Prohibited Acts - The following are considered prohibited acts for purposes of this Act:

- (a) Operation and maintenance of a health facility without a license;
- (b) Non-compliance with the standards and requirements on construction, operation and maintenance;
- (c) Refusal to allow required inspections as determined by the BHFS and CHDs and;
- (d) Misrepresentation and/or falsifications in the submission of licensing/renewal requirements;

SEC 16. Administrative Proceedings and Sanctions - Upon verified information of the conduct of prohibited act/s, the DOH, through the BHFS, shall conduct an administrative hearing with proper notices to determine the conduct of prohibited actions and the persons liable.

In cases where there is finding of prohibited actions and determination of the persons liable, the DOH, through the BHFS and CHDs, are authorized to impose any or all of the following sanctions:

- (a) Suspension of license;
- (b) Revocation of license;
- (c) Closure of the health facility;
- (d) Administrative fine as prescribed by the DOH, which shall be adjusted yearly based on the Consumer Price Index;
- (e) Filing of criminal charges against persons liable and;
- (f) Permanent disqualification from owning and operating health facilities.

Review of all administrative decisions shall lodge with the Secretary of Health subject to the rules and regulations of the Administrative Code of 1987.

SEC 17. Penalties - The commission of prohibited acts as described in this Act shall be punishable by imprisonment of not less than six months but not more than five years and/or a fine of not less than 500,000 pesos but not more than 1 million pesos.

The fine shall be adjusted yearly based on the Consumer Price Index.

SEC 18. Appropriations - The current DOH appropriations under the General Appropriations Act (GAA) shall be used to carry out the initial implementation of this

Act. Thereafter, subsequent appropriations for purposes of this Act shall be increasingly derived from the Health Regulation Fund, with augmentation from the GAA if the former is determined to be insufficient.

SEC 19. Implementing Rules - The Department of Health shall promulgate the implementing rules and guidelines of this Act one hundred twenty (120) days after the passage of the Act.

SEC 20. Separability Clause - If any part, section or provision of this Act shall be declared invalid or unconstitutional, other provisions or parts thereof which are not affected thereby shall remain in full force and effect.

SEC 21. Repealing Clause - Republic acts 4226 and 4688 are explicitly repealed. All other laws or part of laws, executive orders, circulars, regulations and memoranda inconsistent with this Act are hereby repealed or amended accordingly.

SEC 22. Effectivity - This act shall take effect fifteen (15) days after publication in the Official Gazette or in two (2) newspapers of general circulation.

Approved,