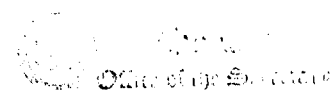


EIGHTEENTH CONGRESS OF THE
REPUBLIC OF THE PHILIPPINES)
First Regular Session)



20 MAY 20 P 3:01

SENATE

S. No. 1540

RECEIVED

Introduced by Senator Manuel "Lito" M. Lapid

AN ACT
PROVIDING FOR A MECHANISM FOR THE PREVENTION OF SHORTAGES OF
DRUGS, MEDICAL DEVICES AND OTHER MEDICAL SUPPLIES ESSENTIAL TO
RESPOND TO EPIDEMICS AND PUBLIC HEALTH EMERGENCIES, AMENDING
FOR THAT PURPOSE REPUBLIC ACT NO. 11332, OTHERWISE KNOWN AS
"MANDATORY REPORTING OF NOTIFIABLE DISEASES AND HEALTH EVENTS
OF PUBLIC HEALTH CONCERN ACT"

EXPLANATORY NOTE

During the early days of the Coronavirus Disease (COVID-19) pandemic in the Philippines, there were reports of an alarming shortage of medical supplies such as face masks¹ and personal protective equipment (PPE)². There were even stories that it is the very frontliners themselves, the doctors, nurses and other medical staff, who are forced to make and improvise their own PPEs due to lack of supply³. Whether there is a correlation between these shortages and the relatively high number of our health workers afflicted with COVID-19 (as compared to other Western Pacific countries⁴) is something that should be checked and investigated upon in the future.

¹ <https://news.mb.com.ph/2020/02/19/dti-looks-for-face-mask-suppliers-to-reduce-shortage/>

² <https://newsinfo.inquirer.net/1242616/hospitals-appeal-for-face-masks>

³ <https://www.rappler.com/nation/255670-photos-medical-frontliners-improvise-personal-protective-equipment-shortage-coronavirus>

⁴ <https://newsinfo.inquirer.net/1262625/high-number-of-virus-hit-health-workers-makes-ph-an-outlier#ixzz6KPG22obT>

Worse, more than two (2) months into the lockdown, the government is facing a new supply problem – shortage in the supplies needed by the testing laboratories⁵.

This pandemic only reveals that without the necessary tools and devices, our country is literally “ill-equipped” and unprepared to face public health emergencies of this magnitude and scale. This proposed measure aims to remedy this dire situation.

Under this amendatory bill to Republic Act No. 11332 or the “Mandatory Reporting of Notifiable Diseases and Health Events of Public Health Concern Act”, a mechanism for the prevention of shortages of drugs, medical devices and other medical supplies essential to respond to epidemics and public health emergencies shall be established. Manufacturers and importers of essential medical items will be required to report to the Food and Drug Administration (FDA) any impending shortage, whether due to permanent discontinuance of production, cessation of its business, logistical or supply-chain difficulties, temporary interruption, or any other cause leading to a substantial disruption in the supply. Through this measure, our government will not be left in the blind as to the demand-supply scenario of essential drugs, medical devices and other medical items.

In view of this, early passage of this bill is sought.



MANUEL "LITO" M. LAPID
Senator

⁵ <https://www.rappler.com/nation/261283-coronavirus-testing-laboratories-facing-supply-shortages>

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

1 SECTION 1. A new Section 8-A to Republic Act No. 11223, otherwise known as
2 "Mandatory Reporting of Notifiable Diseases and Health Events of Public Health
3 Concern Act" is hereby inserted to read as follows:

4
5 **"SECTION 8-A. PREVENTING THE SHORTAGES OF DRUGS,**
6 **MEDICAL DEVICES AND OTHER MEDICAL SUPPLIES ESSENTIAL**
7 **TO RESPOND TO EPIDEMICS OR PUBLIC HEALTH**
8 **EMERGENCIES. –**

9 a) A MANUFACTURER OR IMPORTER OF DRUGS, MEDICAL
10 DEVICES AND OTHER MEDICAL SUPPLIES DEEMED
11 ESSENTIAL IN CONNECTION WITH RESPONDING TO AN
12 EPIDEMIC OR PUBLIC HEALTH EMERGENCY SHALL

1 DURING, OR IN ADVANCE OF, SAID EPIDEMIC OR
2 PUBLIC HEALTH EMERGENCY NOTIFY THE FOOD AND
3 DRUG ADMINISTRATION (FDA) OF A PERMANENT
4 DISCONTINUANCE OF PRODUCTION, CESSATION OF ITS
5 BUSINESS, LOGISTICAL OR SUPPLY-CHAIN
6 DIFFICULTIES, TEMPORARY INTERRUPTION, OR ANY
7 OTHER CAUSE LEADING TO A SUBSTANTIAL
8 DISRUPTION IN THE SUPPLY OF THE DRUGS, MEDICAL
9 DEVICES AND OTHER MEDICAL SUPPLIES, AND THE
10 REASONS FOR SUCH DISCONTINUANCE OR
11 DISRUPTION.

12 b) THE NOTICE REQUIRED BY SUBSECTION (A) ABOVE
13 SHALL BE SUBMITTED TO THE FDA: (1) AT LEAST ONE (1)
14 MONTH PRIOR TO THE DATE OF THE DISCONTINUANCE
15 OR INTERRUPTION; OR (2) IF PRIOR NOTIFICATION IS
16 RENDERED IMPOSSIBLE BY THE CIRCUMSTANCES, AS
17 SOON AS PRACTICABLE.

18 c) THE FDA SHALL ESTABLISH AND MAINTAIN AN UP-TO-
19 DATE LIST OF DRUGS, MEDICAL DEVICES AND SUPPLIES
20 COVERED BY THE NOTIFICATION REQUIREMENT UNDER
21 SUBSECTION (A) HEREOF.

22 d) THE FDA MAY DISCLOSE THE INFORMATION COLLECTED
23 UNDER THIS SECTION TO RELEVANT PARTIES AND
24 ORGANIZATIONS, INCLUDING HOSPITALS AND OTHER
25 HEALTH PROVIDERS, PHYSICIAN ORGANIZATIONS,
26 SUPPLY CHAIN PARTNERS, AND GOVERNMENT
27 AGENCIES AND LOCAL GOVERNMENT UNITS, AND TO
28 THE GENERAL PUBLIC, SUBJECT TO THE CONDITION
29 THAT THE DISCLOSURE WOULD NOT ADVERSELY AFFECT
30 THE PUBLIC HEALTH, SUCH AS BY INCREASING THE
31 POSSIBILITY OF UNNECESSARY OVER-PURCHASE OF
32 PRODUCTS OR OTHER DISRUPTION OF THE

1 **AVAILABILITY OF MEDICAL PRODUCTS TO PATIENTS.**

2
3 Sec. 2. A new Subsection (f) is hereby added to Section 9 of Republic Act No.
4 11332, to read as follows:

5
6 **“(F) FAILURE TO TIMELY COMPLY WITH THE NOTIFICATION**
7 **REQUIREMENT UNDER SECTION 8-A OF THIS ACT.”**

8
9 Sec. 3. *Repealing Clause.* — All laws, presidential decrees, executive orders,
10 proclamations, rules and regulations, or any part thereof, which are inconsistent with
11 the provisions of this Act are hereby repealed or modified accordingly.

12
13 Sec. 4. *Separability Clause.* – If any provision or part of this Act, or the
14 application thereof to any person or circumstance, is held unconstitutional or invalid,
15 the remainder of this Act shall not be affected thereby.

16
17 Sec. 5. *Effectivity Clause.* — This Act shall take effect fifteen (15) days from its
18 publication in the Official Gazette or in at least two (2) newspapers of general
19 circulation.

20
21 *Approved,*