# Law No. (8) of 2021
# on
# Issuing the Law of Organizing Blood operations and plasma collection for manufacturing and exportation of its derivatives

## In the Name of the People
## President of the Republic

The House of Representatives has agreed the following law and we have issued it:

**(Article One)**

The provisions of the accompanying law shall apply to blood operations, plasma collection and manufacturing of its derivatives, plasma exportation for manufacturing then recovery, its importation and exportation.

**(Article Two)**

Law No. (178) of 1960 on collection, storage and distribution of blood and its compounds in the southern region shall be repealed. Any other provisions that may contradict the provisions of the accompanying law shall be null and void.

**(Article Three)**

The stakeholders' addressees by the provisions of the accompanying law shall be committed to reconcile their situation in accordance with its provisions, within a grace period not exceeding three months as from the date of issuance of the executive regulations of the accompanying law.

**(Article Four)**

The Prime Minister shall issue the executive regulations of the accompanying law within three months as from the date of enforcing of this law based on the proposal of the minister concerned with health. The existing decisions shall be valid in a manner that does not contradict the provisions of the accompanying law until issuance of the executive regulations.

**(Article Five)**

This DECREE shall be published in the 'Official Gazette' and shall come into effect from the day following its publication therein.
This law shall be stamped with the seal of the state, and shall be applied as one of its laws.

Issued by the Presidency of the Republic on Ramadan 3rd, 1442 AH, corresponding to April 15th, 2021

**Abdel Fattah El-Sisi**

# Law of Organizing Blood operations and plasma collection for manufacturing and exportation of its derivatives

## (Chapter One)
## Definitions

### (Article One)

**For the purposes of applying the provisions of this Law, the following terms shall have the meanings set out for each term hereunder:**

Competent Ministry: It is the Ministry concerned with health affairs.
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**Blood Operations:** They are collecting, testing, storing, distributing or transporting blood, its compounds and derivatives except for the plasma for the purpose of manufacturing.
Plasma: It is a blood derivative. It includes therapeutic and collected plasma for the purpose of manufacturing.
**Plasma Derivatives:** They are biological preparations derived from the components of human blood plasma. They include for example: albumin, clotting factors and other plasma derivatives.
**Plasma Collection Center:** It is a center licensed for donation, collection, storage, analysis or distribution of plasma for manufacturing purposes.
**Plasma Exportation for manufacturing then recovery:** Blood plasma exported out of the Arab Republic of Egypt for manufacturing purposes and recovery in the form of plasma derivatives.
**Regular Donor:** Every volunteer who donates plasma on a regular basis according to the medical rules.
**Unified Procurement Authority:** It refers to the Egyptian Authority for Unified Procurement, Medical Supply and Managing the Medical Technology.

## (Chapter Two)
## Regulating Blood Operations

### (Article Two)

Without prejudice to the provisions of licensing blood operations centers stipulated by any other law, blood operations shall be prohibited to be carried out in a specialized fixed or mobile center except after obtaining a license from the competent ministry.
This license shall be only granted to the governmental and non-governmental entities under which the blood operations are subject to its jurisdiction.
The competent minister shall determine the basic specifications and requirements that shall be met by the center in accordance with the presentation of the Blood Operations Control Board.

### (Article Three)

The registration applicant shall pay the following fees:
Amount that does not exceed twenty thousand pounds for the examination upon submitting the registration request.
Amount that does not exceed one hundred thousand LE for issuing the license.
Amount that does not exceed fifty thousand LE for renewing the license.
These fees shall be paid by any of the electronic payment methods specified by law. The government entities shall be exempted from paying these fees.

The executive regulations of this law shall specify the categories of these fees, the data and procedures for submitting and renewing the registration request and the grievance procedures against the decision issued in this regard.

**(Article Four)**

The physician licensed to manage the blood operations center shall be aware of the amount of blood donated from the donors, where this procedure shall be under his supervision and responsibility.
In all cases, blood donation shall be voluntary and free of charge.

**(Article Five)**

Each blood operations center shall prepare an electronic or paper record in which the names of the medically fit donors, who are allowed to donate in this center, shall be recorded. These centers shall be connected to each other in order to make the names registered in their records available to all centers.
A statement of the method of registration in the records, verification of the donor's identity and the rules for changing the donation center shall be issued by a decision of the competent minister. A card shall be issued for each donor, provided that the executive regulations of this law shall determine the conditions and data of its issuance.

**(Article Six)**

**A Blood Operations Control Council shall be established in the competent ministry, headed by the competent minister or his representative and with the membership of:**
General director of National Blood Transfusion Services at the competent ministry (rapporteur).
A representative of the Ministry of Defense and Military Production, to be nominated by the Minister of Defense and Military Production.
A representative of the Ministry of Interior, to be nominated by the Minister of Interior.
A representative of the Ministry of Higher Education and Scientific Research, to be nominated by the Minister of Higher Education and Scientific Research.
Secretary of the Supreme Council of University Hospitals.
A representative of the Unified Procurement Authority, to be nominated by the President of Egyptian Drug Authority.
A representative of the Egyptian Drug Authority, to be nominated by the President of Egyptian Drug Authority.
A representative of the General Authority for Health Insurance, to be nominated by the chairman of the Authority.
A representative of the Public Authority for Health Care, to be nominated by the chairman of the Authority.
A representative of the Public Authority for Health Accreditation and Control, to be nominated by the President of the Authority.
Head of central of the Central Administration for Non-Governmental Therapeutic Institutions and Medical Licensing in the competent ministry.
Director of the General Department for Blood and its Derivatives Affairs at the competent ministry.
A representative of the medical associations subject to the provisions of the issued law regulating the practice of private work promulgated by Law No. (149) of 2019, to be nominated by the Minister of Social Solidarity.
A representative of the private blood centers, chosen by the competent minister.
Two experienced persons, chosen by the Prime Minister after being presented to the competent minister.

The Prime Minister shall issue a decision of naming the Blood Operations Control Board.

**(Article Seven)**

The Blood Operations Control council shall be responsible for the following:
1. Technical supervision of blood operations centers and inspection of fulfilling the requirements and specifications stipulated for these centers.
2. Unifying the method and manner of work and the materials used in blood operations centers without restricting the purposes of scientific research.
3. Establishing a central electronic database linked to all blood operations centers and Egyptian Drug Authority and the Unified Procurement Authority to indicate the amount (of blood) collected, disbursed and the available stock at all centers.
4. Evaluation of the technical researches relevant to the aspects related to blood operations and evaluation of the work of licensed blood operations centers annually without prejudice to the freedom of the scientific research.
5. Setting the specifications and requirements that shall be met in the centers specialized in blood operations.
6. Setting rules for determining the prices of blood, its compounds and derivatives, prices of blood services in the government and in the private sectors, and setting a price for blood transfusion services in the private sector for citizens, all aforementioned shall comply with the applicable international standards.
7. Reviewing and developing blood operations regulations.
8. Preparing the internal regulations of the Blood Operations Control council and its guideline. This regulation shall be issued by a decision of the competent minister.

**(Chapter Three)**

Plasma collection for manufacturing and exportation of its derivatives

**(Article Eight)**

It's prohibited to collect blood plasma except by a licensed center.
It shall be also prohibited to manufacture blood plasma except by a licensed factory. All aforementioned shall be conducted in compliance with the applicable international standards.

**(Article Nine)**

The license of operating a blood plasma collection center and its renewal shall be issued by a decision from the Egyptian Drug Authority. Additionally the technical operation license for the factory and its renewal shall be issued by a decision from the Egyptian Drug Authority in coordination with UPA.
The license applicant shall pay an examination charges not exceeding forty thousand LE upon submitting the application and pay for licensing a charge not exceeding two hundred thousand LE, as well as a charge not exceeding one hundred thousand LE shall be paid at license renewal, knowing that, these charges shall be paid by any of the electronic payment methods legally specified. Government entities shall be exempted from paying these charges.
The executive regulations of this law shall specify the categories of these charges, the specification, licensing requirements, data and procedures for submitting and renewing the licensing request and the grievance procedures against the decision issued in this regard

**(Article Ten)**

It shall be prohibited to obtain blood plasma except from a medically fit donor.
The executive regulations of this law shall determine the donation conditions and the number of

times for donation in compliance with internationally recognized standards, and according to the health and age status of the donors and the conditions and circumstances in which the donor becomes a regular donor.

**(Article Eleven)**

The blood plasma collection center shall grant the donor a compensation which commensurate with transportation expenses, feeding expenses, working hours and any other expenses incurred by the donor for the sake of his donation. The executive regulations of this law shall determine the rules for calculating this compensation.

**(Article Twelve)**

The blood plasma collection center may dispose of the amount collected to any of the factories subjected to the provisions of this law and transfer plasma for manufacturing then recovery and export finished plasma derivatives after achieving self-sufficiency in accordance with the controls set by Egyptian Drug Authority in coordination with the Unified Procurement Authority.

**(Article Thirteen)**

The factory subjected to the provisions of this law may dispose of plasma derivatives through: sale or export.

It may import or export blood plasma as finished products.

All aforementioned shall be carried out in accordance with the provisions, rules and procedures issued by a decision of Egyptian Drug Authority in coordination with the Unified Procurement Authority, after achieving self-sufficiency in plasma derivatives.

**(Article Fourteen)**

The blood plasma collection center shall be responsible for adverse events occurred for the donor due to and during donation process.

## (Chapter Four)
## General Provisions

**(Article Fifteen)**

Taking into account the provisions of article eleven of this law, the donation of blood or plasma shall be voluntary and free of charge.

In all cases, the donation shall be carried out based on a free will and free from the defects of consent as determined by the executive regulations of this law.

The child donation shall not be accepted and the consent of his parents or those who have trusteeship or guardianship over him also shall not be accepted. As well as the donation shall not be accepted from non-eligible or incompetent person and the consent of his legal representative shall not be considered.

The exclusion of the donor shall be based on medical reasons and not for other discrimination reasons after conducting the medical examinations and analyzes.

**(Article Sixteen)**

All entities working in the field of blood operations and plasma collection shall be committed to the confidentiality of the donor and receiver data and not to disclose them except by virtue of an order on a bill issued by the judge of provisional matters. In the court of first instance to which these authorities affiliate or by a decision of the competent investigation authority.

(Article Seventeen)

All centers concerned with collecting blood and plasma must conduct the necessary medical examinations determined by the executive regulations of this law before using blood, its components, plasma and its derivatives except for the cases required for scientific research purposes.

(Article Eighteen)

The medical customs release of any blood units, its components, plasma or its derivatives, imported or donated shall be prohibited except after making sure that they are free of all infectious diseases and viruses determined by a decision issued by the competent minister in coordination with the Egyptian Drug Authority. The examination shall be by testing samples from all batches contained in the consignments followed by issuing official approved certificate stating that they are free from those diseases and viruses taking into consideration the controls and other rules specified by the executive regulations of this law in this regard.

(Article Nineteen)

Blood or its components and plasma shall be freely dispensed for therapeutic purpose for the patients of all free treatment departments in the state-affiliated hospitals in accordance with the controls issued by a decision of the competent minister.

(Article Twenty)

The Minister of Justice, in coordination with each of the competent ministers, the Minister of Defense and Military Production, the Minister of Interior, the Minister of Higher Education and Scientific Research and the Chairman of the Egyptian Drug Authority, each within his jurisdiction, shall issue a decision granting the status of judicial officers to employees who undertake supervision, control and inspection of establishments subject to the provisions of this law.

## (Chapter Five)
## Penalties

(Article Twenty one)

**Without prejudice to more aggressive penalty, whoever commits any of the following acts shall be punished with a fine of not less than one hundred thousand LE and not exceeding one million LE:**

1. Managed a blood operations center without a license, in violation of the provisions of this law and its executive regulations.
2. Managed a blood plasma collection center or a factory for manufacturing of its derivatives without a license, in violation of the provisions of this law and its executive regulations.
3. Exported, imported blood plasma or commenced to in violation of the provisions of this law and the decisions issued in implementation to it.
4. Obtained blood or plasma from a medically unfit donor in violation of the provisions of this law and its executive regulations.
5. Violated the provisions of articles (fifteen and sixteen) of this law.
6. Refrained deliberately from disbursing blood despite its availability or sold it at a price does not match the set prices.

Without prejudice to the rights of bona fide third parties, the court may, in addition to the penalty stipulated in the preceding paragraph, confiscate the devices, tools and supplies that are the subject of the violation and close down the center or factory.

The fine shall be doubled in case of recidivism.

## (Article Twenty Two)

The person responsible for the actual management of a legal person shall be punished with the same penalties for acts committed in violation of the provisions of this law, if it is proven that he was aware of them and if his breach of management duties facilitated the occurrence of the crime.

The legal person shall be jointly liable for the fulfillment of the financial penalties and compensations adjudged if the violation was committed by one of its employees in the name of the legal person and for its benefit.

## (Article Twenty Three)

The authority concerned with issuing the license may administratively close the center or factory if it was managed without a license or without supervision of a human doctor, without implementing the specifications and requirements determined by the executive regulations of this law.

The executive regulations of this law shall determine the period of closure and its procedures, the cases of cancelling the licensing decision and the dates of submitting a petition and its adjudicating.



ISBN at the Egyptian National Library and Archives 65/2021
The General Organization for Government Printing Offices
25814/ 2020- 19/4/2021- 1049