

DEPARTMENT OF HEALTH DEPARTMENT OF TRADE AND INDUSTRY

JOINT ADMINISTRATIVE ORDER

No. 2020 - DOOI

SUBJECT:

Guidelines for the Implementation of Executive Order No. 118 on

Regulation of Prices for COVID-19 Reverse Transcription-

Polymerase Chain Reaction (RT-PCR) Testing and Test Kits

I. RATIONALE

Department of Health (DOH) Department Memorandum 2020-0439 or the Omnibus Interim Guidelines on Prevention, Detection, Isolation, Treatment, and Reintegration Strategies for COVID-19 has been issued to ensure risk-based, targeted testing. The demand for testing has grown to include essential travelers, overseas Filipinos and workers, and other individuals beyond the priority population for testing.

To date, the country has significantly increased its laboratory testing capacity with the operation of 168 licensed COVID-19 laboratories in all its 17 regions. Through these laboratories, a total of 5,388,872 tests have been conducted as of November 19, 2020. The private sector, hospitals, and diagnostic facilities, in particular, have significantly contributed to this improvement in our laboratory testing capacity. They have played a vital role in the realization of the whole-of-system, whole-of-government, and whole-of-society response to the COVID-19 pandemic. However, there is a need to ensure the protection of Filipinos from undue financial risks when availing of these essential health services.

Section 4-r of Republic Act No. 11494 or the "Bayanihan to Recover As One Act" grants the President temporary authority to enforce measures to protect the people from hoarding, profiteering, injurious speculations, manipulation of prices in restraint of trade or other pernicious practices affecting supply, distribution and movement of medicine and medical supplies whether imported or locally produced or manufactured.

Further, RA 10623 or the amendment to the "Price Act", provides that the President, upon recommendation of an implementing agency, may impose a price ceiling on any basic necessity or prime commodity, including drugs as may be further determined and classified by the DOH as basic or prime commodity, during the existence or effects of a calamity or emergency.

Based from the foregoing, Executive Order (EO) No. 118 dated 04 November 2020 mandates the Department of Health (DOH), in coordination with the Department of Trade and Industry (DTI), to determine, formulate and implement a price range for COVID-19 testing conducted by hospitals, laboratories, and other health establishments and facilities including the test kits used in the conduct of said tests, subject to existing rules, and regulations.

II. OBJECTIVES

, f =2E

14

This DOH-DTI Joint Administrative Order (JAO) sets the guidelines for the implementation of EO No. 118, to wit:

- A. Establish the processes and parameters in imposing the price range for COVID-19 diagnostic testing and test kits that will foster transparency, accountability, and fairness to all stakeholders;
- B. Determine mechanisms for the review of the price range, implementation, and monitoring of compliance; and
- C. Identify the roles and responsibilities of the different DOH offices and the DTI involved in the price regulation of COVID-19 testing and test kits.

III. SCOPE AND COVERAGE

This JAO shall apply to all private and public hospitals, laboratories, and other health facilities and establishments, and all other public and private entities involved.

This JAO covers the price range for plate-based RT-PCR testing using the top-down approach. As such, supplemental guidelines on per item costing and price range of test kits and other testing modalities such as cartridge-based RT-PCR tests, and antigen tests, among others, shall be issued separately.

IV. DEFINITION OF TERMS

- A. Health Care Providers (HCP) refers to (i) health facilities, which may be publicly or privately owned; (ii) health care professional, who may be a doctor of medicine, nurse, midwife, dentist, or other allied professional or practitioner duly licensed to practice in the Philippines; and (iii) pharmacies or drug outlets, laboratories, and diagnostic clinics (RA 11223 or the Universal Health Care Law).
- **B.** Licensed COVID-19 Testing Laboratory refers to a health facility that has complied to the standards and requirements set by RITM and HFSRB/CHD-RLED and has obtained a license to operate (LTO) as a COVID-19 testing laboratory (AO 2020-0014)
- C. Mandated Price Range refers to the range of prices determined by the DOH, in coordination with the DTI, to be just and reasonable based on the established processes and parameters;
- **D.** Testing refers to the COVID-19 testing procedures, including all charges related to basic testing services, conducted in hospitals, laboratories, and other testing facilities licensed by the DOH to conduct COVID-19 testing, as such, the term refers to SERVICES being rendered by such facilities.
- E. Test Kits refers to any FDA-registered kits used for the diagnosis, screening, and surveillance of COVID-19. As used in this, test kits shall refer to real time reverse transcriptase polymerase chain reaction (rRT-PCR) test kits and other testing modalities, as may be determined by the DOH.
- **F. Public Sector or Entities** refer to agencies, instrumentalities of the government, including Government-Owned or Controlled Corporations, whether stock or non-stock, and local government units.
- **G. Private Sector or Entities** refer to all those not otherwise covered by the definition of the Public Sector above. These would also include facilities that are under a public-private partnership agreement.

V. GUIDING PRINCIPLES

1,7

- A. Rational price reduction shall be the goal in setting the price range for the goods and services covered by EO No. 118.
- B. Balance of equity, access, and consumer's choice shall guide the setting of fair price ranges. The price range must be just, equitable, and sensitive to all stakeholders.
- C. Setting fair price ranges shall follow an evidence-based, information-driven, and a consultative process promotive of quality, efficiency, effectiveness, and innovation in the delivery of the identified goods and service.
- D. Prices shall be made transparent to the public through readily available and accessible platforms upholding the value of informed choice.

VI. GENERAL GUIDELINES

- A. The DOH, with the DTI, shall set the price range of COVID-19 testing and test kits to ensure quality of service, affordability, and availability to patients and consumers. This shall capitalize on the costing exercises performed by PhilHealth in determining the amount of PhilHealth COVID-19 Testing Packages.
- B. A set of price range of COVID-19 testing per modality for public and private sector and entities shall be imposed to consider their varying costing frameworks, and other pertinent factors that affect pricing.
- C. The DOH and DTI shall ensure transparency, accountability, and good governance in the process of determining the price range through the conduct of public consultations involving various stakeholders such as academic institutions, patient advocacy organizations, consumer groups, HCPs, and other relevant industries.
- D. The mandated price range shall be published using different available venues, such as the official agency website, other social media platforms, and newspapers of general circulation. The cost of publication shall be for the account of and at the expense of the DOH.
- E. For their costs to be considered, all HCPs, licensed COVID-19 testing laboratories, manufacturers, wholesalers, distributors and retailers upon the request of the DOH or the DTI shall submit any and all pertinent data on the prices of different testing and test kits
- F. The costs associated with a faster turnaround time and other premium services such as but not limited to home or community swabbing, shall be within the mandated price range for testing.

VII. SPECIFIC GUIDELINES

A. Determination of Mandated Price Range

- 1. To enable the DOH and DTI to determine the mandated price range for COVID-19 testing and test kits, they shall gather data and information on prices of testing and test kits through local and international publicly available databases, and third party research firms; and manufacturers, distributors, wholesalers, and consumers (such as patients and HCPs).
- 2. In the interim, a top-down approach shall be used to determine the price range for COVID-19 testing.
 - a. Data on retail prices and other relevant information shall be gathered through a survey. Selection process of survey respondents shall ensure adequate representation from both public and private laboratories across all regions.
 - b. Data analysis shall determine the minimum, median, and maximum retail prices of testing conducted by the licensed COVID-19 laboratories.

- c. In setting the price range, the median to the 75th percentile price shall serve as the price range, median price being the reference price, and the 75th percentile price as the price cap.
- d. Different price ranges for public and private licensed COVID-19 laboratories shall be implemented to account for the differences in the costing frameworks.
- 3. Corresponding issuances on the mandated price range per testing modality and test kits shall be issued.
- 4. In order to ensure responsiveness to the needs of stakeholders, the DOH and DTI shall further solicit inputs from patients, HCPs, and consumers in determining the price range of testing and test kits, as far as practicable.
- 5. The DOH-Pharmaceutical Division (PD), DOH-Health Facilities Services and Regulatory Bureau (HFSRB), DTI-Consumer Policy and Advocacy Bureau (CPAB), and DTI-Board of Investments (BOI) shall conduct price evaluations and provide technical advice and support to the Secretary of Health (SOH) and Secretary of Trade and Industry (STI) on whether or not to subject a specific diagnostic test modality for the price regulation. Based thereon, the DOH shall issue within 15 days from the effectivity of the JAO the price range for testing and test kits.

B. Implementation

- 1. No HCP or licensed COVID-19 testing facilities shall charge patients for COVID-19 testing at a price exceeding the mandated price range for COVID-19 testing issued by the DOH.
- 2. As provided under EO 118, compliance with the price range set by the DOH and DTI shall form part of the standards for the licensing of hospitals, laboratories, and other facilities as DOH licensed establishments for COVID-19 testing.
- 3. HCPs or licensed COVID-19 testing facilities, at their own discretion, may charge patients for COVID-19 testing at a price below the reference price, provided that quality of service shall still be maintained.

C. Publication and Posting of Price List

- 1. The DOH through the CHDs shall release an electronic version of the list of prevailing prices to be distributed in all hospitals, laboratories, and other health facilities licensed by the DOH to conduct COVID-19 testing.
- 2. All COVID-19 testing facilities are required to post a clear copy of the price list in conspicuous areas within their premises. It shall be made available to the consumers and regularly updated as the situation may warrant.
- 3. The standard DOH-developed Information, Education, and Communication (IEC) material shall be part of the licensing and inspection checklist for HFSRB.

D. Monitoring, Evaluation, and Enforcement

- 1. The mandated price range for COVID-19 testing and test kits shall be subject to review every month by the DOH through the PD, HFSRB, RITM, and PhilHealth, together with the DTI.
- 2. Complaints on overcharging of COVID-19 testing facilities shall be filed with HFSRB Complaints Unit, while complaints on overpricing of test kits shall be coursed through the Fair Trade Enforcement Bureau.
- 3. The HFSRB, PhilHealth, with the assistance of DTI shall conduct random on-site monitoring for compliance to this JAO. Notice of violations shall be issued to the erring individual or institution, which shall then be referred to the DTI Adjudication Division.

- 4. Upon the authority of the DOH, the DTI-FTEB shall proceed with adjudication process, as applicable, and file the necessary criminal charges with the Regional Trial Court (RTC).
- 5. The preceding provision does not preclude HFSRB from initiating criminal charges.
- 6. Sanctions and penalties for non-compliance are detailed in Section IX of this JAO.

VIII. ROLES AND RESPONSIBILITIES

A. Department of Health shall:

- 1. Set and disseminate the price range for conducting COVID-19 testing and test kits;
- 2. Review and update the price range as necessary;
- 3. Coordinate with the DTI on all matters concerning review and implementation of this JAO; and
- 4. Provide the DTI monitoring team with service vehicles and personal protective equipment.

B. DOH Health Facilities and Services Regulatory Bureau shall:

- 1. Provide technical assistance in the costing, determination, and review of price range for testing and test kits;
- 2. Monitor the cost of COVID-19 testing by HCPs and licensed COVID-19 testing facilities;
- 3. Investigate alleged violations by HCPs and licensed COVID-19 testing laboratories on price range set by the DOH and DTI, in accordance with appropriate laws;
- 4. Impose appropriate sanctions to hospitals and other HCPs for non-compliance with any of the provisions of this JAO; and
- 5. Conduct random on-site monitoring for COVID-19 laboratories, hospitals and other HCPs

C. Research Institute for Tropical Medicine shall:

- 1. Provide technical assistance in the costing, determination, and review of price range for testing and test kits;
- 2. Continue the issuance of validation reports to aid the laboratories in the choice of test kits to be used based on the clear specifications for the indicators of quality in a test kit; and
- 3. Continue assessment of laboratories on their COVID-19 testing compliant to key performance indicators and other quality related issues.

D. DOH Pharmaceutical Division shall:

- 1. Provide technical assistance in the costing, determination, and review of price range for testing and test kits; and
- 2. Convene stakeholders and conduct public consultations as necessary.

E. Health Promotion Bureau and Communications Management Unit shall:

- 1. Propose and develop a communication plan on the dissemination of information related to the imposition of the price range;
- 2. Publish the price range in the official DOH website and other social media platforms; and
- 3. Develop a standard IEC material for the price range of COVID-19 test kits and Frequently Asked Questions (FAQs) which shall be used by all drug outlets.

F. DOH Legal Service shall:

- Assist HFSRB in investigating alleged violations by HCPs and licensed COVID-19 testing laboratories; and
- 2. Provide legal assistance on all matters related to the implementation of this Order.

G. DOH Centers for Health Development Regulations, Licensing and Enforcement Division and Ministry of Health - BARMM Regulation, Licensing and Enforcement Cluster shall:

- 1. Monitor the compliance of all COVID-19 testing laboratories to the implementation of the mandated price range; and
- 2. Submit violators of the mandated y price range to the HFSRB for investigation.

H. Food and Drug Administration shall:

- 1. Ensure the quality of COVID-19 test kits available in the market;
- 2. Monitor compliance of manufacturers, importer, trader, distributors, wholesalers and retailers;
- 3. Collect information regarding the prices of the COVID-19 test kits upon registration; and
- 4. Continuously update DOH and DTI of the FDA registered COVID-19 diagnostic test kits.

I. Philippine Health Insurance Corporation shall:

- 1. Ensure the payment of valid claims within sixty (60) days from submission of claims with complete documentary requirements;
- 2. Monitor the cost of COVID-19 testing by HCPs and licensed COVID-19 testing facilities;
- 3. Incorporate the mandated price range set by the DOH, in coordination with DTI, in revising/determining the cost of their benefit package for COVID-19 testing;
- 4. Take appropriate measures against hospitals and other HCPs for failure to comply with the mandated price range, and any other provisions of this JAO; and
- 5. Conduct random on-site monitoring for hospitals and other HCPs.

J. Department of Trade and Industry shall:

- 1. Assist the DOH in obtaining price and supply related data and information from manufacturers, importers, distributors, and retailers, and analyses thereof;
- 2. Assist in the evaluation and determination of the mandated price range for conducting COVID-19 testing and test kits;
- 3. Assist in the conduct of price monitoring of COVID-19 test and test kits, document the same and provide copy thereof to the DOH; and
- 4. Assist in the adjudication of consumer complaints directly filed with DTI Consumer Care and endorsed by DOH.

K. HCPs and Licensed COVID-19 Testing Laboratories shall:

- 1. Provide test kits and COVID-19 testing services at rates within the set price ranges;
- 2. Cease charging for any and all additional costs associated with COVID-19 testing services; and
- 3. Provide routine documentation and data as requested by the DOH, DTI, and any associated agencies.

IX. SANCTIONS AND PENALTIES

A. Non-Compliance to the Mandated Price Range for COVID-19 Test Kits

Pursuant to RA No. 7581, as amended, imprisonment for a period of not less than one (1) year nor more than ten (10) years or a fine of not less than Five thousand pesos (P5,000) nor more than One million pesos (P1,000,000), or both, at the discretion of the court.

B. Non-compliance to the Mandated Price Range for COVID-19 Testing

A fact finding team shall be organized by the HFSRB upon receipt of complaint regarding violation of the price range set in this guideline. After diligent and thorough evaluation of the gathered evidences, any HCPs, licensed COVID-19 testing laboratory, or any other entity, if found to have indeed violated provisions of the AO, shall be penalized and sanctioned as follows:

First Violation 15-day suspension of LTO as a COVID-19 testing

laboratory and an administrative fine of twenty thousand

pesos (PhP 20,000.00)

Second Violation 30-day suspension of LTO as a COVID-19 testing

laboratory and an administrative fine of thirty thousand

pesos (PhP 30,000.00)

Third Violation Revocation of LTO as a COVID-19 testing laboratory.

The HCP, licensed COVID-19 testing laboratory or any other entity can only reapply for a new LTO one year after its revocation. Any HCP, licensed COVID-19 testing laboratory or any other entity aggrieved by the decision of the HFSRB can file an appeal to the Secretary of Health (SOH) upon receipt of the complaint resolution. HFSRB shall endorse all pertinent documents relating to the complaint to the Office of the Secretary of Health. The decision of the SOH shall be final and executory.

Non-compliance with this JAO by any PhilHealth-accredited Health Care Providers and licensed COVID-19 testing facilities or laboratories shall give rise to administrative liability under RA No. 7875, as amended by RA 11223, for violation of pertinent law and DOH rules and regulations, and breach of performance commitment.

X. REPEALING CLAUSE

All orders, rules, regulations, and other related issuances inconsistent with or contrary to this JAO are hereby repealed, amended, or modified accordingly.

XI. SEPARABILITY CLAUSE

If for any reason, any portion of this JAO shall be declared unconstitutional and/or rendered invalid by any court of law or any competent authority, parts or provisions not affected shall remain in full force and effect.

XII. EFFECTIVITY DATE

This JAO shall be effective immediately upon publication in a newspaper of general circulation and upon filing with the Office of the National Administrative Register (ONAR) of the University of the Philippines Law Center of three (3) certified copies of this Order, and shall be valid until throughout the duration of the state of public health emergency.

NOV Done this 24 day of ___ 2020.

Department of Health

FRANCISCO TOUQUE III, MD, MSc Secretary of Health

Department of Trade and Industry

RAMON M. LOPEZ
Secretary of Trade and Industry