

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 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other words, the mandate that subjects such types of facilities under the regulatory control of the Department is now outdated.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 grow, 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:

- 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 need to be regulated. This proposed measure introduces a paradigm shift from the 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. In addition, 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



SIXTEENTH CONGRESS OF THE REPUBLIC OF THE PHILIPPINES First Regular Session

*13 JUL 31 P3:05

SENATE

)

S.B. No. 1190



Introduced by Senator Loren Legarda

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

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

SECTION 1. *Title.* - This Act shall be known as "The Health Facilities Regulation Act of 2013".

3

4

5

6

7

8

9

10

11

12

13

14

1

2

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." Towards this end, it is 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.

16 17

15

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

18 19

20

- (a) To enhance the administrative and technical capacity of government in health regulation;
- 21 (b) To strengthen the government regulatory control powers in implementing 22 health regulations;

23	(c)	To expand government's regulatory coverage over health facilities, and
24		include the industries that provide them; and,
25	(d)	To provide coherence in the government's regulatory processes.
26		
27	SEC	2 4. Definition of Terms As used in this Act, the following terms shall
28	mean:	
29	(a)	BFAD refers to the Bureau of Food and Drug;
30	(b)	BHDT refers to the Bureau of Health Devices and Technology;
31	(c)	BHFS refers to the Bureau of Health Facilities and Services;
32	(d)	BOQ refers to the Bureau of Quarantine;
33	(e)	BUREAU refers to the Bureau of Health Facilities and Services;
34	(f)	CHD refers to Center for Health Development of the Department of
35		Health in different regions of the country tasked to implement
36		regulatory functions therein;
37	(g)	COA refers to the Commission on Audit;
38	(h)	DOH refers to the Department of Health;
39	(i)	DFA refers to the Department of Foreign Affairs;
40	(j)	PHIC refers to the Philippine Health Insurance Corporation;
41	(k)	POEA refers to the Philippine Overseas Employment Administration;
42		and '
43	(1)	HEALTH FACILITIES refer to institutions that provide diagnostic,
44		therapeutic, rehabilitative and other health care services.
45		
46	SEC	5. Health Facilities Regulation Structure The DOH, through the
47	BHFS, has	the primary role of regulating health facilities to ensure safety, quality,
48	access and	affordability thereof: Provided, that the CHDs shall be primarily tasked to
49	enforce reg	gulatory activities in their respective regions.
50		
51	SEC	C 6. Powers and Functions The DOH, through the BHFS shall have the
52	following s	general powers and functions:
53	(a)	Prescribe measures to rationalize the establishment of health facilities all
54		over the country in accordance with national health goals;
55	(b)	Prescribe measures to regulate the establishment, operation,
56		maintenance, and use of health facilities;

- Formulate, enforce and periodically review rules and regulations on the 57 (c) regulation of health facilities duly approved by the Secretary of Health; 58 (d) Prescribe regulatory standards for health facilities and promulgate the 59 necessary policy instruments and arrangements with other pertinent 60 government agencies for the enforcement thereof; 61 Grant permits for the construction, renovation and expansion of health 62 (e) facilities; 63 Register, license, accredit or certify health facilities and suspend and (f) 64 revoke the license, accreditation or certification of the same in 65 accordance with the provisions of this Act and its implementing rules 66 and regulations; 67 (g) Provide exemptions from registration, licensure, accreditation or 68 certification with proper notice to the public; 69 Undertake inspections of health facilities to ensure compliance with this (h) 70 Act and its implementing rules and regulations; 71 Levy, assess and collect appropriate fees pursuant to its functions; 72 (i) Publish an annual listing of all registered, licensed, accredited or 73 (j)
 - certified health facilities;
 - public-private partnerships Develop towards quality (k) assurance endeavors such as, but not limited to:
 - Voluntary accreditation processes and mechanisms; and, (i)
 - (ii) Adverse event reporting and monitoring;

74

75

76

77

78

79

80

81

82

83

84

85

86

87

- Require all regulated health facilities to submit to the BHFS and CHDs (1) 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
- Regulate and enforce standards on the management of health facility (n) wastes;
- 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 88 implementation of the provisions of this Act; and 89

(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 the 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 based on the 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. This fund 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

159	Section 8, 9 and 10 of this Act, which shall be one of the bases for performance		
160	evaluation and disbursement of the Health Facilities Regulation Fund to the BHFS		
161	and the CHDs.		
162			
163	SEC	C 15. Prohibited Acts The following are considered prohibited acts for	
164	purposes o	of this Act:	
165	(a)	Operation and maintenance of a health facility without a license;	
166	(b)	Non-compliance with the standards and requirements on construction,	
167		operation and maintenance;	
168	(c)	Refusal to allow required inspections as determined by the BHFS and	
169		CHDs and;	
170	(d)	Misrepresentation and/or falsifications in the submission of licensing/	
171		renewal requirements;	
172			
173	SEC	2 16. Administrative Proceedings and Sanctions Upon verified	
174	informatio	on of the conduct of prohibited act/s, the DOH, through the BHFS, shall	
175	conduct an administrative hearing with proper notices to determine the conduct of		
176	prohibited actions and the persons liable.		
177	In cases where there is finding of prohibited actions and determination of the		
178	persons liable, the DOH, through the BHFS and CHDs, are authorized to impose		
179	any or all o	of the following sanctions:	
180	(a)	Suspension of license;	
181	(b)	Revocation of license;	
182	(c)	Closure of the health facility;	
183	(d)	Administrative fine as prescribed by the DOH, which shall be adjusted	
184		yearly based on the Consumer Price Index;	
185	(e)	Filing of criminal charges against persons liable and;	
186	(f)	Permanent disqualification from owning and operating health facilities.	
187	Review of all administrative decisions is lodged with the Secretary of Healtl		
188	subject to t	the rules and regulations of the Administrative Code of 1987.	
189			
190	SEC	2 17. Penalties The commission of prohibited acts as described in this	
191	Act shall b	be punishable by imprisonment of not less than six months but not more	
192	than five years and/or a fine of not less than Five Hundred Thousand Pesos		

193	(P500,000.00) but not more than One Million Pesos (P1,000,000.00). The fine shall be		
194	adjusted yearly based on the Consumer Price Index.		
195			
196	SEC 18. Appropriations The current DOH appropriations under the		
197	General Appropriations Act (GAA) shall be used to carry out the initial		
198	implementation of this Act. Thereafter, subsequent appropriations for purposes of		
199	this Act shall be increasingly derived from the Health Regulation Fund, with		
200	augmentation from the GAA if the former is determined by the DOH to be		
201	insufficient.		
202			
203	SEC 19. Implementing Rules The Department of Health shall promulgate		
204	the implementing rules and guidelines of this Act one hundred twenty (120) days		
205	after the passage of the Act.		
206			
207	SEC 20. Separability Clause If any part, section or provision of this Act is		
208	declared invalid or unconstitutional, other parts or provisions hereof not affected		
209	thereby shall remain in full force and effect.		
210			
211	SEC 21. Repealing Clause Republic Act No. 4226 and Republic Act No.		
212	4688 are hereby repealed. All other laws, decrees, executive orders, circulars,		
213	regulations and memoranda, or parts thereof, inconsistent with this Act are hereby		
214	repealed or amended accordingly.		
215	,		
216	SEC 22. Effectivity This act shall take effect fifteen (15) days after		
217	publication in two (2) newspapers of general circulation.		
218			
219	Approved,		