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ABOGADOS



# IMPACT ON THE HEALTH SECTOR OF COVID-19

## LIFE SCIENCES

# INDEX

<b>I. About the state of emergency</b>	<b>3</b>
<b>1. Access to essential goods and services</b>	<b>3</b>
<b>2. Permitted activities</b>	<b>5</b>
<b>II. Legal impact on the health sector</b>	<b>6</b>
<b>1. Activities of regulatory authorities</b>	<b>6</b>
1.1. Digemid	6
1.2. Digesa	7
1.3. INS	8
1.4. Senasa	9
<b>2. Activities of pharmaceutical establishments</b>	<b>10</b>
<b>3. Deadlines suspended in administrative procedures</b>	<b>10</b>
<b>4. State Contracting on health issues</b>	<b>11</b>
<b>5. Protection of personal data related to health</b>	<b>15</b>
<b>6. Import of pharmaceutical products, medical devices, cosmetics, complementary, related or similar nature</b>	<b>18</b>
<b>7. Criminal impacts</b>	<b>20</b>
<b>8. Labor impacts</b>	<b>22</b>



## **I. About the state of emergency**

Last Sunday, March 15, the Peruvian government declared a State of National Emergency throughout the country until March 30, and imposed mandatory social isolation (quarantine) as a result of the outbreak of COVID-19.

In order to ensure the social isolation and the integrity of basic services, a series of measures were put in place to strengthen the health system, as well as ensuring the supply of goods and services essential for the protection of public health.

### **1. Access to essential goods and services**

The Declaration of Emergency provided for by Supreme Decree No. 044-2020-PCM, aims to provide for social isolation. Along these lines, such isolation extends its effects to all sectors and strata of the productive chains.

However, the rule seeks to ensure that, at this particular situation, access to public services and essential goods and services is maintained, considering as such: food supply, medicines, continuity of water services, sanitation, energy, gas, fuel, telecommunications, cleaning and collection of solid waste, funeral services and others established in the referred Decree.

Likewise, Article 2.2 of said Decree guarantees the adequate provision and access to the essential goods and services covered by Article 4 of the aforementioned rule. By way of reference, Article 4 states the following:

"Article 4.- Limitation to the exercise of the right to freedom of transit of persons 4.1 During the validity of the State of National Emergency and the quarantine, persons may only move through public use routes for the provision and access to the following essential goods and services:

(...)

a) Acquisition, production and supply of food, including its storage and distribution for sale to the public.

b) Acquisition, production and supply of pharmaceutical and essential products.

(...)"

In that sense, even when not expressly indicated, medical devices, apparatus, equipment and accessories that by their nature and use are essential to carry out health services are also included.

In addition, the rule states that, in addition to public entities, private entities may determine which services and goods they qualify as "complementary and related" necessary to provide adequate access to essential goods and services.

In an attempt to maintain order, the Ministry of Production published a list of companies that could be considered to be in the exception, however, the opposite effect was generated and many companies expressed their disagreement by not being included. What the Ministry is currently doing is to send communications to companies under the heading of "authorization for the production of essential goods and services".

## **2. Permitted Health Sector Activities**

Health establishments (hospitals, clinics, post offices, among others), pharmaceutical establishments (laboratories, drugstores, apothecaries and pharmacies), opticians and orthopedic products, as well as food and beverages sales establishments, agrochemicals, research, are permitted sector activities.

Along these lines, during the State of Emergency, the Care and Diagnostic Centers in cases of emergency and urgent care shall be accessible. The private, public and Armed Forces health centers may and must continue with the emergency and urgent care service and other activities related to treatments that may not be postponed in order to safeguard the lives of patients.

It is provided that all companies in the production chain of permitted activities may continue to operate.

It must be noted that it is expected that the Ministry of Health and other ministries involved may issue provisions that give greater scope on such activities linked to their sector by the powers granted.



## II. Legal impact on the health sector

### 1. Activities of regulatory authorities

#### 1.1. Digemid

The Directorate of Medicines, Supplies and Drugs (Digemid) is responsible for authorizing health records of pharmaceuticals, medical devices and health products.

Digemid, through a press release on the website <http://www.digemid.minsa.gob.pe/>, indicated that the priority attention at the table of parties and through the Single Window of Foreign Trade (VUCE) shall be carried out with the following procedures:

- Registration and major changes in the health records of pharmaceutical products and medical devices related to the prevention, diagnosis and treatment of COVID-19 and other priority diseases.
- Batch release certificate for biological products.
- Compulsory Health Notification of medical products.
- For the fulfillment of the above, Digemid has designated qualified personnel to attend such procedures. With regard to health products, priority is being given to procedures referred to the records of soaps and gels.

## 1.2. Digesa

The General Directorate of Environmental Health and Food Safety - DIGESA is responsible for the technical, regulatory, monitoring and control aspects of environmental health, as well as food safety in food and beverages intended for human consumption and industrially produced additives of national or foreign production, with the exception of fishery and aquaculture foods. It is competent to grant, recognize rights, certifications, issue technical opinions, authorizations, permits and registrations within the framework of its competencies.

Digesa plays an important role in strengthening monitoring, containment and response systems to COVID-19. The protection of the environment for the health and health of workers is under the coordination of Digesa, according to R.M. No.039-2020/MINSA.

Among the activities to be carried out are:

- Provide technical assistance for proper management of biocontaminated solid residues: bags, garbage cans and rigid containers for sharps.
- Provide technical assistance for the implementation of cleaning and disinfection services to health establishments designated for the care of imported cases.
- Provide technical assistance in cleaning and disinfection of environments and ambulances.



### 1.3.INS

The National Institute of Health (INS) is an entity dedicated to the research of priority health problems and technological development and has the mandate to propose policies and standards, promote, develop and disseminate scientific-technological research and provide health services in the fields of public health, control of communicable and non-communicable diseases, food and nutrition, biological production, quality control of food, pharmaceuticals and related products, occupational health, environmental protection and intercultural health, to contribute to improving the quality of life of the population.

The INS is the only official and authorized entity for the processing of samples and delivery of results in PERU.

For the consultation of results, a link has been enabled: [https://www.ins.gob.pe/resultado\\_coronavirus/](https://www.ins.gob.pe/resultado_coronavirus/) which may be accessed with the NUMBER of the patient's ID:

The image shows a screenshot of a web portal for consulting COVID-19 results. At the top, there is a blue header with the logos of the Peruvian Ministry of Health and the Instituto Nacional de Salud (INS), and a green button labeled 'CONSULTA DE RESULTADOS COVID - 19'. Below the header, the main content area is white and contains a form with three input fields: 'Ingrese el número de Identidad', 'Ingrese el código captcha', and a CAPTCHA image showing the number '861x'. A blue 'Consultar' button is positioned below the form.

In order to strengthen regional laboratories, accelerate and decentralize the diagnosis of Covid19, the Ministry of Health (Minsa), through the INS, delivered the diagnostic kits to laboratories in the regions of La Libertad, Piura, Lambayeque and Cajamarca. Soon, it shall be distributed to the regions of Ucayali, Ica, Cusco, San Martin and Arequipa.



## 1.4.Senasa

The National Service of Agrarian Health - SENASA maintains a system of Phytosanitary and Animal Health Surveillance that protects the country from the entry of plagues and diseases, as well as a system of quarantine of plagues of plants and animals, in places where there are import operations.

In the framework of Articles 2 and 8 of the D.S. N°044-2020-PCM, Minagri has issued several communiqués referring to the measures adopted to ensure the acquisition, production and supply of food through which the normal supply to the wholesale markets of Lima and provinces is guaranteed, therefore, no speculative practices are justified in any product of the family basket.

The following activities shall continue to be carried out with the minimum necessary personnel:

- Harvest of products at a national level.
- Maintenance of agricultural health.
- Transport of food to the various processing and transformation centers, as well as storage, distribution and commercialization.
- Primary and secondary food processing centers.
- Collection and sale of agricultural and livestock foods.
- Care and maintenance of plants, animals, agricultural and forestry activities.
- Import and export of agricultural products.
- Transport of food products in ports and airports.

## **2. Activities of pharmaceutical establishments**

National laboratories, drugstores (importers) and pharmacies are establishments that may continue with their activities in order that the population has access to essential and necessary goods.

The national laboratories shall be able to continue with the production, as well as the drugstores shall be able to continue importing and distributing those products that are part of the health plan that faces the outbreak of the COVID-19 and other priority diseases.

Those responsible for these establishments must take all the prevention measures ordered by the government to safeguard the safety of their employees.

## **3. Deadlines suspended in administrative procedures**

Emergency Decree No. 026-2020 expressly stated that the administrative procedures shall be suspended for 30 working days from March 15. Administrative entities must comply with such provision and, if necessary, confirm which procedures shall be subject to such suspension.

Subsequently, Supreme Decree 029-2020 established the suspension for 30 working days, starting from March 21, of the calculation of the periods of initiation and processing of administrative procedures and procedures of any kind (registration, renewal, sanctioning procedures, control and monitoring, among others subject to a response from the authority)

The Ministry of Health through Secretarial Resolution 042-2020-MINSA, established internal provisions for emergency care during the health emergency period. One of the measures adopted is to temporarily receive requests through a virtual report table, created through the e-mail box [mesadepartesvirtual@minsa.gob.pe](mailto:mesadepartesvirtual@minsa.gob.pe). Requirements from external entities must be linked to exceptional, temporary and complementary measures to prevent the spread of the coronavirus (COVID-19).

#### **4. State Contracting on health issues**

Through Supreme Decree No. 008-2020-SA, published on March 11, 2020, a national health emergency was declared for a period of ninety (90) calendar days, due to the existence of COVID-19.

This declaration allows for the configuration of the case of direct contracting due to an emergency situation, as provided for in Article 27(b) of Law No. 30225, Act on State Contracting, which is subject to the following conditions:

- (i) The public entities are authorized to immediately contract goods, services in general, consulting or works strictly necessary to meet the requirements generated as a direct consequence of the Health Emergency, without being subject to the formal requirements of the State Contracting Act and its Regulations.
- (ii) Once the contracting has been carried out, the Public Entity is obliged to regularize -within a period of ten (10) working days after the delivery of the good, the first delivery in the case of supplies, the beginning of the service, or the beginning of the execution of the work- documentation referred to the preparatory actions, the report or reports containing the legal technical support of the direct contracting, the resolution or agreement that approves it, as well as the contract and its requirements, which at the date of contracting has not been prepared, approved or signed, as appropriate.
- (iii) The public entity must register and publish, within the deadline indicated in (i), the reports and the resolution or agreements mentioned in the Electronic System of State Contracting - SEACE.
- (iv) For the regularization of the guarantee, the term may be extended for ten (10) additional days.

The described procedure may be used by all Public Entities in any sector and level of government, providing that the contracting is strictly necessary to meet the requirements generated as a direct consequence of the Health Emergency.

Notwithstanding the above, on March 14, 2020 Supreme Decree No. 010-2020-SA was issued, adopting the Action Plan and the List of Goods and Services required to deal with the Health Emergency declared by Supreme Decree No. 008-2020-SA, comprising the Ministry of Health, the National Health Institute - INS and the Social Health Insurance - ESSALUD, the content of which may be consulted below:

**[https://cdn.www.gob.pe/uploads/document/file/566595/Anexo\\_II\\_COVID\\_19.pdf](https://cdn.www.gob.pe/uploads/document/file/566595/Anexo_II_COVID_19.pdf)**

In another order of considerations, on March 17, 2020, the General Directorate for Supply of the Ministry of Economy and Finance issued Directorial Resolution No. 001-2020-EF-54.01, which suspended for fifteen (15) calendar days the calculation of the terms of (a) The selection procedures called prior to March 16, 2020 and (b) The improvement of the contracts to be executed; likewise, the call for new selection procedures was suspended for the same period [2].

This rule excludes from the scope of the suspension described above, contracting related to the continuity of essential services, which include the supply of food, pharmaceutical products, medical devices, apparatus, equipment and accessories that, due to their nature and use, are essential for carrying out health services, as we indicated when analyzing the purpose of Supreme Decree No. 044-2020- PCM.

For the same reason, even when the rule issued by the MEF does not mention it, the performance of contracts entered into before March 16, 2020 is not suspended or deferred as long as their purpose is related to the continuity of those essential services. Therefore, contractors must perform their obligations within the established time limits, being subject to the application of penalties and other measures by the Contracting Entities.

Any action or conduct by the authority that prevents a private party from guaranteeing the continuity of essential services in the field of public health, may be subject of criminal legal procedures that are developed later in this document.

## 5. Protection of personal data related to health

The Ministry of Justice through the National Authority of Personal Data Protection reported that sharing a patient's health and therefore, including data related to the COVID1, without their express consent, constitutes an infringement of Law No. 29733.

**<https://www.gob.pe/institucion/minjus/noticias/108768-divulgar-datospersonales-de-pacientes-con-coronavirus-puede-ser-multado-hasta-con-215-mil-soles>**

Regarding the protection of personal data of patients, the General Health Act must be taken into account, which makes health professionals and other professionals linked to the medical act responsible. The dissemination of personal data of patients related to health through social networks is considered sensitive data and therefore, it may not be disseminated with the exceptions indicated by the same rule.

Article 25 of Law No. 26842, the General Health Act, states that any information related to the medical act is confidential, incurring in civil or criminal liability if such information is disclosed. The Act also provides for exceptions:

- a) When there is written consent from the patient;
- b) When requested by the competent judicial authority;
- c) When it is used for academic or scientific research purposes, provided that the information obtained from the medical record is recorded anonymously;



- d) When it is provided to the patient's family or relatives with the purpose of benefiting the patient, provided that the latter does not expressly forbid it;
- e) When dealing with diseases and damages of mandatory declaration and notification, as long as it is provided to the Health Authority;
- f) When it is provided to the insurance company or financing administrator related to the care provided to the patient, provided that it is for the purpose of reimbursement, payment of benefits, control or audit; and,
- g) When necessary to maintain continuity of medical care for the patient.

With regard to the information related to physical or mental health, it is considered sensitive data according to Article 2 of the D.S. No. 003-2013-JUS. In the case of sensitive data, consent must be granted in writing through a handwritten signature, digital signature or any other authentication mechanism that guarantees the unequivocal will of the holder, except for the case indicated in Article 14 of Law No. 29733, Act on the Protection of Personal Data.

Article 14 of Law No. 29733 states that the consent of the holder of personal data is not required for the purposes of its treatment. In the case of personal data relating to health and necessary, in circumstances of risk, for the prevention, diagnosis and medical or surgical treatment of the holder, provided that such treatment is carried out in health establishments or by professionals in the health sciences, subject to professional secrecy; or when there are reasons of public interest provided for by law or when they must be treated for reasons of public health, both reasons must be qualified as such by the Ministry of Health; or for the performance of epidemiological or similar studies; while appropriate decoupling procedures are applied.

Likewise, the Act states that it may refuse to exercise of rights of access, suppression and opposition for reasons based on the protection of rights and interests of third parties or when this may hinder the development of health and environmental control functions. (Article 27).

## **6. Import of pharmaceutical products, medical devices, cosmetics, complementary, related or similar nature**

In accordance with the provisions of Article 8.3 of Supreme Decree No. 044-2020-PCM, the transport of cargo in general is not included within the restriction of temporary border closures ordered by the government. Furthermore, it is stated that the competent entities shall take the necessary measures to ensure the entry and exit of goods to and from the country.

On this basis, it is clear that the ports, airports and the public entities related to these entries (imports) and departures (exports) shall continue their work in order to ensure these processes.

In the specific case of pharmaceutical products, considered as essential goods based on Article 4 of the aforementioned Decree, it has been provided that their entry into the country shall enjoy priority attention, so customs officials have been, in practice, focusing their efforts so that the import process of these goods is carried out in the shortest possible time. As mentioned above, this provision would also include those complementary and related goods, as well as goods of an analogous (similar) nature to pharmaceutical products.

On the other hand, Article 9.3. provides that domestic cargo transport is not subject to restrictions, a provision that also covers the transport of imported pharmaceutical products from the port/airport or customs warehouse to the importer's premises in order to complete the import logistics process.

Although the provision on free national cargo transport is applicable, and even more so, to goods considered as essential (such as imported pharmaceutical products), it would be advisable for the driver transporting the goods to the importer's premises to have the respective supporting documentation regarding the nature of the goods and the condition of "import cargo" of the goods. This is in order to be able to duly prove such transfer before any intervention and/or request of the police or members of the armed forces.

It is understood that the pharmaceutical products (as well as those complementary, related or analogous to them) must have, if appropriate, the corresponding records and/or health authorizations necessary to authorize their import. If there is any change on this subject, customers shall be informed.

## 7. Criminal impacts

Although pharmaceutical establishments, and those related to the health sector, may and must continue to operate during the Government's state of emergency, they are obliged to take all measures issued to prevent the spread of the COVID-19. Failure to comply with these measures in the health establishments permitted to operate (for example, to dispense with the use of masks, distance of 1 meter between their personnel, among others), may result in the commission of the crime provided for in Article 292 of the Criminal Code, which is punishable by a term of imprisonment of not less than 6 (six) months and not more than 3 (three) years for anyone who violates the measures imposed by law or authorities to prevent the spread of a disease, epidemic or plague.

It is important to emphasize that for the commission of the aforementioned crime, it is not required that some collaborator or user of any health sector establishment be infected with COVID-19, but for this purpose it is sufficient to fail to comply with the health guidelines issued by the authority.

On the other hand, if the health establishment deals with the case of a patient with symptoms of COVID-19 without being authorized to do so, it could incur in the commission of the aforementioned crime, provided for in Article 292 of the Criminal Code, even though it has implemented the prevention measures to avoid its spread.

On the other hand, resistance to obeying a specific order legally issued by any of the authorities responsible for enforcing the State of Emergency decreed could lead to the commission of the crime of disobedience and resistance to authority, provided for in Article 368 of the Criminal Code, which carries a penalty of imprisonment of not less than 3 (three) nor more than 6 (six) years.

However, in the event that any authority is deemed to be arbitrarily charging non-compliance with a COVID-19 safety or prevention measure to a health establishment that is within the permitted operating exceptions, could be referred to the Office of the Prosecutor for Crime Prevention, alleging the imminent commission of the crime of abuse of authority.

## **8. Labor impacts**

In labor issues, as has been said, the establishments previously mentioned in this document may continue to operate. This means that workers may (and even must) continue to attend their workplaces to provide services in person.

Employers are empowered to implement a Remote Work system, whose regulations have been issued by the Government precisely to use in this situation. In essence, this work system consists of the employer being able to unilaterally modify the workplace of the workers, without the need for their acceptance, with the aim of having them work from their homes. This scheme involves relaxing the demands and requirements imposed by the regular teleworking scheme.

Finally, it must be noted that a technical document has been issued, adopted by Ministerial Resolution No. 084-2020-MINSA, which establishes general and special measures for health personnel in charge of the care of COVID-19 cases, ranging from the use of personal protection equipment, training, compliance with a series of hygiene obligations, monitoring, etc.



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