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SENATE
S.B. No. 411

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Introduced by SENATOR LOREN LEGARDA

AN ACT ENHANCING THE REGULATION OF HEALTH FACILITIES AND APPROPRIATING FUNDS THEREFOR

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 no longer 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other words, the mandate that subjects such types of facilities under the regulatory control of the Department is now outdated.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 expand and evolve. Consequently, the regulation of this field should also be enhanced to respond to such changes as it greatly affects the welfare of the people. Health regulations should be transformed in order to maintain its relevance and expand its scope of authority and include the whole industry.

For years, the regulation of health facilities focused on the specific activities and objects that need to be regulated. This proposed measure introduces a paradigm shift 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 tighter control on health costs. 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.

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 THEREFOR

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

1 **SECTION 1. Title.** - This Act shall be known as "The Health Facilities
2 Regulation Act."
3

4 **SEC 2. Declaration of Policy.** - The State shall adopt an integrated and
5 comprehensive approach to health development which shall endeavor to
6 make essential goods, health and other social services available to all the
7 people at affordable cost. Towards this end, the State shall ensure the quality,
8 safety, accessibility and affordability of health services and health facilities for
9 the people, especially the poor. The State shall further enhance its regulatory
10 capacity, capability, efficiency and coherence in order to regulate not only the
11 health facilities but related industries.
12

13 **SEC 3. Objectives** - This Act shall adhere to the following objectives:
14

- 15 (a) To enhance the administrative and technical capacity of government
16 in health regulation;
17 (b) To strengthen the government regulatory control powers in
18 implementing health regulations;
19 (c) To expand government's regulatory coverage over health facilities,
20 and include the industries that provide them; and,
21 (d) To provide coherence in the government's regulatory processes.
22

23 **SEC 4. Definition of Terms.** - As used in this Act, the following terms shall
24 mean:
25

- 26 (a) BFAD refers to the Bureau of Food and Drugs;
27 (b) BHDT refers to the Bureau of Health Devices and Technology;
28 (c) BHFS refers to the Bureau of Health Facilities and Services;
29 (d) BOQ refers to the Bureau of Quarantine;
30 (e) BUREAU refers to the Bureau of Health Facilities and Services;
31 (f) CHD refers to Center for Health Development of the Department of
32 Health in different regions of the country tasked to implement
33 regulatory functions therein;
34

- 1 (g) COA refers to the Commission on Audit;
- 2 (h) DOH refers to the Department of Health;
- 3 (i) DFA refers to the Department of Foreign Affairs;
- 4 (j) PHIC refers to the Philippine Health Insurance Corporation;
- 5 (k) POEA refers to the Philippine Overseas Employment
- 6 Administration; and
- 7 (l) HEALTH FACILITIES refer to institutions that provide diagnostic,
- 8 therapeutic, rehabilitative and other health care services.
- 9

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

14
 15 **SEC 6. Powers and Functions.** – The DOH, through the BHFS shall have the
 16 following general powers and functions:

- 17 (a) Prescribe measures to rationalize the establishment of health
- 18 facilities all over the country in accordance with national health
- 19 goals;
- 20 (b) Prescribe measures to regulate the establishment, operation,
- 21 maintenance, and use of health facilities;
- 22 (c) Formulate, enforce and periodically review rules and regulations
- 23 on the regulation of health facilities duly approved by the Secretary
- 24 of Health;
- 25 (d) Prescribe regulatory standards for health facilities and promulgate
- 26 the necessary policy instruments and arrangements with other
- 27 pertinent government agencies for the enforcement thereof;
- 28 (e) Grant permits for the construction, renovation and expansion of
- 29 health facilities;
- 30 (f) Register, license, accredit or certify health facilities and suspend
- 31 and revoke the license, accreditation or certification of the same in
- 32 accordance with the provisions of this Act and its implementing
- 33 rules and regulations;
- 34 (g) Provide exemptions from registration, licensure, accreditation or
- 35 certification with proper notice to the public;
- 36 (h) Undertake inspections of health facilities to ensure compliance
- 37 with this Act and its implementing rules and regulations;
- 38 (i) Levy, assess and collect appropriate fees pursuant to its functions;
- 39 (j) Publish an annual listing of all registered, licensed, accredited or
- 40 certified health facilities;
- 41 (k) Develop public-private partnerships towards quality assurance
- 42 endeavors such as, but not limited to:
- 43 (i) Voluntary accreditation processes and mechanisms; and,
- 44 (ii) Adverse event reporting and monitoring;
- 45 (l) Require all regulated health facilities to submit to the BHFS and
- 46 CHDs any adverse event that caused or contributed to death,
- 47 serious illness or serious injury to a patient;
- 48 (m) Require all regulated health facilities to report notifiable diseases
- 49 to the appropriate DOH office in accordance with national policies
- 50 (n) Regulate and enforce standards on the management of health
- 51 facility wastes;
- 52 (o) Coordinate the regulation of health facilities with other
- 53 government agencies involved directly or indirectly with health
- 54 regulation;
- 55 (p) Call on the assistance of any instrumentality of the government for
- 56 the implementation of the provisions of this Act; and

1 (q) Exercise such other powers and responsibilities that shall
2 ultimately contribute to the better health status of the Filipino
3 people as determined by the Secretary.
4

5 **SEC 7. Validity of the Registration, License, Accreditation or**
6 **Certification.** – The validity of the registration, license, accreditation or
7 certification for health facilities shall be prescribed by the BHFS.
8

9 **SEC. 8. Regulation of the Price of Health Care Services.** – The President of
10 the Philippines, upon recommendation of the Secretary of the Health, shall
11 have the power to impose the maximum price over diagnostic, therapeutic,
12 rehabilitative and other health care services rendered in health facilities.
13

14 The power to impose maximum prices over health care services shall be
15 exercised within such period of time as the situation may warrant as
16 determined by the President of the Philippines. No court, except the Supreme
17 Court of the Philippines, shall issue any temporary restraining order or
18 preliminary injunction or preliminary mandatory injunction that will prevent
19 the immediate execution of the exercise of this power of the President of the
20 Philippines.
21

22 The DOH, together with the PHIC, in consultation with stakeholders, shall
23 formulate the implementing rules and regulations of this Act within 120 days
24 after the enactment of the same.
25

26 **SEC. 9. Regulation Capability Strengthening.** – The DOH, through the
27 BHFS, shall endeavor to strengthen its regulatory capabilities as well as those
28 of the CHDs through process and systems reforms congruent with national
29 health reforms such as, but not limited to, the establishment of a harmonized
30 regulation system together with other DOH regulatory offices, namely, BFAD,
31 BHDT and BOQ: *Provided*, that the CHDs shall enforce DOH regulatory
32 mandates in the their respective regions.
33

34 **SEC. 10. Information Technology.** – The DOH, through the BHFS, shall
35 establish an information technology linkage with other health regulatory
36 agencies within a year subsequent to the enactment of this Act. A web page
37 dedicated to the compilation and maintenance of DOH regulation database
38 shall be developed and maintained.
39

40 **SEC. 11. Quality Seal.** – The DOH, through the BHFS, shall, in coordination
41 with other DOH regulatory offices, implement a quality seals system for
42 health facilities through the following activities:
43

- 44 (a) Adoption of quality standards that would enable international
45 competitiveness whenever applicable;
46 (b) Critical capacity building of the BHFS and CHDs;
47 (c) Enhancement of all necessary regulatory infrastructure; and,
48 (d) Development of necessary requirements, such as but not limited
49 to, sets of criteria, incentive packages, and advocacy scheme.
50

51 **SEC 12. Cost Restructuring.** – The DOH, through the BHFS, is hereby
52 mandated to restructure its fee schedule to a level commensurate to the cost
53 of regulatory administration; *Provided*, that no increase in fees shall be
54 implemented without proper consultation with necessary stakeholders.
55

56 **SEC 13. Health Facilities Regulation Fund.** – A Health Facilities

1 Regulation Fund is hereby established to institute an efficient, sustainable
2 and cost-effective regulatory system for health facilities through incentives in
3 the form of disbursements to BHFS and CHDs based on performance and
4 compliance to Sections 9, 10, 11 and 12 of this Act and based on the
5 implementing rules and regulations to be formulated by the DOH and subject
6 to COA rules and regulations; *Provided*, that the same fund shall also be used
7 to upgrade the critical capacity and regulatory infrastructure of BHFS and
8 CHDs; *Provided further*, that no amount thereof shall be used for payment of
9 salaries and other allowances.

10
11 The fund shall be held in trust and derived from all receipts from registration,
12 licensing, accreditation and certification fees, sale of publications and
13 services, assessment, fines, penalties and other fees imposed by the BHFS
14 and the CHDs. This fund may be augmented by grants, donations,
15 endowments from various domestic or foreign sources, as allowed under the
16 Administrative Code of 1987.

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

22
23 **SEC 15. Prohibited Acts.** - The following are considered prohibited acts for
24 purposes of this Act:

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

32
33 **SEC 16. Administrative Proceedings and Sanctions.** - Upon verified
34 information of the conduct of prohibited act/s, the DOH, through the BHFS,
35 shall conduct an administrative hearing with proper notices to determine the
36 conduct of prohibited actions and the persons liable.

37
38 In cases where there is finding of prohibited actions and determination of the
39 persons liable, the DOH, through the BHFS and CHDs, are authorized to
40 impose any or all of the following sanctions:

- 41
42 (a) Suspension of license;
- 43 (b) Revocation of license;
- 44 (c) Closure of the health facility;
- 45 (d) Administrative fine as prescribed by the DOH, which shall be
46 adjusted yearly based on the Consumer Price Index;
- 47 (e) Filing of criminal charges against persons liable and;
- 48 (f) Permanent disqualification from owning and operating health
49 facilities.

50
51 Review of all administrative decisions is lodged with the Secretary of Health
52 subject to the rules and regulations of the Administrative Code of 1987.

53
54 **SEC 17. Penalties.** - The commission of prohibited acts as described in this
55 Act shall be punishable by imprisonment of not less than six months but not

1 more than five years and/or a fine of not less than Five Hundred Thousand
2 Pesos (P500,000.00) but not more than One Million Pesos (P1,000,000.00).
3 The fine shall be adjusted yearly based on the Consumer Price Index.
4

5 **SEC 18. Appropriations.** – The current DOH appropriations under the
6 General Appropriations Act (GAA) shall be used to carry out the initial
7 implementation of this Act. Thereafter, subsequent appropriations for
8 purposes of this Act shall be increasingly derived from the Health Regulation
9 Fund, with augmentation from the GAA if the former is determined by the
10 DOH to be insufficient.
11

12 **SEC 19. Implementing Rules.** – The Department of Health shall promulgate
13 the implementing rules and guidelines of this Act one hundred twenty (120)
14 days after the passage of the Act.
15

16 **SEC 20. Separability Clause.** – If any part, section or provision of this Act is
17 declared invalid or unconstitutional, other parts or provisions hereof not
18 affected thereby shall remain in full force and effect.
19

20 **SEC 21. Repealing Clause.** – Republic Act No. 4226 and Republic Act No.
21 4688 are hereby repealed. All other laws, decrees, executive orders, circulars,
22 regulations and memoranda, or parts thereof, inconsistent with this Act are
23 hereby repealed or amended accordingly.
24

25 **SEC 22. Effectivity.** – This act shall take effect fifteen (15) days after
26 publication in two (2) newspapers of general circulation.
27

28 Approved,