

From the official minutes of the PNE, 16 June 2011, Plenary Session of the House of Representatives, in which the following bill was passed:

Organ donation and transplantation and other provisions

CHAPTER A

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1 (Article 1 of Directive 2010/53/EU)

Subject matter

The provisions of Chapters A to F of this Act regulate the general principles and conditions for the removal of organs from living and deceased persons for the purpose of transplantation into the human body. Directive 2010/53/EU (originally 2010/45/EU) of the European Council and of the Council of 7 July 2010 (Official Gazette L. 207, 06.08.2010, p. 0014-0029) on the quality and safety standards of these organs is incorporated into Greek legislation and measures are adopted for its implementation. The framework of criminal provisions to combat organ trafficking is strengthened.

Article 2 (Article 2 of Directive 2010/53/EU)

Scope of application

The provisions of Chapters A to F of this Regulation shall apply to the donation, testing, classification, removal, preservation, transport and transplantation of human organs (hereinafter referred to as 'organs') intended for transplantation.

This Regulation shall not apply to

1. autotransplantation,
2. the donation, procurement, testing, coding, processing, preservation, storage and distribution of human tissues and cells intended for human applications, as well as of processed products derived from human tissues and cells intended for human applications, governed by the provisions of Decree Law 26/2008 (A51), which implemented Directive 2004/23/EC of the European Parliament and of the Council of 31. 3.2004 (EEL 102/7.4.2004) and the related Directives 2006/17/EC (EEL 38/9.2.2006) and 2006/86/EC (EEL 294/25.10.2006). It also does not apply to tissues and cells used as autologous grafts during a single surgical procedure,
3. the donation of blood and blood components, which is regulated by Decree-Law No 138/2005 (A195),
4. the collection and use of reproductive cells for the purpose of applying medically assisted reproduction methods, which is regulated by Law No. 3305/2005 (A17).

Article 3 (Article 3 of Directive 2010/53/EU)

Definitions

For the purposes of this document

- (a) "authorisation" means the approval, after verification of conditions, the granting of an authorisation and registration by the competent authority,
- (b) 'competent authority' means the authority, body, organisation and/or institution responsible for implementing the provisions of this Regulation,
- (c) 'abortion' means the final destination of an organ when it is not used for transplantation

- (d) 'donor' means any person who donates one or more organs during his lifetime or after his death
- (e) 'donation' means the donation of human organs for transplantation, organ donation and transplantation and other arrangements
- (f) 'donor characterisation' means the collection of appropriate data on the characteristics of the donor necessary to evaluate his suitability for organ donation in order to carry out a better risk assessment, minimise the risks for the recipient and optimise organ distribution
- (g) 'European organ exchange organisation' means a public or private, non-profit organisation dealing with national and cross-border exchanges of organs, the majority of whose member countries are Member States of the European Union,
- (h) 'Organ' means a differentiated part of the human body, formed by various tissues, which retains its structure, vascularisation and capacity to develop physiological functions with a significant degree of autonomy. Parts of an organ are also considered to fall within this definition if they serve the same purpose as the complete organ in the human body and meet the structural and vascular requirements,
- (i) 'organ characterisation' means the collection of appropriate information on the characteristics of an organ, necessary to evaluate its suitability in order to carry out a proper risk assessment, minimise the risks for the recipient and optimise organ allocation,
- (j) 'procurement' means the process by which donated organs are made available,
- (k) 'procurement organisation' means the public or private hospital or hospital unit that undertakes or coordinates the procurement of organs
- (l) 'preservation' means the use of chemical agents, changes in environmental conditions or other means to prevent or retard biological or physical deterioration of human organs from procurement to transplantation
- (m) 'recipient' means a person who receives an organ transplantation
- (n) 'serious adverse event' means any unexpected adverse event occurring at any stage in the chain from donation to transplantation which might lead to the transmission of a communicable disease, be fatal or life-threatening, result in disability or incapacity of the patient, or cause or prolong hospitalisation or morbidity
- (o) 'serious adverse reaction' means any unanticipated response, including a communicable disease, in the living donor or in the recipient that may occur at any stage of the chain from donation to transplantation that is fatal or life-threatening, disabling or incapacitating, and which results in or prolongs hospitalisation or morbidity
- (p) 'procedures' means written instructions that describe the steps in a specific procedure, including the materials and methods to be used and the expected end result
- (q) 'transplantation' means a procedure by which an attempt is made to restore certain functions of the human body by transferring an organ from a donor to a recipient
- (r) 'transplantation unit' means an organised unit of a health care establishment of a public or private non-profit making body in which the transplantation of organs is carried out, subject to authorisation,
- (s) 'traceability' means the ability to trace and identify: (a) the organ at any stage in the chain from donation to transplantation or abortion; (b) the donor; (c) the procurement organisation; (d) the recipient in the transplantation centre; (e) products and materials coming into contact with the organ in question.

CHAPTER B

GENERAL PRINCIPLES - CONDITIONS FOR ORGAN DONATION

Article 4

Therapeutic purpose of donation and transplantation

1. The removal of organs from a living or deceased donor for the purpose of transplantation shall be carried out only for therapeutic purposes.
2. In particular, the removal of organs from a living donor for transplantation shall be carried out where organs from deceased persons are not available at the time of removal, there is no alternative therapeutic method of comparable effectiveness, and the transplantation does not pose a serious and obvious risk to the life or health of the donor.

Article 5 (Article 13 of Directive 2010/53/EU)

Prohibition of remuneration

1. The donation of human organs from dead and living donors shall be voluntary and unpaid. In order to ensure that the procurement of organs is carried out on a non-profit basis, the receipt of any financial compensation from the donor, whether before or after the removal of the organ, the granting of any financial compensation by the organ recipient or his family to the donor or his family or to the doctors or other health professionals involved in the chain from organ removal to transplantation, as well as any financial transaction between the donor and the recipient, whether directly or through the intermediary of a third party, shall be prohibited.
2. The concept of financial compensation does not include cases of costs and compensation referred to in Article 6, nor compensation due as a result of an error during the procedure of organ removal and transplantation.
3. The disclosure of the need for, or availability of, human organs shall be prohibited where it is made for the purpose of offering or seeking a corresponding financial or comparative advantage.

Article 6 (Article 13 of Directive 2010/53/EU)

Costs - Compensation

1. The principle of unpaid donation shall not preclude the granting of compensation to the living donor, provided that such compensation is strictly limited to compensating for the costs and loss of income associated with the donation, so as not to create an economic incentive or advantage for the potential donor.
2. The costs of removal of one or more organs from a living or deceased donor, their preservation, transport and transplantation shall be borne by the insurance organisation of the recipient or potential recipient. If the latter are not insured, they are covered by a special appropriation entered each year in the budget of the Ministry of Health and Social Solidarity under a specific code number.
3. As regards the living donor in particular, the expenses referred to in paragraph 2 shall cover (a) medical and paramedical operations before and after the removal of organs; (b) medicines; (c) material means of medical rehabilitation or relief; (d) hospitalization before and after the removal of organs; (e) the employment of a specialist nurse; (f) the costs of travel to the removal organisation and the donor's accommodation; (g) any positive loss due to absence from work; (h) remuneration for work missed in preparing and carrying out the removal and restoring the health of the donor.
4. With regard to a deceased donor, the costs referred to in paragraph 2 shall cover: a) the medical and paramedical operations prior to the removal of the organ; b) the hospitalisation and transport necessary for the removal of the organ.
5. A joint decision of the Ministers for Labour and Social Security and for Health and Social Solidarity shall regulate specific matters relating to the payment of costs.

6. In the event of the disability or death of the donor or future donor due to complications arising from the removal of one or more organs or from the necessary preparation and preliminary examinations, compensation, in addition to the benefits of the insurance institutions provided for in paragraphs 2 to 4, shall be paid by decision of the Minister for Health and Social Solidarity to the donor or recipients of maintenance from the donor or future donor. The allowance shall be paid from the special budget appropriations of the Ministry of Health and Social Solidarity referred to in paragraph 1 of this Article. A decision of the Minister of Health and Social Solidarity shall determine the necessary supporting documents to be submitted to the competent department of the Ministry of Health and Social Solidarity.

Article 7

Obligation to provide information

1. Information on the potential living donor

a. Information to living persons wishing to become organ donors for transplantation purposes shall be provided by a physician of a relevant specialty or by the physician or medical team of Organ Removal Organisations or by physicians of Transplantation Units or Transplant Coordinators or designated employees of the National Transplantation Organisation who are specially trained for this purpose.

b. The information shall cover, in particular, the nature of the organ removal operation, the necessary preparation of the donor, the procedure and the time required for the recovery of the donor's health, the risks to life and health and the benefits to the recipient.

In addition, it must cover the type and amount of costs covered under Article 6 and the relevant procedures.

c. The information must be complete, easily understandable, objective and given in a discreet manner and with respect for the freedom, personality, religious, social and philosophical convictions of the individual. It may be repeated several times, each time with the participation of several different doctors, if the potential donor so wishes. The provision of information in accordance with the provisions of this document is attested by a pre-printed form, signed by the donor and the donor's doctor(s) providing the information, a copy of which is kept in the donor's medical file. This form is drawn up by the National Transplant Organisation and distributed to all hospitals in the country and in particular to removal organisations.

2. Information for persons exercising parental authority over a deceased child.

a. Information to the parents or guardian of a minor, deceased person for the removal of his or her organ or organs, in accordance with Article 9, shall be provided by the minor's attending physician or by the physician or medical team of the Removal Organizations or by the physicians of the Transplantation Units or Transplantation Coordinators or designated for this purpose and specially trained employees of the National Transplantation Organization.

b. The information shall relate in particular to the necessity of the donation of the organ(s) and the benefits for the recipient, as well as the urgency of the removal.

c. The information must be complete, easily understandable, objective and provided in a discreet manner and with respect for the freedom, personality, religious, social and philosophical convictions of the individual. The provision of information in accordance with the provisions of this Regulation shall be evidenced by a form, signed by the persons giving consent on behalf of the deceased minor donor and by the physician or physicians providing the information, a copy of which shall be kept in the donor's medical file. This form is drawn up by the National Transplant Organisation and distributed to all nursing institutions in the country and in particular to removal organisations.

3. Any citizen can contact health care providers, removal organisations and transplant units, as well as transplant coordinators and the National Transplant Organisation, in order to obtain specific information on organ donation and transplantation.

4. The National Transplant Agency carries out a public information campaign on organ donation and transplantation. In addition, the Minister of Health and Social Solidarity may enter into an agreement to undertake information activities with other ministers, such as the Minister of National Defence, the Minister of Education, Lifelong Learning and Religious Affairs, the Church of Greece and other relevant bodies.

Special attention shall be paid to the content of information brochures and the website of the National Transplant Organisation.

Article 8

Removal of organs from a living donor

1. The removal of organs from a living donor shall be permitted only when the transplantation is to be carried out: a) to his/her spouse, b) to a patient to whom the donor has been bound by a civil union, in accordance with the provisions of Act no. 3719/2008, for more than three years; c) to a relative up to the fourth degree of consanguinity, in a straight or lateral line; d) to a relative up to the second degree of consanguinity; e) to a person with whom the donor has a personal relationship and is emotionally linked; f) to a person with whom the donor has a personal relationship and is emotionally linked. In this case, authorisation is required by a court decision, issued in a voluntary procedure, after verifying all the conditions for the removal of an organ from a living person and, in addition, the mental health of the potential donor, the personal relationship and emotional attachment of the potential recipient, as well as the altruism of the offer, (f) if the spouse or relative with the aforementioned degree of kinship of a patient in need of a transplant wishes to donate the necessary organ, but there is no histocompatibility, the organ is removed and at the same time the patient is promoted to the National Registry; g) if there is no histocompatibility between two potential transplant recipients and their spouse or living relative with the degree of relationship indicated above, but there is histocompatibility between a candidate recipient and the spouse or living relative of the other, organ donation is permitted on a reciprocal basis, by decision of the National Transplant Agency.

2. Removal must only be carried out by an adult person.

3. Removal of organs from a living donor for transplantation purposes is permitted only if the donor is not under legal guardianship and has legal capacity, after having been informed in accordance with Article 7.

4. Consent shall be given by one of the following means: (a) a notarial deed; (b) a document attesting to the authenticity of the donor's signature. Consent shall be explicit and specific. The documents referred to in points (a) and (b) shall be kept in the donor's medical file.

5. The donor's consent may be freely withdrawn up to the moment when the medical procedure for organ removal begins. Such withdrawal may be carried out by any means.

Article 9

Removal of organs from a deceased donor

1. The removal of one or more organs from a deceased person shall be carried out if the person is an adult and if the conditions set out in the following paragraph are fulfilled. The removal of a minor is permitted if the parents or the parent having custody of the child consent to it. If there are no parents or if they have relinquished parental authority, consent must be given by the guardian.

Consent is given: a) by a document in which the authenticity of the signature is certified; b) by an oral statement entered in a special register kept by the removal organisation or transplantation unit. Two witnesses must be present at the declaration and must co-sign the special register. The consent must be explicit and specific. The documents referred to in points (a) and (b) shall be kept in the donor's medical file.

2. The removal of one or more organs from an adult, deceased person shall be carried out if, during his lifetime, he did not express his objection in accordance with paragraph 3. This paragraph shall enter into force as of 1.6.2013 in order to provide comprehensive information to citizens during this period through the implementation of a specific information campaign. A decision of the Minister of Health and Social Solidarity shall determine the manner and all technical details concerning the expression of positive or negative statements from each person and the manner of their collection by the EMO.

3. The National Transplant Organisation keeps a file in which citizens' statements on their opposition to the removal of their organs after death are recorded. Any adult citizen can send the National Transplantation Agency a statement to that effect, certified by an authenticated signature. No specific form is required for the declaration, as long as the person's precise wishes are expressed expressly and unambiguously. This declaration is freely revocable. It can be revoked by means of a new declaration of revocation, which must be sent in the same way to the National Transplant Agency. The original declaration is deleted from the file and is deemed not to have been made.

4. The collection and processing of the data contained in the file referred to in paragraph 3 shall be subject to the provisions of Law. 2472/1997. Particular emphasis is placed on safeguarding the confidentiality of this information. Access to this file is restricted to the relevant officials of the National Transplant Organisation and transplant coordinators.

5. Organ removal from a deceased donor must be carried out after death, the criterion for which is brain stem necrosis, in accordance with modern and widely accepted scientific standards, as defined in the CDC decision on the diagnosis of brain death (Decision 9 of 21/20.3.1985). A decision of the Minister of Health and Social Solidarity determines precisely the criterion for the occurrence of death, after an opinion of the Central Health Council (CCHS). Similarly, a "Code of Practice" is established on the procedure for diagnosing and confirming brain death.

6. When the attending physician diagnoses brain stem necrosis and when the function of certain organs is maintained by artificial means, he is required to draw up a death certificate together with an anaesthetist and a neurologist or neurosurgeon. The death certificate must not involve a doctor who is a member of the transplant team. The attending physician must then inform the transplant co-ordinator, if there is one in the hospital, and the National Transplant Organisation without delay as to whether the deceased adult has declared his or her refusal to become a deceased organ donor. If the deceased is a minor, the attending physician, together with the Transplant Coordinator, if present in the hospital, ensures that the persons competent to consent to organ removal are found, informed and consented to. Once consent has been obtained, he informs the National Transplant Organisation without delay. If the transplant is to take place, the deceased person must continue to be placed on life support.

7. The removal of organs from a deceased donor must be carried out with due respect for the body of the deceased person. Particular attention shall be paid to the restoration of his image.

Article 10

Preservation of anonymity

The identity of the deceased organ donor shall not be disclosed to the recipient and his/her family. The identity of the recipient shall also not be disclosed to the family of the deceased donor. Only the success of the transplant can be revealed.

Article 11

Donation to a specific person

Organ donation after the death of the donor may not be made to a designated recipient. The suggestion of a recipient by the body or the organ donor shall not be taken into account, but the established order of priority shall be followed.

CHAPTER C

QUALITY AND SAFETY OF ORGANS

Article 12 (Article 4 of Directive 2010/53/EU)

Quality and safety framework

1. All stages in the chain from donation to transplantation or organ rejection are governed by a quality and safety framework, which is determined by a decision of the Minister for Health and Social Solidarity on the proposal of the National Transplantation Organisation and an opinion of KESY. The quality and safety framework must cover the health professionals involved, the medical protocols, the facilities, the equipment, the records kept and any other relevant issues.
2. The quality and safety framework shall provide for the adoption and implementation of procedures
 - (a) for verifying the identity of the donor,
 - (b) for verifying the consent of the living donor or the lack of opposition of the deceased donor or the consent of the parents or the permission of the guardian when the deceased donor is a minor
 - (c) verify the characterisation of the organ and the donor in accordance with Article 16 and the Annex,
 - (d) for the procurement, maintenance, packaging and labelling of organs in accordance with Articles 13, 14 and 17
 - (e) for the transport of human organs in accordance with Article 17,
 - (f) for ensuring traceability, in accordance with Article 20, but also for the protection of individuals with regard to the processing of personal data and the protection of medical confidentiality,
 - (g) for the accurate, rapid and verifiable reporting of serious adverse events and reactions, in accordance with Article 21(1)
 - (h) for the management of serious adverse events and reactions, in accordance with Article 21(2).The procedures referred to in points (f), (g) and (h) shall be undertaken by removal organisations, transplantation units and European organ exchange organisations.
3. The quality and safety framework shall also ensure that health professionals involved in all stages of the chain from donation to transplantation or disposal of organs are adequately qualified or trained and competent. It also provides for the organisation and implementation of specific training programmes for these health professionals.

Article 13 (Article 5 of Directive 2010/53/EU)

Removal organisations

1. Organ removal shall take place in 'Organ removal units', which shall be public or non-profit hospitals or private clinics that have received the relevant licence.
2. The licence is granted by decision of the Minister of Health and Social Solidarity, after a check on compliance with the legal requirements. It is valid for three years and may be renewed for an equal period according to the same procedure.
3. To obtain the licence, private clinics must have an interface with the National Transplant Organisation and Transplant Units.
4. A presidential decree, on the proposal of the Minister of Health and Social Solidarity and the National Transplant Agency and the opinion of the CPSH, will define the conditions that the Transplant Agency must meet in terms of facilities, equipment, organisation, medical, nursing and other necessary personnel, institutions, and any other relevant matters. It also establishes the procedure for granting, renewing or revoking the authorisation of the transplant company. The

same presidential decree shall establish the technical details of the interconnection of private clinics with the National Transplant Organisation and Transplant Units.

5. Checks shall be carried out on Removal Organisations to ensure that they meet the conditions and comply with the provisions of this Law in general. The Presidential Decree referred to in paragraph 4 shall determine the competent inspection bodies, the frequency of regular inspections and the possibility of carrying out extraordinary inspections, the criteria for assessing compliance with the quality and safety framework referred to in Article 12 and any other relevant matters. The College of Health and Welfare Services Inspectors (HSSI) may be entrusted with the inspection.

6. If it is found that the necessary conditions are no longer fulfilled, the licence of the removal agency shall be revoked.

7. Notwithstanding the provisions of paragraphs 1 to 6 of this Article:

A. If a hospital meets the required conditions but does not have the necessary and really on-call medical staff, 24 hours a day, every day, all year round, it shall receive the licence of a Harvesting Organisation, but only for the removal of organs from a deceased donor and only by the medical staff of the Transplantation Unit, where the transplantation will take place.

B. After consultation with the medical staff of the procurement organisation, the procurement may be carried out by the medical staff of the Transplantation Unit, for maximum protection of the donor and success of the transplantation.

Γ. Hospitals, public or non-profit hospitals or private non-profit institutions that have obtained a licence to operate a transplantation unit shall at the same time constitute a transplantation organisation, without the need to obtain the relevant licence.

8. At the request of the European Commission or another Member State of the European Union, the Ministry of Health and Social Solidarity shall provide information on the regulatory framework applicable to Removal Organisations.

9. Removal Agencies shall comply with the provisions of this Law.

Article 14 (Article 6 of Directive 2010/53/EU)

Removal of organs

For the purposes of granting a licence to a removal organisation in accordance with Article 13, the following shall be taken into account:

1. Medical operations for organ removal, such as the selection and evaluation of a potential donor, shall be carried out in accordance with the recommendations and guidance of a physician. For the selection of the doctor, the provisions of Decree 38/2010 (A 78), which transposed Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 into Greek law, shall apply.

2. The decision of the Minister of Health and Social Solidarity referred to in Article 13(4) also defines the specifications for the design, construction, maintenance and operation of the operating theatres where the removal of organs is carried out, for the specialisation and specific training of the health professionals who collaborate in this operation, as well as the medical protocols for ensuring the quality and safety of the organs removed.

3. The management of the material and equipment used for organ removal must be carried out in accordance with Union, international and national legislation, standards and guidelines on sterile and medical equipment.

Article 15 (Article 9 of Directive 2010/53/EU)

Transplantation units

1. Organ transplants shall be carried out exclusively in specially organised units, 'Transplantation Units' of public or non-profit institutions which have received the relevant licence.

2. The licence is granted by decision of the Minister of Health and Social Solidarity, after a proposal of the National Transplant Organisation and an opinion of the C.S.Y., after verification of compliance with the legal requirements. The authorisation specifies the activities that the transplant unit may undertake. It is valid for three years and can be renewed for an equal period following the same procedure.
3. A presidential decree, on the proposal of the Minister of Health and Social Solidarity and on the advice of the National Transplant Organisation and the C.S.Y., will determine the conditions that the Transplant Unit must meet in terms of facilities, equipment, organisation, medical, nursing and other necessary personnel. The procedure for granting, renewing or revoking authorisation and any other relevant matters shall also be established.
4. Inspections shall be carried out in the transplant units to ensure that the conditions are met and that they comply with the provisions of this Act in general. A presidential decree, proposed by the Minister for Health and Social Solidarity, determines the competent control bodies, the frequency of regular controls and the possibility of carrying out extraordinary controls, the criteria for assessing compliance with the quality and safety framework referred to in Article 12 and any other relevant matter. This control may be entrusted to the College of Health and Welfare Inspectors (HSCI).
5. If it is established that the necessary conditions are no longer met, the licence shall be revoked on the recommendation of the National Transplantation Agency.
6. Transplant units are under the supervision and control of the Minister of Health and Social Solidarity and submit an annual report on their activities to the National Transplant Agency within the first two months of the following year.
7. Transplantation units must, before carrying out a transplantation, check that
 - a) organ and donor characterisation has been completed and recorded in accordance with the provisions of this document and the Annex,
 - b) the storage and transport conditions of the organs sent have been met.
8. The Ministry of Health and Social Solidarity, at the request of the European Commission or another Member State of the European Union, provides information on the conditions for granting authorisation to transplantation units.
9. Transplantation units are available 24 hours a day, 365 days a year.

Article 16 (Article 7 of Directive 2010/53/EU)
Characterisation of organs and donors

1. All organs to be removed and all potential donors shall be characterised prior to transplantation by collecting the information listed in the Annex.
Part A of the Annex contains the minimum set of data that must be collected for each donation. Part B of the Annex contains the additional set of information to be collected following a decision by the medical team, taking into account the availability of this information and the particular circumstances of each case.
2. By way of derogation from paragraph 1, even if not all the minimum data specified in Part A of the Annex are available, organ transplantation may, where appropriate, be performed if, following a risk-benefit analysis in the specific case, including in emergency situations where there is a threat to the patient's life, the expected benefits outweigh the risks due to the existence of incomplete data.
3. In order to meet the requirements of the quality and safety framework referred to in Article 12, the medical team performing organ removal shall ensure that all necessary information is collected. In particular, when performing organ removal from a living donor, the medical team shall ensure that the necessary information is collected from the living donor, providing the information needed to understand the consequences of the donation. The information provided to the potential donor in accordance with Article 7 shall cover, inter alia, the risks to the health and life of the recipient arising from organ transplantation in the absence of sufficient information. The information shall be collected by means of a verbal statement from the potential donor, by handing over documents

from the donor's medical records and by submitting the donor to medical examinations. When carrying out organ removal from a deceased donor, the medical team must, as far as possible, ensure that the above information is obtained from the relatives of the deceased donor or other persons. The medical team shall request the medical records of the potential living or deceased donor, as well as any relevant information from the donor's treating physician and/or the public or private hospital where the donor was admitted or treated in the past. The treating physician and/or the hospital must forward the medical record and all relevant information without delay. In urgent cases, the necessary information can be provided orally.

The medical team should make it clear to all persons from whom information is requested that it is important that it be transmitted rapidly.

4. The tests required for organ and donor characterisation must be carried out by laboratories with suitably trained or qualified and competent personnel and with appropriate facilities and equipment.

5. Procurement organisations, health care professionals or other entities, as well as laboratories involved in organ and donor characterisation must transmit organ and donor characterisation data to the Transplantation Unit in a timely manner.

6. Where organs are exchanged between Member States of the European Union, it is necessary to ensure that the information on organ and donor characterisation, as specified in the Annex, is transmitted to the other Member State in accordance with the procedures established by the European Commission pursuant to Article 29 of Directive 2010/53/EU.

Article 17 (Article 8 of Directive 2010/53/EU)

Organ transfer, donors, potential recipient, transplantation team

1. The National Centre for Emergency Assistance (hereinafter referred to as NACA), provided for by Law. 1579/1985 (A217), is entrusted with the transfer:

(a) the removal of organs from the Removal Units to the Transplantation Units,

(b) patients who are potential donors after death, from any health facility to the Removal Units or Transplantation Units,

(c) prospective recipients and their necessary accompanying persons, whether doctors, nurses or intimate partners, from wherever they may be, to the Transplantation Unit where the transplantation will take place,

(d) the medical team of the Transplantation Unit performing the organ removal, to the Removal Organisation.

2. The ECDC will endeavour to find a suitable means of transport by land, air or sea. To facilitate its work, it may request the assistance of hospitals, especially if they are removal and transplantation units, which should facilitate transport by providing ambulances or other vehicles.

3. Transport costs shall be covered in accordance with Article 6 of this Act in conjunction with Article 31 of Act No. 2072/1992 (A125).

4. In exceptional cases, when, due to special and adverse circumstances, the organ transport and transplantation may be cancelled, the N.C.A.B. may request the assistance of the National Health Operational Centre (hereinafter referred to as N.H.O.C.E.Y.), provided for in Article 15 of Law No 3370/2005 (A176).

5. All institutions and persons involved in the transport of organs to transplantation units are obliged to:

- (a) select and implement appropriate procedures to ensure the integrity of the organ during transport and a transport time appropriate to the requirements.
 - (b) ensure that the packaging used for the transport of organs is labelled with the following information (aa) identification of the procurement organisation, including address and telephone number; (b) identification of the transplantation unit for which the organs are intended, including address and telephone number; (c) a statement that the package contains a human organ, specifying the type of organ and its right or left-hand position, if such specification is required, and the indication "VULCAN"; (d) a statement of the recommended transport conditions, including instructions for keeping the package at an appropriate temperature
 - (c) ensure that the organs transported are accompanied by the organ and donor characterisation report.
6. The requirement of paragraph 1(b) need not be complied with where transport takes place within the same building.

Article 18 (Article 12 of Directive 2010/53/EU)

Health personnel

1. Health professionals involved in each step of the process from donation to transplantation shall be adequately trained, qualified and capable of carrying out their tasks. They shall receive specific training, as provided for in Article 12(3), in order to keep abreast of scientific developments, to use the experience gained and to adopt best practices.
2. The task of promoting organ donation and assisting in transplantation, both at central level and at hospital level, shall be entrusted to 'Transplantation Coordinators'. For this purpose, Transplant Coordinators shall serve in the posts established in the National Transplant Organization and its Branches, if any, as specifically provided for in paragraph 2 of Article 27, in the hospitals in which they serve, and in particular in those in which an Intensive Care Unit operates, in those that have been authorized as an Abortion Organization or Transplant Unit, as well as in other institutions, if necessary, such as the National Transplant Organization and the National Transplant Centre.
3. Transplantation coordinators may be graduates or holders of an equivalent foreign degree in medicine, with or without specialisation, nursing, health visiting and social work, holding a special training certificate from the National Transplantation Agency.
4. The National Transplantation Agency is responsible for organising a special training programme each year of a total duration of one year and for issuing a training certificate.
5. A presidential decree, issued on the proposal of the Minister of Health and Social Solidarity, after consultation with the National Transplantation Agency, shall determine the qualifications and duties of Transplantation Coordinators, the organisation and content of the training programme, the conditions for obtaining the special training certificate and any other relevant matters.

Article 19

Target candidates

1. The National Transplant Organisation maintains a National Registry, where every potential recipient is registered after being certified as suitable for transplantation. The certification is carried out by a transplantation unit of his or her choice and by his or her attending physician, on the basis of criteria derived from medical science and ethics. The national register is the only one kept and is uniform throughout the country. The geographical division of the country and the allocation of any type of graft on the basis of geographical proximity to the removal organisation is prohibited.
2. Recipients on the National Register are required by the National Transplant Organisation to submit, at least once a year, a certificate from their doctor on their state of health. If a question of unfitness for transplantation arises, the National Transplantation Agency invites the potential recipient for a new assessment. The decision of the Transplantation Unit carrying out the

assessment on the unfitness of the potential recipient must be specifically justified and communicated to both the National Transplantation Organisation and the potential recipient. On the basis of this decision, the National Transplant Organisation removes the patient from the National Registry.

3. A potential recipient who is not entered in the National Registry because he/she is considered unsuitable for transplantation or who is removed from the National Registry due to confirmed emerging unfitness, may appeal to the National Transplantation Agency, which will refer him/her to another Transplantation Unit for a final decision in collaboration with his/her treating physician.

4. If the cause of ineligibility for transplantation ceases to exist, the patient may be reassessed and re-registered in the National Register.

5. The allocation of transplants to potential recipients in the National Registry must be carried out in such a way as to ensure transparency and equal treatment of potential recipients. The ranking of candidates in the National Registry is based on a weighted scoring system, based on medical data. The criteria for inclusion in the National Register include, in particular, the type of organ to be transplanted, the stage of the disease suffered by the potential recipient, the blood group of the donor and recipient, histocompatibility, the urgency of the operation, age, body weight and medical history. In the event of a tie between the scores of potential recipients, the decisive criterion shall be their clinical examination, certified by a medical team, together with geographical proximity to the transplant unit in cases where, due to the nature of the transplant, any delay would jeopardise the transplant.

6. The medical criteria by organ type, the system for classifying future recipients in the National Registry and any other relevant organisational matters shall be determined by decision of the Minister for Health and Social Solidarity, after a proposal from the National Transplant Organisation and an opinion from the National Transplant Centre.

7. Recipient candidates have the right to be informed of their order of classification in the National Registry, as and when it is updated.

Article 20

(Article 10 of Directive 2010/53/EU)

Traceability

1. Particular attention shall be paid to the traceability of all organs removed, disposed of, transported and transplanted, in order to safeguard the health of donors and recipients. Only the doctor or medical team responsible for the care of the donor and/or recipient has access to the information that ensures the traceability of organs. No information relating directly or indirectly to the identity of the donor and/or the recipient shall be disclosed to the donor, the recipient and their families, in application of the principle of anonymity laid down in Article 10 of this Regulation.

2. Removal organisations and transplantation centres involved in the chain from donation to transplantation or disposal of the organ shall keep a register, whether electronic or not, containing: (a) the information necessary to ensure traceability at each step of the chain from donation to transplantation or disposal of the organ; and (b) information on organ and donor characterisation, as defined in the Annex, in accordance with the quality and safety framework. The information contained in this register shall be sent to the National Transplantation Agency after each organ removal or transplantation.

The National Transplantation Organisation shall be responsible for setting up a file, electronic or otherwise, containing the information referred to in paragraph 1, on organs, donors and recipients, in order to enable the identification of each donation, each organ and each recipient connected thereto. The provisions of Law No. 2472/1997 (A50).

4. The records referred to in paragraphs 2 and 3 shall be kept for at least thirty years after donation. They may be kept in electronic form.

5. Where organs are exchanged with other Member States of the European Union, the information necessary to ensure the traceability of organs shall be transmitted in accordance with the procedures established by the European Commission pursuant to Article 29 of Directive 2010/53/EU.

Article 21

(Article 11 of Directive 2010/53/EU)

Reporting system and management of serious adverse events and reactions

1. Removal organisations and transplantation units shall set up a registration system and promptly report to the National Transplantation Agency: (a) serious adverse events which may affect the quality and safety of organs and which may be related to the testing, characterisation, procurement, maintenance and transport of organs; (b) any serious adverse reaction observed during or after transplantation and which may be related to the above activities; (c) the procedures they have in place to manage serious adverse events and reactions. The National Transplant Agency shall relate this information to the register referred to in Article 20(3) and transmit it to the institutions in a timely manner, where necessary.
2. The National Transplant Agency shall be responsible for establishing appropriate procedures for the management of serious adverse events or reactions by procurement organisations and transplantation units in accordance with the quality and safety framework referred to in Article 12.
3. Where organs are exchanged with other Member States of the European Union, serious adverse events and reactions shall be reported in accordance with the specific procedures established by the European Commission pursuant to Article 29 of Directive 2010/45/EU.
4. Where the organ donor is also a tissue donor, the National Transplant Agency shall ensure the interconnection, by electronic or non-electronic means, between the reporting system referred to in paragraph 1 of this Article and the reporting system established pursuant to Article 11 of Legislative Decree 26/2008 transposing Directive 2004/23 of the European Parliament and of the Council of 31 March 2004 (A 61).

Article 22

(Article 15 of Directive 2010/53/EU)

Quality and safety issues in relation to living donations

1. Where organs are removed from living donors, all necessary measures shall be taken to ensure the highest protection of donors and the quality and safety of organs intended for transplantation.
2. Living donors shall be selected on the basis of their health status and medical history by appropriately trained or qualified and competent health professionals. On the basis of these criteria, potential donors may be excluded if it is suspected that the removal of organs from them would pose an unacceptable risk to the health of the recipient.
3. Removal organisations are required to report to the National Transplant Agency, which keeps the records, the identity of living donors, information on the health status of donors before and after the removal of one or more organs, as well as the necessary information on the removal operation and the organs themselves.
4. Removal Organisations, as well as any health professional, medical team or public or private hospital, who undertake the care of a living donor after donation, must report to the National Transplantation Agency any incident and information that: (a) may be related to the quality and safety of the donated organ and, consequently, to the safety of the recipient; and (b) any serious adverse event and reaction caused to the donor as a result of the donation and diagnosed during the monitoring of the donor's health status. The National Transplant Agency is responsible for collecting this information and transmitting it to the Transplant Units in order to protect the health of the recipient.

5. The provisions of Law no. 2472/1997 (A 50).

CHAPTER OBLIGATIONS OF THE COMPETENT AUTHORITIES

Article 23

(Article 17 of Directive 2010/53/EU)

Competent authorities

1. The competent authorities for the application of the provisions of this Article shall be.
2. In cases of simultaneous donation and/or transplantation of organs, tissues and cells, the National Transplant Organisation shall cooperate with the National Authority for Medically Assisted Reproduction, which was established by Law No. 3305/2005 (A 17).

Article 24

(Article 17 of Directive 2010/53/EU)

National transplantation organisation

1. The National Transplantation Organisation (NTO) is established as a non-profit organisation under the supervision of the Ministry of Health and Social Solidarity.
2. The purpose of the National Transplant Agency is to assist the Ministry of Health and Social Solidarity in the formulation and implementation of national policy in the field of organ, tissue and cell transplantation. The National Transplant Agency may delegate some or all of its tasks to another body supervised by the Ministry of Health and Social Solidarity and deemed appropriate. This body may also assist the National Transplantation Agency in carrying out its tasks.
3. In order to fulfil its tasks, the National Transplantation Organisation shall in particular take the following measures
 - Recommend the quality and safety framework referred to in Article 12 and adapt it to recent developments.
 - Recommends the granting, renewal or withdrawal of authorisation to removal organisations, transplantation units, tissue and cell procurement organisations, tissue and cell banks, private cord blood banks, cord blood banks, tissue and cell application units and cells.
 - Ensures that removal organisations, transplantation units, tissue and cell procurement organisations, tissue and cell banks, private cord blood banks, umbilical cord blood banks and tissue and cell establishments are regularly audited to ensure that they comply with the requirements of this law.
 - Carries out an annual evaluation of the functioning and results of Removal Organisations, Transplantation Units, Procurement Organisations, Tissue and Cell Application Units and submits a report to the Ministry of Health and Social Solidarity.
 - Implement a system for reporting and managing serious adverse events and/or reactions in accordance with Article 20.
 - Provides appropriate guidance to health care institutions, professionals and other actors involved at each stage of the chain from donation to transplantation or organ disposal, including, where appropriate, guidance on the collection of important post-operative information to assess the quality and safety of transplanted organs.
 - It shall participate, where possible, in the European Union network in accordance with Article 32.
 - Supervises the exchange of organs with other Member States of the European Union and with third countries in accordance with Article 30.
 - It shall ensure that the fundamental right to protection of personal data is fully and effectively promoted in all organ transplantation activities.

Article 25

Management of the National Transplantation Organisation

1. The National Transplantation Agency shall be governed by an eleven-member Board of Directors, comprising:
 - a. a professor or associate professor of medicine or biology or biochemistry, specialising in a field of knowledge relevant to organ or tissue and cell transplantation,
 - b. a director of a bone marrow transplantation centre or of a tissue and cell bank
 - c. a director of an intensive care unit,
 - d. a director of a transplantation unit,
 - e. a director of a tissue compatibility centre, who is
 - a director of a transplantation centre who is involved in transplantation, f. a director of a prestigious legal person
 - g. a representative of the Panhellenic Medical Association (P.I.S.), or a representative of the Panhellenic Association of Bioscientists,
 - h. the head of the department responsible for transplantation the head of the Transplantation Directorate of the Ministry of Health and Social Solidarity,
 - i. a representative of the Church of Greece,
 - j. a recipient or potential recipient of an organ, tissue or cell transplant proposed by the National Confederation of People with Special Needs
 - k. a representative of the National Association of Graduate Nurses - Nurses of Greece.The members referred to in cases b, c, d, and e shall abstain from Board meetings and decisions when a matter concerning the nursing home in which they serve or a patient treated in the nursing home in which they serve is under discussion. In this case, their alternate shall attend the Board.
2. The president, vice-president and other members of the board of directors of the National Transplant Organisation and their deputies shall be appointed by decision of the Minister for Health and Social Solidarity.
3. The term of office of the President and the members of the Board of Directors of the National Transplantation Agency shall be three years and may be renewed.
4. A joint decision of the Ministers of Finance and Health and Social Solidarity shall determine the remuneration of the President and the members of the Board of Directors.

Article 26

Resources of the National Transplantation Agency

The resources of the National Transplantation Agency are:

- a. A fixed annual grant from the ordinary budget of the Ministry of Health and Social Solidarity.
- b. Donations, inheritances, legacies and any kind of sponsorship from third parties.
- c. Collection of all types of costs for bone marrow research, collection and transfer from the International Bone Marrow Research Banks, from the patients' insurance institutions or from the special allocation of the Ministry of Health and Social Solidarity in the case of uninsured beneficiaries and from the International Bone Marrow Research Banks.

Article 27

Staff of the National Transplantation Agency

1. There are eight posts for specialists, recruited on a five-year private law contract, renewable once. The specific duties of these staff members shall be laid down in the internal rules of procedure referred to in Article 28.

2. These posts shall be filled in accordance with the provisions of Law No 3812/2009 (A 234). The secondment of employees, either permanent or employed under a private employment contract of indefinite duration, of the Ministry of Health and Social Solidarity or its subordinate bodies, Health Regions and hospitals supervised by the Ministry of Health and Social Solidarity is authorised. The removal is carried out by decision of the Minister of Health and Social Solidarity after obtaining the agreement of the

the Board of Directors of the National Transplant Organisation and the body to which the official belongs, for a maximum period of three years, which may be renewed.

3. Fifteen posts are created for staff employed under private employment contracts of indefinite duration, recruited in accordance with the provisions of Law no. 2190/1994. Eight of these posts are transplant coordinators. The others are administrative staff.

Staff may be employed on a fixed-term private-law employment relationship in accordance with the provisions of Article 21 of Law No 2190/1994 (A 28).

4. For the recruitment of staff to the posts referred to in the preceding paragraphs, the qualifications for appointment are as follows:

a. for the posts referred to in paragraph 1, those provided for in the provisions of paragraph 1. 2 of Article 25 of Law no. 1943/1991 (A 50),

b. for the posts referred to in paragraph 2, those provided for in respect of each branch or speciality by Decree-Law No 50/2001 (A 39).

5. The remuneration of such staff shall be paid in accordance with the provisions of Act No 3205/2003 (A 297) and Act No 3205/2003 (A 297). 3833/2010 (A 40).

6. A lawyer shall be appointed as a legal advisor with a fixed salary, responsible for the legal guidance of the board and staff, as well as for their representation in and out of court. The appointment shall be subject to the possession of a licence to practise as a lawyer before the Court of Justice or the Court of Appeal.

7. To fulfil the purpose of the National Transplant Organisation, Transplant Coordinators shall be available 24 hours a day, 365 days a year.

Article 28

Operating rules of the National Transplantation Organisation

1. A presidential decree, issued on the proposal of the Ministers of Finance and Health and Social Solidarity, shall draw up the Rules of Operation of the National Transplant Organisation, which shall regulate the organisation and structure of its departments, the assignment of staff responsibilities, the organisation of the on-call service of transplant coordinators, the appointment of an ethics committee or other scientific committees, management control, the status and disciplinary control of staff, and any other relevant matters. The composition of the Management Board and the staff of the National Transplantation Agency may be changed according to the same procedure.

2. By joint decision of the Ministers of Finance and Health and Social Solidarity, regional branches of the National Transplantation Organisation may be established and up to ten posts of medical and other staff may be created for each branch. A presidential decree, issued on the proposal of the Ministers of Finance and Health and Social Solidarity, shall determine the location, local jurisdiction, structure and personnel, as well as the responsibilities of the branch and the distribution of staff positions by category, sector and specialty.

CHAPTER E
EXCHANGE OF ORGANS WITH THIRD COUNTRIES AND EUROPEAN ORGAN EXCHANGE
ORGANISATIONS - EXCHANGE OF INFORMATION

Article 29
(Article 20 of Directive 2010/53/EU)
Exchange of organs with third countries

1. Organ exchange with third countries outside the European Union shall be supervised by the National Transplantation Organisation, which may conclude agreements independently or jointly with European organ exchange organisations with its counterparts in third countries.
2. Organ exchanges with third countries shall only be authorised if the organs
 - (a) can be traced from the donor to the recipient and vice versa; and
 - (b) meet quality and safety requirements equivalent to those laid down in this Act.

Article 30
(Article 21 of Directive 2010/53/EU)
European Organ Exchange Organisations

The National Transplant Organisation may enter into written agreements with European organ exchange organisations, provided that they meet the quality and safety requirements established by this Law, and contract them out:

- (a) carry out the activities provided for in the framework of quality and safety;
- (b) specific tasks relating to the exchange of documents to and from the Member States of the European Union and third countries.

Article 31
(Article 18 of Directive 2010/53/EU)
Records and reports on removal organisations and transplantation centres

1. The National Transplantation Agency shall:
 - (a) keep a register of the activities of removal organisations and transplantation centres, aggregated data on living and deceased donors and the types and quantities of organs removed and transplanted or otherwise disposed of, in accordance with the provisions on the protection of personal data and statistical confidentiality,
 - (b) draw up and make public an annual report on these activities; and
 - (c) establish and maintain registers of removal organisations and transplantation units.
2. At the request of the European Commission or another Member State of the European Union, the Ministry of Health and Social Solidarity shall provide information on the registers of removal organisations and transplantation units.

Article 32
(Article 19 of Directive 2010/53/EU)
Exchange of information

The National Transplantation Agency and experts in organ transplantation may participate in a network of competent authorities responsible for transplantation, established by the European Commission in accordance with Article 19 of Directive 2010/53/EU, with a view to exchanging information on the experience gained in the implementation of this Directive.

Article 33
(Article 22 of Directive 2010/53/EU)
Report to the European Commission

The Ministry of Health and Social Solidarity shall submit to the European Commission, no later than 27 August 2013 and every three years thereafter, a report on the activities carried out in accordance with the provisions of this Law and on the experience gained in its implementation.

CHAPTER F
PROTECTION OF PERSONAL DATA - MEDICAL CONFIDENTIALITY - CRIMINAL PROVISIONS

Article 34
(Article 16 of Directive 2010/53/EU)
Protection of personal data, confidentiality and security of processing

1. All records and registers referred to above contain sensitive personal data within the meaning of Law No 2472/1997. Any activity relating to organ donation and transplantation is subject to the provisions of Law No 2472/1997, which transposed Directive 95/46/EC, in order to ensure that the fundamental right to protection of personal data is fully and effectively guaranteed.
2. All bodies involved in organ donation and transplantation must adopt appropriate technical measures to ensure that:
 - (a) the data processed are kept confidential and secure, in accordance with Article 10 of Law. 2472/1997. Any unauthorised access to data and systems that allow the identification of the donor or recipient must be punished, as established in Articles 21 to 23 of Law 2472/1997. 2472/1997,
 - B) it is not possible to verify the identity of the donors and recipients whose data are processed under the above-mentioned provisions of the Law, with the exception of Article 7 of Law 2472/1997. 2472/1997. Any use of systems or data to verify the identity of donors or recipients for purposes other than those permitted by Article 7 of Law No. 2472/97 is prohibited. 2472/1997, including for medical reasons, shall be punished as provided for in Articles 21 to 23 of the Law. 2472/1997,
 - (C) the principles relating to data quality, as defined in Article 5 of Law No. 2472/1997. In addition to the doctors involved in organ removal and/or transplantation, doctors providing assistance to the donor and the recipient may have access to the relevant personal data files, in accordance with Article 10 on the quality assurance of organs traceability and only for therapeutic purposes.
4. Health professionals involved in organ removal and transplantation shall be subject to the rule of protection of medical confidentiality laid down in the Code of Medical Ethics, in accordance with Article 13 of Act No 3418/2005 (A 287) and Article 371 of the of the Criminal Code.

Article 35
(Article 23 of Directive 2010/53/EU)
Criminal sanctions

1. Any person who intentionally removes an instrument in breach of the provisions of Articles 4, 8 and 9 shall be punished by a term of imprisonment of at least two years and a fine of at least EUR 15 000.
2. Any person who has one or more organs removed for a consideration shall be liable to a term of imprisonment of not less than four months. The court may, however, in the light of all the circumstances, freely assess all the circumstances and find that the act has gone unpunished.
3. Any person who publicly announces the offer of his institution in exchange for financial consideration shall be liable to a term of imprisonment of not less than four months.

4. Any person who accepts or receives financial compensation for mediating the removal of another person's organs for transplantation purposes, whether the removal, transplantation or both are carried out, shall be punished by a term of imprisonment of at least two weeks and a fine of at least fifteen thousand (15,000) euros.
5. Anyone who receives or offers to receive, for a financial consideration, organs of human origin shall be liable to a term of imprisonment of at least four months and a fine. If the purpose of obtaining the organs is to resell them, he shall be liable to a term of imprisonment of at least three years and a fine of at least EUR 15 000.
6. Whoever instructs, facilitates or participates in any way in the transplantation of an organ to a recipient other than the recipient according to the order of classification of potential recipients in the National Register, referred to in Article 19, shall be punished by a term of imprisonment of no less than two years and a fine of no less than fifteen thousand (15,000) euro.
7. Whoever instructs, facilitates or participates in any way in the transplantation of an organ to a recipient who is not included in the National Registry, pursuant to Article 19, shall be punished by imprisonment of no less than two years and a fine of no less than fifteen thousand (15,000) euro.
8. Any person who completes the National Register, pursuant to Article 19, in violation of the legally established criteria for the classification of potential recipients shall be punished by a term of imprisonment of at least two years and a fine of at least fifteen thousand (15,000) Euro.
9. Any person who in any way obstructs any of the following
unlawfully obstructing the removal of a graft, its storage or transfer, or its storage or implantation, shall be punished by a term of imprisonment of at least one year and a fine of at least six thousand (6,000) Euros. If the commission of the offence referred to in the previous paragraph resulted in the non-use of the graft, the offender shall be punished by a term of imprisonment of at least two years and a fine of at least EUR 15 000.
10. Any person who performs organ removal or transplantation in violation of Article 13 on Procurement Organisations and Article 15 on Transplantation Units shall be punished by a term of imprisonment of at least two years and a fine of at least fifteen thousand (15,000) euros.
11. Penalties for the offences provided for in paragraphs 1 to 10 shall be imposed if they are not punished more severely by another penal provision.

Article 36

Aggravating circumstances

1. If the offences provided for in Article 35 are committed repeatedly, professionally or habitually, or if the victim is a minor or a person with disturbed mental or conscience functions, they shall be punishable by imprisonment. Any person who has been irrevocably convicted of an offence under this Act within the last ten years for a felony or within the last five years for a misdemeanour shall be considered a recidivist.
2. If the offences referred to in Article 35 are committed within the framework of a criminal organisation, the perpetrator shall be punished by imprisonment of at least ten years and a fine.

Article 37

Local limits of the law

The offences provided for in Articles 35 and 36 are punishable if committed by a citizen or a foreigner, regardless of where they are committed.

Article 38

Confiscation - Disposition of revenues

1. In case of conviction under Articles 35 and 36, the court shall order the mandatory confiscation of the financial consideration illegally given, as well as of movable and immovable property acquired with such consideration.

2. The proceeds of fines or penalties imposed under Articles 35 and 36 and of confiscation under paragraph 1 shall constitute public revenue and shall be collected in accordance with CEDAW. They shall be entered in the budget of the Ministry of Health and Social Affairs and shall be entered in the special code number from which transplantation expenses of uninsured beneficiaries are paid. A joint decision by the Ministers of Finance, Justice, Transparency and Human Rights and Health and Social Affairs will determine how these revenues are to be transferred to the Ministry of Health and Social Affairs.

Solidarity and its entry in the special code number, as well as any other necessary details.

Article 38 Confiscation - Disposition of Revenue

1. In the event of conviction under Articles 35 and 36, the court shall order the mandatory confiscation of the financial consideration illegally given, as well as of the movable and immovable property acquired with such consideration.

2. The proceeds of fines or penalties imposed under Articles 35 and 36 and of confiscation under paragraph 1 shall constitute public revenue and shall be collected in accordance with CEDAW. They shall be entered in the budget of the Ministry of Health and Social Affairs and shall be entered in the special code number from which transplantation expenses of uninsured beneficiaries are paid. A joint decision by the Ministers of Finance, Justice, Transparency and Human Rights and Health and Social Affairs will determine how these revenues are to be transferred to the Ministry of Health and Social Affairs.

Solidarity and its entry in the special code number, as well as any other necessary details.

Article 39

Prohibition to practice medicine

When a physician is convicted of the offences referred to in Articles 35 and 36, the court shall impose a lifetime ban on practicing medicine. The provisions providing for disciplinary or administrative sanctions shall remain unaffected. The prohibition to practice shall take effect upon expiry of the prison sentence. If, in addition to the sentence, a security measure has been imposed, the prohibition takes effect upon expiry of the measure. The prohibition from practising medicine also entails the cessation of the operation of the medical practice for an equal period.

Article 40

Trafficking in human beings for the purpose of the removal of tissues, cells or organs

In paragraph 1 of Article 323 A of the Penal Code, the word "cells" is inserted after the words "for the purpose of removal".

Article 41

(Article 23 of Directive 2010/53/EU)

Information to the European Commission

The Ministry of Health and Social Solidarity shall inform the European Commission of the sanctions applicable to violations of the provisions of this Law by 27 August 2012, and of any subsequent amendments to these provisions.

3. All costs related to research, collection and transfer of bone marrow from unrelated donors through international research banks can be paid directly by the National Transplant Organisation and subsequently claimed by insurance funds or the Ministry of Health and Social Solidarity for uninsured patients. The National Transplant Agency may receive payments from international research centres for bone marrow research services provided by itself or by units under its supervision. In the latter case, it shall reimburse the supervised units for the amounts due to them.

Article 45

Preservation of anonymity

The identity of the deceased donor of tissues and cells shall not be disclosed to the recipient and his/her family. No

The identity of the recipient shall not be disclosed to the deceased donor's family either. Only the success of the transplantation may be disclosed.

Article 46

Donation to a designated person

1. The donation of tissues and cells after the death of the donor may not be made to a designated recipient. A suggestion of the recipient by the donor of the body or organs shall not be taken into account, but the established order of priority shall be followed.

2. The provision of paragraph 1 shall not apply to the donation of reproductive cells as defined in Article 8 of Act No. 3305/2005, and to the donation of whole blood for allogeneic use to a relative.

Article 47

Obligation to inform about the removal of tissues and cells

1. Article 7 of this Law in conjunction with Annex I of Decree 26/2008 shall apply to the notification of a living or deceased tissue and cell donor.

2. For reproductive cells, the provisions of Act No 3305/2005 (A 17) shall apply.

3. For OPA, the provisions of the following Article shall apply.

Article 48

Obligation to inform about the collection of umbilical cord blood

1. It shall be mandatory to provide information on the removal of OPA.

2. The information shall be provided to the parents of the child to be conceived. In case of absence, death or disability of one parent or if the parents are not married or not bound by a civil union or are separated or the marriage has been dissolved, it is sufficient that the information be given to the mother of the foetus. In the case of surrogacy, the information shall be given to the woman who is presumed to be the mother of the child within the meaning of section 1464(a) of the Civil Code and, if married, to her husband.

3. In addition to the information provided for in article 13 of decree 26/2008, the information shall concern the most recent scientific data on the possibility of using OPA for therapeutic purposes, the expected benefits of autologous use compared with those of non-autologous use. Emphasis is placed on the distinction between private and public banks of OPA and on the distinction between the nature of OPA for autologous and allogeneic use, congenital or not. The information also covers the financial burden of the donor.

4. The information must be provided in comprehensible, complete and objective terms and not create unfounded expectations. It should be provided in two phases, sufficiently distant from each other and at least three months before birth. In the first phase, it is provided by the mother's obstetrician-gynaecologist or by an independent specialist obstetrician-gynaecologist in the same speciality as the mother.

The first stage shall be provided by the mother's independent obstetrician-gynaecologist or by the mother or a specialist in the field of tissue and cell preservation chosen by the parents or the mother, in the cases referred to above, and if there is interest, the second stage shall be provided by an obstetrician-gynaecologist or another specialist in the field of tissue and cell preservation other than the one who participated in the first information stage.

5. At both information stages, the doctors providing the information, the parents or the mother, in the cases provided for above, sign a form, a copy of which is kept in the mother's medical record. The content of these forms is drawn up by the competent Directorate of the Ministry of Health and Social Solidarity, on the proposal of the National Transplant Organisation and the opinion of the Transplant Centre. The signed forms bear the distinctive mark of the Ministry of Health and Social Solidarity.

6. It is prohibited to issue any information sheet in printed or electronic form or any other material relating to the supply, collection, testing, treatment, maintenance, preservation and/or availability of donors, the distribution and supply of human tissues and/or cells and/or patient products, without the prior approval of the competent Directorate of the Ministry of Health and Social Solidarity, both for its publication and content. This approval is granted following a request submitted within one month from the date of submission. The deadline is extended to three months if the competent Directorate considers that an opinion of the National Transplant Organisation or the National Transplant Centre is required. The applicant shall be informed of this in writing. If the competent Directorate does not respond within the legal deadline, the applicant has the right to have the information document issued and/or used. The competent Directorate of the Ministry of Health and Social Solidarity can carry out checks on all types of information activities of Procurement Organisations, Tissue Banks and Transplant Organisations, including on the Internet. If it is discovered that misleading information has been disseminated, the competent directorate shall require the organisations providing it to comply with its instructions, failing which the Minister of Health and Social Welfare shall be informed of the withdrawal of the organisation's operating licence.

Article 49

Procurement of tissues and cells from living and deceased donors

1. The procurement of tissues and cells, i.e., the procedure by which tissues and cells are made available in accordance with case 6 of Article 3 of Decree 26/2008, shall be carried out in accordance with the provisions of Articles 8 and 9. Declarations of opposition by citizens to the removal of their organs after death also apply to the removal of tissues and cells. The registers kept by the National Transplant Agency in accordance with paragraph 3 of Article 9 also include citizens' statements on their objection to the removal of tissues and cells from their bodies after death. Paragraphs 6 and 7 of Article 9 shall also apply in the case of removal of tissues and cells.

2. The provisions of Article 8(1) and (2) shall not apply to bone marrow procurement. Bone marrow may be procured from a donor who is a minor when the transplant is to be carried out on his sibling(s) or a relative up to the second degree of consanguinity, whether by direct or collateral line, provided that there is tissue compatibility between them and that the procurement is necessary for the recipient's life, there is no other compatible donor available who has the legal capacity to give valid consent to the transplantation, and both parents consent to the transplantation, even if only one of them has custody of the minor child. If there are no parents or if both parents have relinquished parental responsibility, consent is given by the Commissioner, after a decision by the

Board of Supervisors. The child, who has reached the age of 12, must also consent to the removal. The consent of the persons concerned is given in the manner provided for in Article 8(4). The documents proving the relationship and the consent of these persons must be kept in the donor's medical file.

3. Paragraph 1 shall not apply to the donation of reproductive cells carried out in accordance with the provisions of Act No. 3305/2005 (A17).

Article 50

Procurement, testing, processing, storage, distribution of PAOs

1. The procurement of OPA shall be carried out only by a viable woman.

2. The donation of OPA for allogeneic use shall be permitted by any person. The provision of paragraph 1 of Article 8 shall not apply.

3. The parents of the pregnant woman must give their consent to the doctor, gynaecologist, midwife and procurement agency by means of a document certified as authentic by a public authority and freely revocable in the same way. In the event of the absence, death or disqualification of one of the parents, or if the parents are not married or not bound by a civil partnership or are separated or the marriage has been dissolved, the consent of the mother of the foetus shall be sufficient. In the case of a surrogate mother, consent shall be given by the woman who is presumed to be the mother of the child in accordance with Article 1464 CC, paragraph a and, if she is married, by her husband.

4. The persons referred to in paragraph 3 shall sign a contract with the tissue establishment responsible for the storage and distribution of the OPA. The storage of OPA may be carried out either in a private cord blood bank, with a view to its possible future use by the donor (autologous), by a relative or by a third party (allogeneic) or in a cord blood bank, with a view to its possible future use by the donor (autologous) or by any person (allogeneic).

It is mandatory that the contract specifies: (a) the potential recipients of the OPA, (b) the duration of the storage period and the possibility of renewal, (c) the possibility of storage of the OPA, and (d) the possibility of future use of the OPA.

(d) the possibility for the contracting parents or mother of the foetus or the child itself to request the tissue establishment to discontinue storage at the end of its storage period, as originally agreed or subsequently modified, for destruction, or for donation to a cord blood bank for use by third parties, or for giving to research.

Article 51

Procurement agencies

1. The procurement of tissues and cells shall be carried out by 'procurement organisations'. With the exception of reproductive cells, for which the provisions of Act No. 3305/2005 shall apply.

Procurement agencies may be public or private non-profit hospitals or private clinics and are required to obtain a relevant authorisation in accordance with Article 5 of Decree No 26/2008.

2. The licence is granted by decision of the Minister for Health and Social Solidarity, after a prior check that the legal requirements are met. The authorisation is valid for three years and may be renewed for an equal period.

3. In order to obtain the licence, private clinics must have a mandatory link with the National Transplantation Organisation, Tissue and Cell Application Units and Tissue Establishments.

4. A presidential decree, on the proposal of the Minister of Health and Social Solidarity and on the advice of the National Transplant Organisation and the C.S.Y., will define the conditions that the Procurement Organisation must meet in terms of facilities, equipment, organisation, the necessary medical, nursing and other personnel, institutions and any other relevant matters. The conditions and modalities of operation of the Procurement Agencies are also established. The procedure for granting, renewing or revoking the authorisation of procurement organisations and the technical

details of the link between private clinics and the National Transplantation Organisation and tissue and cell units shall also be laid down.

5. Procurement Organisations shall be monitored to ensure that they meet the requirements and comply with the provisions of Decree 26/2008 and this Act. The Presidential Decree referred to in paragraph 4 defines the competent inspection bodies, the frequency of regular inspections and the possibility of carrying out extraordinary inspections, the criteria for assessing compliance with quality and safety requirements and any other relevant matters. Inspection may be entrusted to the College of Health and Welfare Inspectors (HSE).

6. If it is found that the above conditions are no longer met, the Supply Agency's licence shall be revoked.

7. Notwithstanding the provisions of paragraphs 1 to 6:

α. If a hospital meets the required conditions but does not have the necessary medical staff and is in fact available 24 hours a day, seven days a week, all year round, it shall be deemed to be licensed by the Procurement Agency, but only for the procurement of tissues and cells from a deceased donor and only by the medical staff of the tissue and cell application unit where the application of tissues and cells to the recipient is to be carried out.

β. After consultation with the medical staff of the procurement organisation, the procurement may be carried out by the medical staff of the Tissue and Cell Application Unit, with a view to maximum protection of the donor and success of the operation.

c. Hospitals of a public or not-for-profit nature that have obtained a licence to operate a tissue and cell unit shall simultaneously operate as procurement organisations without being required to obtain the relevant licence.

9. The authorisation for tissue and cell procurement shall be granted irrespective of whether the hospital has obtained an authorisation for organ removal.

10. At the request of the European Commission or another Member State of the European Union, the Ministry of Health and Social Solidarity shall provide information on the regulatory framework for procurement organisations.

Article 52

Definition and distinction of tissue establishments

1. The activities of analysis, processing, preservation, storage or distribution of tissues and cells intended for human application are carried out in tissue establishments, as defined in Article 3, indent 15 of Decree 26/2008.

2. Tissue establishments are divided into three categories:

a. Tissue and cell banks (T.I.C.), where all types of tissues and cells for autologous or allogeneic transplantation are tested, preserved, stored and distributed, regardless of whether the recipient is a relative or a third person.

b. Private umbilical cord blood banks (IPBs), where only OPA is tested, preserved, stored, and distributed for future use for therapeutic purposes, autologous or allogeneic, to a relative or third person, if the donor agrees.

c. 'Cord blood banks' (B.B.B.), where the testing, storage, preservation and distribution of OPA are carried out exclusively for future therapeutic use, either autologous or allogeneic, whether the recipient is a relative or a third person.

3. Tissue establishments of all types must comply with the provisions of Decree 26/2008.

4. The Register of tissue establishments, which the Ministry of Health and Social Solidarity is required to maintain in accordance with Article 10(2) of Decree 26/2008, covers all three types of tissue establishments.

5. Services of collection, testing, processing, preservation, storage, distribution and supply of human tissues and/or cells and/or derived products

The supply and procurement of cells, cells and tissue-derived products provided by tissue banks for family or autologous use may be remunerated.

Article 53

Tissue and cell banks

1. The "Tissue and cell banks" shall operate: a) in the hospital establishments of the N.P.I.D. or N.P.I.D. Economy, Competitiveness and Navigation, b) the Democritus Research Centre, c) the Medical and Biological Research Institute of the Academy of Athens, d) the National Research Foundation and e) the National Research Foundation. N.P.I.D.

The operating licence referred to in Article 6(1) of Decree No 26/2008 is granted by decision of the Minister of Health and Social Affairs and the ministers responsible for each case, on the proposal of the National Transfusion Organisation. A prerequisite for the granting of an operating licence within the meaning of Article 6(2) of Decree No 26/2008 is the verification of compliance with the requirements set out in paragraph 2.

2. A decision of the Minister for Health and Social Solidarity, following a proposal of the National Transplant Organisation and an opinion of the KES, shall define the specific measures for implementing the provisions of Article 17 of Decree 26/2008 relating to the scientific officer, Article 18 relating to the staff to be employed, Article 30 on the requirements for the establishment, designation, approval or authorization of tissue banks, Article 31 on the requirements for the approval of tissue and cell preparation procedures and any other provisions relating to the operation of tissue banks, and regulates other technical matters.

3. Tissue and cell banks are subject to inspections in accordance with Article 7 of Decree 26/2008. By decision of the Minister for Health and Social Solidarity, the inspection of the Tissue and Cell Bank may be entrusted to independent Greek or foreign bodies accredited for this purpose. The same decision specifies the time of the inspection, the obligation to notify the results to the Ministry of Health and Social Solidarity and any other relevant issue.

4. If it is determined that the above conditions are no longer met, the license of the tissue and cell bank is revoked.

5. The authorisation shall specify the activities that the tissue and cell bank may undertake. The authorisation shall be valid for three years and may be renewed for an equal period in accordance with the same procedure.

Article 54 Private cord blood banks

Private cord blood banks

1. Private cord blood banks shall operate in private clinics or take the form of a private limited liability company.

The operating licence referred to in Article 6(1) of Decree No 26/2008 is granted by decision of the Minister for Health and Social Affairs, on the proposal of the National Transplant Organisation. A prerequisite for the granting of an operating licence within the meaning of paragraph 2 of Article 6 of Decree No 26/2008 is verification that the requirements set out in paragraphs 2 to 4 have been met.

2. By decision of the Minister of Health and Social Solidarity, on the proposal of the National Transplant Organisation and the opinion of the C.S.Y., the specific measures for the implementation of the measures provided for in Article 17 of Decree-Law. 26/2008 on the scientific officer, article 18 on the required personnel, article 30 on the requirements for the establishment, designation, approval or authorization of tissue banks, article 31 on the requirements for the approval of tissue and cell preparation procedures and any other provisions relating to the operation of tissue banks, and other technical matters.

3. A prerequisite for the granting of a licence to operate a private cord blood bank is the establishment of the solvency, professional reliability and good financial standing of the private clinic or N.P.I.D. For this reason, bank certificates for the solvency of the company or a copy or extract from the company's balance sheet or a solemn statement of the company's total turnover must be submitted when submitting the application to the competent department of the Ministry of Health and Social Solidarity. If the applicant private bank is deemed to meet all legal requirements, it must, within ten days of written notification from the competent department of the Ministry of Health and Social Solidarity, deposit a letter of guarantee of one hundred thousand (100 000) euros with the Ministry of Health and Social Solidarity. The guarantee will be forfeited if the private cord blood bank ceases to operate before the expiry of its licence for a reason concerning it or if its licence is permanently withdrawn following an inspection. In this case, the amount of the guarantee will be recovered as public revenue in accordance with CEDAW. It shall be deposited in a special account of the Ministry of Health and Social Solidarity and shall be used for the financial support of the tissue institution to which the OPA units are transferred, in accordance with paragraph 4 of this Article. Failure to deposit the security deposit in due time and in due form shall result in the rejection of the application for an operating licence.

A decision of the Minister for Health and Social Solidarity shall lay down the period of validity, details of the release, return and forfeiture of the deposit and any other relevant matters. Similarly, an adjustment of the amount of the letter of guarantee is authorised.

4. A prerequisite for granting a licence to operate a private cord blood bank is the submission to the competent department of the Ministry of Health and Social Solidarity of a written agreement linking the applicant with another private cord blood bank or a private cord blood bank.

Tissue and Cell Bank or a cord blood bank, with regard to the transfer to it of the stored OPA units in the event of temporary or permanent cessation of its operations.

5. A public fee of €500 must be paid when the application is submitted. A decision of the Minister of Health and Social Solidarity establishes the procedures, the required supporting documents and any other matters relating to inspectors and the granting or withdrawal of an operating licence. The amount of the fee may be amended in the same way.

6. Private cord blood banks are subject to inspections in accordance with Article 7 of Decree 26/2008.

By decision of the Minister for Health and Social Solidarity, the inspection may be entrusted to independent Greek or foreign bodies accredited for this purpose. The same decision specifies the time when the inspection must be carried out, the obligation to notify the results to the Ministry of Health and Social Solidarity and any other relevant issue.

7. If it is determined that the above conditions are no longer met, the licence of the private cord blood bank shall be revoked.

8. The licence shall specify the activities that the private cord blood bank in question may undertake. The licence shall be valid for three years and may be renewed for an equal period in accordance with the same procedure.

Article 55

Cord blood banks

1. Cord blood banks operate exclusively: a) in hospital institutions of the N.P.D. or N.P.I.D. a) at the following institutions 1) the Ministries of Health and Social Solidarity, of Childhood, of Lifelong Learning and Religious Affairs, of National Amnesty, of Economy, Competitiveness and Navigation, where appropriate, under the supervision of the Ministries of Health and Social Solidarity, Children, Lifelong Learning and Religious Affairs, National Amnesty, b) the Democritus Research Centre, c) the Institute of Medical and Biological Research of the Academy of Athens, and d) the National Research Foundation.

The operating licence, provided for in Article 6(1) of Decree No 26/2008, is granted by a decision of the Minister for Health and Social Affairs and the ministers responsible for each case, on the proposal of the National Metamorphosis Organisation. The prerequisite for issuing the operating licence, within the meaning of Article 6(2) of Decree No 26/2008, is verification that the requirements set out in paragraph 2 have been met.

2. By decision of the Minister of Health and Social Solidarity, upon proposal of the National Transplant Organisation and opinion of the C.S.Y., defines the specific measures for implementing the provisions of article 17 of decree 26/2008 on the scientific responsible person, article 18 on the personnel to be employed, article 30 on the requirements for the establishment, designation, approval or authorization of tissue banks, article 31 on the requirements for the approval of tissue and cell preparation procedures and any other measures to be adopted to ensure the implementation of the provisions of article 17 of decree 26/2008 on the scientific responsible person, Article 18 on the staff to be employed, Article 30 on the requirements for the establishment, designation, approval or authorisation of tissue banks, Article 31 on the requirements for the approval of tissue and cell preparation procedures and any other measure to be adopted to ensure the implementation of the provisions of Article 17 of Decree 26/2008. and any other provisions relating to the approval of tissue establishments and other technical matters.

3. Audits are carried out at cord blood banks in accordance with Article 7 of Decree 26/2008. By decision of the Minister for Health and Social Solidarity, the inspection may be entrusted to independent Greek or foreign bodies accredited for this purpose. The same decision specifies the time when the inspection must be carried out, the obligation to notify the results to the Ministry of Health and Social Solidarity and any other relevant issue.

4. If it is determined that the above conditions are no longer met, the licence of the cord blood bank shall be revoked.

5. The licence shall specify the activities that the cord blood bank may undertake. The authorisation shall be valid for three years and renewable for an equal period in accordance with the same procedure.

Article 56

Operation of a tissue bank without a licence

If the competent inspection bodies determine that a tissue bank, in any form, is operating without a licence, it shall be ordered to cease its activities by a reasoned decision of the Minister of Health and Social Solidarity. In addition, offenders are subject to a fine of one million (1,000,000) euro, to be collected as public revenue in accordance with the provisions of the ECHR. Offenders may not apply for an operating licence for two years.

Article 57

Tissue and cell establishments

1. The application of tissues and cells in accordance with Article 3(12) of Decree 26/2008 is carried out in tissue and cell application units. Reproductive cells for which the provisions of Act No. 3305/2005 and keratoplasty procedures are also performed in health facilities of public health institutions that meet the requirements for performing ophthalmological microsurgical procedures.

2. Tissue and cell application units shall operate in health care institutions of public or non-profit nature that have obtained the relevant licence.

3. The licence is granted by decision of the Minister of Health and Social Solidarity, after a proposal of the National Transplant Organisation and an opinion of the C.S.Y., after verification of compliance with legal requirements. The authorisation specifies the activities that the unit may undertake. It is valid for three years and is renewable for an equal period according to the same procedure.

4. A decision of the Minister of Health and Social Solidarity, issued on the basis of a proposal of the National Transplant Organisation and an opinion of the Centre for Health and Social Solidarity, establishes the conditions that the Tissue and Cells Unit must meet in terms of facilities, equipment, organisation, the necessary medical, nursing and other personnel. The procedure for granting, renewing or revoking the authorisation and any other relevant matters is also established.
5. Inspections shall be carried out in tissue and cell units to ensure compliance with the conditions and provisions of this Regulation. A decision of the Minister for Health and Social Solidarity shall determine the competent control bodies, the frequency of regular inspections and the possibility of carrying out extraordinary inspections, the criteria for assessing compliance with quality and safety requirements and any other relevant matters. This control may be entrusted to the Health and Care Services Inspectorate (HSSI).
6. If it is established that the above conditions are no longer met, the licence shall be revoked, subject to notification by the National Transplantation Agency.
7. Tissue and cell application units are under the supervision and control of the Minister of Health and Social Solidarity and submit an annual report on their activities to the National Transplant Agency within the first two months of the following year.
8. A hospital can receive one transplantation unit and one tissue and cell unit at the same time.
9. The Ministry of Health and Social Solidarity shall, at the request of the European Commission or another Member State of the European Union, provide information on the conditions for licensing a tissue and cell transplantation unit.

Article 58

National registry of voluntary bone marrow donors

The National Agency for Transplantation shall establish a "National Registry of Voluntary Bone Marrow Donors", which shall be a single registry for the whole country and shall contain the data of voluntary bone marrow donors.

Article 59

Criminal sanctions

1. Whoever, in violation of Article 43, removes tissues and cells for non-therapeutic purposes or stores and uses for research purposes tissues and cells removed for transplantation purposes without complying with information and consent requirements shall be punished by imprisonment of at least two years and a fine of at least fifteen thousand (15,000) euros. The same punishment shall be imposed on any person who intentionally infringes the provision of Article 49.
2. Any person who undergoes the removal of body tissues or cells for profit shall be punished by a term of imprisonment of not less than four months. However, the court may, in the light of all the circumstances, freely assess all the circumstances and find that the act goes unpunished.
3. Any person who publicly announces the offering of tissues or cells for consideration shall be liable to a term of imprisonment of at least four months.
4. Any person who accepts or receives financial compensation for mediating the removal of another person's tissues or cells for the purpose of transplantation, whether the removal, transplantation or both are carried out, shall be liable to a term of imprisonment of at least two years and a fine of at least fifteen thousand (15,000) euros.
5. Any person receiving or offering to receive, in exchange for payment, human tissues or cells shall be liable to a term of imprisonment of at least four months and a fine. If the purpose of obtaining the grafts is resale, the offender shall be punished by a term of imprisonment of at least three years and a fine of at least EUR 15 000.

6. Any person who instructs, facilitates or participates in any way in the transplantation of tissues or cells to a recipient other than the recipient shall be punished by a term of imprisonment of at least two years and a fine of at least fifteen thousand (15,000) euros.

7. Any person who in any way unlawfully obstructs the procurement, storage or transport of tissues and cells or their preservation or application shall be liable to a term of imprisonment of at least one year and a fine of at least six thousand (6 000) euros. If the commission of the offence referred to in the preceding paragraph resulted in the object not being used, the offender shall be liable to a term of imprisonment of at least two years and a fine of at least EUR 15 000.

8. Any person who undertakes the procurement of tissues and cells in violation of Article 51 or the processing, preservation, storage or distribution of tissues and cells in violation of Articles 52 to 55 or the application of tissues and cells in violation of Article 57 shall be punished by a term of imprisonment of at least two years and a fine of at least fifteen thousand (15,000) euros.

9. The penalties for the offences provided for in paragraphs 1 to 8 of this Article shall be imposed if they are not punished more severely by another criminal provision.

Article 60 Aggravating circumstances **Aggravating circumstances**

1. If the offences referred to in Article 59 are committed repeatedly, professionally or habitually, or if the victim is a minor or a person with disturbed mental or conscience functions, they shall be punishable by imprisonment. Any person who has been irrevocably convicted of an offence under this Act within the last ten years for a felony or within the last five years for a misdemeanour shall be considered a recidivist.

2. If the offences referred to in Article 59 are committed within the framework of a criminal organisation, the perpetrator shall be punished by imprisonment of at least ten years and a fine.

Article 61 **Local limits of the law**

The offences provided for in Articles 59 and 36 are punishable if committed by a citizen regardless of the place of commission.

Article 62 **Confiscation - Disposal of proceeds**

1. In case of conviction for an offence provided for in Articles 59 and 60, the court shall order the confiscation of the financial consideration illegally given and of the movable and immovable property acquired with such consideration.

2. The proceeds of fines or penalties imposed under Articles 59 and 60 and of confiscation under paragraph 1 shall constitute public revenue and shall be collected in accordance with CEDAW. They shall be entered in the budget of the Ministry of Health and Social Affairs and shall be entered in the special code number from which transplantation expenses of uninsured beneficiaries are paid. A joint decision of the Ministers of Finance, Justice, Transparency and Human Rights and Health and Social Solidarity shall determine the manner of transferring these revenues to the Ministry of Health and Social Solidarity and their entry in the special code number, as well as any other necessary details.

Article 63

Prohibition from practising medicine

When a medical practitioner is convicted of a criminal offence under Articles 59 and 60, the court may order a prohibition from exercising his profession for one to five years if it considers that the offence is related to the medical profession. The provisions providing for disciplinary or administrative sanctions remain unaffected. Disqualification from exercising the medical profession comes into effect when the prison sentence expires. If, in addition to the sentence, a security measure has been imposed, the prohibition takes effect upon expiry of the measure. The prohibition from practising medicine also entails the cessation of operation of the medical practice for an equal period.

CHAPTER G

FINAL PROVISIONS AND OTHER PROVISIONS OF THE MINISTRY OF HEALTH AND SOCIAL SOLIDARITY

Article 64

Repealed provisions

1. With effect from the entry into force of this Regulation, the following shall be repealed
(A) Articles 1 to 20 of Law No 2737/1999.
(B) Paragraph 3 of Paragraph G of Article 20 of Act No. 2737/1999. 3172/2003 (A 197).
2. Ministerial Decrees and Presidential Decrees issued under Law No. 2737/1999 shall remain in force until the adoption of the relevant decisions provided for in this Law, provided that they do not contradict its content.

Article 65

Transitional provisions

1. The National Registry of Candidate Recipients maintained by the National Transplant Organisation, pursuant to Article 7 of Law No. 2737/1999, shall continue to be maintained after the entry into force of this Law.
2. The Registers of Organ and Tissue Donors, as well as the Registers of those from whom organs and tissues have been received for transplantation, maintained by the National Transplant Organisation, pursuant to Article 8 of Law No. 2737/1999, shall be maintained as such or continue to be maintained pursuant to this Law.
3. Data on living donor transplantation, which are transmitted to the National Transplantation Organisation and kept in a special archive pursuant to Article 11 of Law No. 2737/1999, shall be kept as such or continue to be kept in accordance with this Law.
4. Declarations of consent to organ donation after death to the National Transplantation Organisation pursuant to paragraphs 2 and 3 of Article 12 of Law No. 2737/1999 shall continue to be kept in a special archive.
5. The list of potential donors who have consented to the removal of tissues and organs after death, drawn up by the National Transplantation Organisation pursuant to Article 12 of Law No. 2737/1999, shall be kept in the archive. 2737/1999, shall be kept as such or continue to be kept in accordance with this Law.
6. The National Registry of Voluntary Bone Marrow Donors maintained by the National Transplant Organisation pursuant to paragraph 4 of Article 6 of Law No. 2737/1999, shall continue to be maintained without interruption after the entry into force of this Law.
7. Until the adoption of the ministerial decision referred to in paragraph 4 of Article 13, organ removal shall be carried out in Transplantation Units.

8. Until the adoption of the ministerial decision referred to in paragraph 3 of Article 15, the Transplantation Units shall operate on the basis of the ministerial decisions adopted pursuant to Law. 3727/1999. After the adoption of the ministerial decision, the Transplant Units shall submit an application for authorisation to operate within twelve months.

9. Staff employed, at the time of publication of this law, in any form of employment at the National Transplant Agency, as well as lawyers with a paid mandate, shall be transferred or transferred, by decision of the Minister of Health and Social Solidarity, to the National Transplant Agency, with the same employment relationship or organisational position, grade, class and specialisation they hold. Transferred staff are classified in salary grades according to Law no. 3205/2003. The period of service at the National Transplant Organisation up to the date of publication of this Regulation shall be taken into account for the purposes of their career development and their classification in the salary scales.

10. The Board of Directors of the National Transplant Agency appointed at the time of the entry into force of this Law shall remain in office until the entry into force of this Law. until the expiry of its term of office.

11. Within six months from the entry into force of this law

Within six months of the entry into force of the Presidential Decrees and Ministerial Decisions provided for in Articles 13, 15, 51 and 57, the hospitals in which Ablation Organizations, Transplantation Units, Procurement Organizations and Tissue and Cell Application Units may operate shall submit an application for an operating license to the Ministry of Health and Social Solidarity.

12. Within one year of the entry into force of the presidential decrees and ministerial decisions referred to in Articles 53, 54 and 55, tissue establishments of all categories operating at the time of the entry into force of this Law shall submit an application for an operating licence to the Ministry of Health and Social Solidarity. If they do not meet the legal requirements for a licence and their application is rejected, they shall transfer the tissue and cell units held to other tissue establishments and inform the Ministry of Health and Social Solidarity in writing.

Until 1.7.2013, organ removal from a deceased person is performed if the deceased person had consented to the donation of his/her organs after his/her death by means of a document addressed to the National Transplantation Organisation. Otherwise, organ removal will be carried out if the spouse or adult children or parents or siblings do not object.

Article 66

Settlement of matters relating to the Health and Welfare Services Inspection Corps, the H.C.A.B. and hospitals

1. Paragraph 9 of Article 3 of Act No. 3074/2002 (A 296), as amended by paragraph 1 of Article 18 of Act No. 3260/2004 (A 151), shall also apply to the Inspector General, Inspectors and Assistants of the Health and Welfare Services Inspectorate (HSSI), retroactively from the date of entry into force of Act No. 3074/2004 (A 151). 2920/2001 (A 131).

2. At the end of paragraph 1 of Article 9 of Law No 3833/2010 (A 40), the following paragraph shall be added "In particular, for the crews of the National Rescue Centre (NAC), by joint decision of the Ministers of Finance and of Health and Social Solidarity, off-site travel by order of the administration per year and per month may be determined in excess of the above limit."

3. At the end of subsection a of section 1 of Act 1108/1980 (A 304), as amended by section 26 of Act 1108/1980 (A 304), as amended by section 26 of Act 1108/1980 (A 304). 1959/1991 (A 123), the following subparagraph shall be added 'Exempted from the traffic restrictions, for the areas of the Attica region and the Thessaloniki regional unit, are diesel-powered ambulances and special diesel-powered mobile units provided by the National Emergency Assistance Centre (NACA) and public hospitals'.

4. The salaries and on-call expenses of medical specialists employed at the University Hospitals "Aigniteio" and "Aretaio" of the University of Athens shall be paid by the University of Athens. From the date of this provision, the annual subsidy of the University Hospitals "Aegineteio" and "Aretaio" from the ordinary state budget (No. F15/2010-C.A.E. 2821) shall cease to be paid.

5. With the exception of the first subparagraph of paragraph 5 of Article 9 of Law No. 2889/2001 (A 37), as replaced and in force by Article 1 of Law No. 3868/2010 (A 129), the remaining subparagraphs shall be replaced by the following:

"The governors of the hospitals of the National Health Service, by decision of the Board of Directors, may conclude contracts: a) with insurance companies, under which they will cover the aforementioned medical services provided to their insured persons in the context of the daily operation of the hospitals outside normal working hours; and b) with private insurance companies, under which they will cover the costs of examinations, diagnostic, interventional and therapeutic procedures carried out during the full-time operation outside normal working hours for their insured persons and for which the services will be subject to a special increased rate. The contracts referred to above shall be submitted for information to the competent public authorities.

6. Employees of public and private sector health services who are exposed to ionising radiation and are dosed according to the radiation protection regulations in force at the time with an individual body dosimeter: (a) when the annual cumulative radiation dose they receive is measured at 25% of the maximum limit allowed by the Radiation Protection Regulations, in the month immediately following, they may be granted radiation protection leave of twenty-one (21) consecutive days; (b) when the annual cumulative radiation dose they receive is measured at 50% of the maximum limit allowed by the Radiation Protection Regulations, in the month immediately following, they shall be granted an additional twenty-one (21) consecutive days of radiation protection leave; (c) where the annual cumulative radiation dose they receive is measured at 75% of the maximum permissible limit laid down in the Radiation Protection Regulation, they shall be granted an additional forty-two (42) consecutive days of radiation protection leave in the following month. In particular, for health care workers exposed to ionising radiation and dosed with an additional hand or finger dosimeter, leave shall be granted in accordance with a, b and c above, taking into account at the same time the corresponding limits for cumulative doses to the extremities. The provisions of Article 13(1)(a) and (b) apply. 2 of Act No 1821/1988 (A 271), 74 Paragraph 1(5) of Act No 2071/1992 (A 149), as well as any other provisions that provide for a licence for radiation protection in the event of fallout, shall be repealed.

7. At the end of paragraph 1 of Article 15 of Act No 3918/2011 (A 31), the words "and with the exception of paragraph 2 of Article 11, which shall come into force upon publication of this Act" shall be added at the end of the last sentence of paragraph 1 of Article 11.

8. Article 13 of Act No. 3868/2010 (A 129), the following paragraph 3 shall be added

"3. Persons receiving care in legal persons under public law providing closed care services, suffering from chronic diseases and for

and for as long as they permanently reside in such institutions, shall contribute to the costs of their care in a percentage of the pension they receive. A decision of the Minister of Health and Social Solidarity, published in the Official Gazette, will determine the rate of contribution, staggered according to the pension of each care recipient, the procedure and methods of payment, the body responsible for monitoring and managing the funds and any other relevant matters. No contrary conditions shall apply to contracts concluded between public institutions providing closed care services and insurance institutions.

9. At the end of Article 13 of v. 2716/1999, paragraph 8 is added as follows:

"8. Persons who are placed in psychosocial rehabilitation units and programmes referred to in Article 9 of this Law, provided by legal persons under public law, shall contribute to the cost of their care for the duration of their stay in these facilities at a percentage of the pension they receive. A decision by the Minister of Health and Social Solidarity, to be published in the Official Gazette, will determine the rate of contribution, graduated according to the pension of each person receiving

care, the procedure and method of payment, the body responsible for monitoring and managing the funds and any other relevant matters. Any conditions to the contrary in the contracts concluded by these institutions providing psychosocial rehabilitation services with insurance institutions are not applicable."

10. 3106/2003 (A 30), the following paragraph 2A shall be added

"2.A. The legal person governed by public law "Centre for Physical and Social Rehabilitation Therapy of Crete", which was established and operates according to the provisions of Article 21 of Law 2716/1999 (A 96) and renamed by Article 1, paragraph 2, IZ, letter j) of Law 2716/1999 (A 96). 3106/2003 (A 30), as amended and in force, is abolished as a separate legal person and merged with the public law legal person "Heraklion Children's Development Centre" established and operating under Law 572/1970 (A 125), maintaining its existing legal form as N. Its organisational posts, staff and immovable property are transferred without observance of any form, act or contract to the merged public law legal person, which replaces it in its rights and obligations. All movable property of the legal person governed by public law that is abolished and merged, as well as the unused balances of the cash management accounts and current accounts, including inactive ones, shall be made available by transfer to the Social Welfare Units defined in paragraph 2 of Article 1 of Act No. 3106/2003 to cover their operational and other needs, by a decision of the Minister of Health and Social Solidarity, determining the accounts of the Social Assistance Units and the counterpart amounts to be transferred, the manner of payment of expenses and the bank's fee for maintaining the accounts and transferring the amount, the closure of the accounts when there are no balances and any other relevant matters. The Presidential Decrees referred to in Article 13 of Law No. 3868/2010 (A 129) shall regulate all individual aspects of the merger'.

12. In hospitals that operate with an interconnection and are managed by a single board of directors, a board of directors shall be established by decision of the governor of the P.M. concerned, which shall be composed of:

- (α) (a) The common governor of the interconnected hospitals or a member of the single collective management body, as chairman of the board; (a) The common governor of the interconnected hospitals or a member of the single collective management body, as chairman of the board.
- (b) The Chief Medical Officer, with his deputy.
- (c) The Head of the Nursing Service, with his deputy.
- (d) The Head of the Administrative and Financial Department, with his legal deputy.
- (e) The Head of the Technical and Hotel Service, with his legal deputy.

The term of office of members of the Board is two years and its operation is governed by the provisions of Articles 13, 14 and 15 of Law No 2690/1999 on the operation of collective management bodies.

The powers exercised by the Board shall be defined by a decision of the administration of the health region concerned.

13. The general coordination of the medical services of the Hospitals that will operate under a single collective administration shall be carried out by the Coordinating Director of the Medical Service of the Hospital with the largest number of beds, excluding Psychiatric Hospitals. The way in which the general co-ordination of the medical services of the hospitals that will operate under a single collective administration is to be exercised is determined by a decision of the administration of the Health Region concerned. The general coordination of the services (Nursing, Administrative-Financial, Technical-Hotel, IT) of the Hospitals that will operate under a single collective administration is carried out by the Head of the respective Services of the Hospital with the largest number of beds, with the exception of Psychiatric Hospitals. The way in which the general coordination of these services of the hospitals that will operate under a single collective administration is carried out is determined by a decision of the administration of the Health Region concerned.

14. In par. 1 of Article 69 of Act. 3918/2011, the following paragraphs are added:

"In cases of interconnection of two (2) or more Hospitals, and regardless of the number of organic beds, one (1) Deputy Governor may be appointed for each interconnected Hospital. By decision of the Minister of Health and Social Solidarity, the Governors and Deputy Governors of the Hospitals may be transferred, and the Governors of the interconnected Hospitals may be dismissed and appointed Deputy Governors of such Hospitals by the same decision. The deputy governor referred to in paragraph 4 of Article 62 of Act No. 3918/2011, shall perform his duties without remuneration if he chooses to be affiliated totally and exclusively with the University and to carry out his clinical and laboratory work in a university clinic, laboratory or hospital unit of the National Health Service."

15. At the end of paragraph 11 of Article 7 of Law No. 1579/1985, the following subparagraphs are added:

"Hospitals and health centres in the country are required to make their ambulances available, properly equipped and staffed, under the coordinating authority of the National Health Service and its branches, in accordance with a monthly schedule submitted in good time to the National Health Service. For this purpose, all drivers, ambulance crews and other personnel of hospitals and health centres, who have their ambulances available, will be trained by the NCHAW."

16. Telemedicine services are provided when available and under the responsibility of the attending physician treating the case in question. The treating physician, in order to protect personal data, is responsible for requesting personal data from the patient or patient to the physician.

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If this is not possible from a first-degree relative, obtain his/her signed authorisation to use telemedicine services. If this is not possible, the treating physician will use telemedicine services at his/her discretion. Instructions from hospitals and health facilities providing telemedicine services are advisory and in no way mandatory.

17. The provisions of Article 1(5) of Act No. 3833/2010 (A 40), as supplemented by Article 90(5) of Act No. 3842/2010 (A 58), as well as the provisions of Article 3 of Act 3842/2010 (A 58), as well as the provisions of Article 3 of Act 3842/2010 (A 58). 3845/2010 (A 65) shall apply to all staff of the Onassis Centre for Cardiac Surgery and only in respect of their salary scheme.

18. Only those endocrinology departments of National Health Service hospitals will be recognised as suitable for the training of endocrinology doctors in ultrasound, only those endocrinology departments that provide a complete endocrinology speciality, that have an ultrasound scanner in their department and that have been certified by the Medical Director or another doctor in the department in performing ultrasound scans.

19. Institutions referred to in paragraphs 2b and 2c of Article 1 of Decree-Law 84/2001 (A 70), which existed before or were established by its provisions, are allowed to house the laboratories of divisions B and C of Part Two of Schedule A, in premises of buildings which are not intended for their main use. These laboratory spaces shall not be counted in the building factor of the lot. Such spaces shall be provided with the artificial lighting and ventilation necessary for their operation. All such establishment spaces shall be classified as "offices" for fire code purposes.

20. At the end of the 1st paragraph of Article 58 of Law No. 3966/2011 (A118), the sentence "with the exception of mayors of municipalities with less than five thousand (5,000) inhabitants who are doctors in the National Health Service and practice medicine in inaccessible medical offices, as defined by Law No. 3868/2010."

21. The provisions of Articles 2 and 3 of Law No. 3919/2011 (A 32) is extended until 15.9.2011 for the professions under the responsibility of the Ministry of Health and Social Solidarity.

22. Notwithstanding the provisions of Paragraph 3 of Article 21 of Act No. 3871/2010 (A 141) for the assumption of sub-charges to be borne partially or entirely in the next financial years of the medium-term financial strategic framework by National Health Service Hospitals and Social Welfare Units, as bodies of the General Administration supervised by the Ministry of Health and Social Solidarity, approval shall be granted by the Governor of the Administrative Region of Health to which they belong, based on the provisions of Act No. 3871/2010 (A 141). 3527/2007 or by

delegation of the Governor of the Administrative Region of Health concerned, approval shall be given to the Governor of the National Health Service Hospital or Social Assistance Unit.

23. For the period from 1.6.2011 until the commencement of operation of the E.O.P.Y., doctors on duty in the integrated hospital support services of the IKA-ETAM pursuant to paragraph 1 of Article 32 of Law 32. 3918/2011 shall continue to prescribe

continue to prescribe in the prescription books of IKA-ETAM, on which a stamp of the Host Institution shall be affixed with the indication "Par- tem".

24. Sub-clause aa of sub-clause c of paragraph 9 of Article 1 of Act No. 3918/2011 (A 31) shall be replaced by the following:

"(aa) National Health System (NHS) hospitals and their decentralised units, as well as Social Welfare Units, subject to approval of a request by the Governor of the Autonomous Region concerned, to meet their immediate operational needs or the operational needs of other hospitals or Social Welfare Units in the Autonomous Region concerned."

25. In Paragraph 6 of Article 5 of Law No 3918/2011, the following paragraph is added

"By decision of the Minister of Health and Social Solidarity and on the recommendation of the Purchasing Coordination Committee (CPC), supplies related to IT goods and services included in the Digital Convergence Operational Programme may be excluded from each institution's Procurement and Services Plan."

26. At the end of paragraph 6 of Article 10 of Law no. 3580/2007, the following paragraph is added

"By decision of the Minister of Health and Social Solidarity and following a recommendation of the Health Purchasing Committee (HPC), supplies related to IT goods and services included in the Digital Convergence Operational Programme may be excluded from the Health Purchasing and Services Plan of each institution."

27. Case A of Paragraph 11 of Article 45 of Law No. 3205/2003 (A 297), as amended by Article 4 of Law No. 3868/2010 (A 129) and Paragraph 3 of Article 62 of Law No. 3918/2011 (A 31) shall be replaced by the following

"11. A. i. Resident physicians in all zones will receive a monthly allowance not to exceed seven (7) active on-call services each month. ii. In Zone C, Directors and Coordinating Directors will receive a monthly allowance not to exceed seven (7) on-call services each month, including up to five (5) active on-call services and up to two (2) on-call services on a daily basis. Other resident physicians will receive a monthly allowance not to exceed eleven (11) hours of service, including up to seven (7) hours of active on-call service and up to four (4) hours of on-call service per day. iii. In Zone B, resident physicians shall receive a monthly allowance not to exceed seven (7) on-call days, of which Coordinating Directors and Directors shall receive up to four (4) active on-call days and up to three (3) on-call days per day and other residents shall receive seven (7) on-call days, of which up to five (5) active on-call days and up to two (2) on-call days per day. i. In Zone A, resident physicians shall receive a monthly allowance not to exceed six (6) on-call days, of which directors shall receive up to three (3) active on-call days and up to three (3) weekday availability days and other residents shall receive six (6) on-call days, of which up to four (4) active on-call days and up to two (2) weekday availability days. Article 6 of Act No 3754/2009. v. Doctors subject to field service in all zones shall receive a monthly allowance not exceeding seven (7) on-call days per month. ni. Members of the Board of Directors shall receive a monthly allowance not to exceed the number of on-call hours provided in the zone Á and divided as follows: lecturers to correspond with Supervisors B, assistant professors to correspond with Supervisors Á, associate professors to correspond with Directors and professors to correspond with Coordinating Directors. The Governor of the hospital determines the number of on-call shifts of each of the above doctors on a monthly basis.

28. In order to safeguard the public interest and protect public health, the expenditure required to pay the subcontributions for the supply of medical devices, medicines and services related to these supplies, which have been harmonised with the lowest prices on the national market of the Price Observatory of Article 24 of Law No 3846/2010. The aforementioned expenditures derive from the supplies of the National Health Service hospitals, including the Psychiatric and University Hospitals,

the Aretaio and Aeginito Hospitals, the Onassis Cardiac Surgery Centre and the Papageorgiou Hospital of Thessaloniki, and were incurred after the submission of Law No 3867/2010 to the Parliament until the publication of Law No 3918/2011.

29. Para. 6 of Article 6 of Law No 3204/2003 shall be replaced as follows:

"6. Posts occupied under these provisions, after being vacated for any reason whatsoever, shall be converted into vacancies in the field service".

30. At the end of sub-clause c of sub-clause I of section 4 of Act No. 3754/2009 (A 43), the following paragraph C1 shall be added

"(C1) Evaluation Board for the development of National Disabled Service Doctors serving in the National Foundation for the Disabled. The Board shall be the General Assembly of the National Disability Service and shall consist of the qualified National Disability Service doctors of the National Disability Institute, from the rank of assessor upwards. The Assembly is convened by the Governor of the E.I.A. or his legal deputy and a quorum is present if 50% of the eligible members of each grade are present. If there is no quorum, the meeting shall be resumed within one week with a legal quorum of 30% of those eligible to attend. If there is still no quorum, the meeting will be resumed after seven (7) days and will be considered to have a quorum, regardless of the number of doctors present. An individual evaluation is considered positive if it obtains 50% + 1 of the votes of those present. The vote is open. During the first fortnight of each year, the General Assembly appoints one (1) rapporteur and his/her substitute for each speciality and, in the absence of a rapporteur, for a related speciality. The second rapporteur shall be the Director of Medical Services with his deputy and, in the absence of the latter, the most senior doctor in the department's medical service. Evaluations shall be carried out twice a year. The rapporteurs shall receive the files of the doctors who are candidates for evaluation by 31 January each year. Within one month of receiving the files, the rapporteurs submit their recommendation to the Secretariat-General.

General Assembly. Within five (5) days the Secretariat will send the recommendations to the medical candidates, who will have fifteen (15) days to present an objection. Within fifteen (15) days from the expiration of the above mentioned deadline, the objections will be accepted and within fifteen (15) days the Director of the Hellenic Medical Association will convene the corresponding General Assembly. The General Assembly, after having listened to the proposals, objections and answers of the rapporteurs, as well as the relevant clarifications, shall take a reasoned decision. The rapporteurs shall receive the files of the doctors concerned for the second time in the same year by 31 July, and the same procedure as described above shall be followed.

31. The following subparagraph is added at the end of paragraph 2 of Section 75 of Act 2071/1992 (A 123)

"Doctors in the National Health Service who, at the time of publication of this Act, are seconded to hospitals in the same or another health region may, at their request and by decision of the Minister of Health and Social Solidarity, be transferred, while retaining their grade, to a vacancy in the same specialty in the hospital to which they are seconded."

32. Similarly, for the purposes of recruitment and promotion, a doctor's length of service in an I- KA hospital is recognised as a period of service in the NSS. Paragraph 1 of Article 19 of Act No 3730/2008 (A 262), as replaced by paragraph 2 of Article 3 of Act No 3868/2010 (A * 129), shall be replaced by the following

"For the purposes of the assessment of applicants for a post of doctor in the NHS, the period of specialisation in an intensive care unit or a corresponding neonatal and paediatric unit and in infectious diseases shall be regarded as a period of service in the NHS and as such shall be taken into account for the further development of doctors in the NHS, whenever completed. Similarly, service in clinics, units or university laboratories established in NHS hospitals and in Aretaio and Aeginito hospitals shall be recognised as service in the NHS for the purposes of recruitment and promotion".

33. Case 6 of the first paragraph of section 44 of Act No. The first paragraph of section 44 of Act 3205/2003 (A 297) is replaced by the following

"Position - Liability of Coordinating Directors, for so long as they exercise the functions of their rank, amounting to two hundred and thirty-five (235) Euros".

34. Subsection b of para. 3 of Article 16 of Law No. 3259/1998 shall be replaced by the following:

"The allowance for additional remuneration, work on days off, night work, overtime work to supplement compulsory working hours and overtime work to cover exceptional or seasonal service needs of all staff, other than medical staff, of hospitals of the National Health Service, the decentralised units of these hospitals and the N.C.A.B., shall be borne by the State budget and the relevant appropriations shall be entered in the relevant budget items of the Ministry of Health and Social Solidarity for the subsidisation of the institutions. The payment of these allowances will be made by means of money orders issued by the aforementioned bodies".

35. Para. 4 of Article 1 of PD 412/1998 shall be replaced by the following:

"4. Obligations of regular remuneration and compensation for additional remuneration, work on days off, night work, overtime work to supplement compulsory working hours, as well as overtime work to cover exceptional or seasonal service needs of all staff and on-call work of medical staff resulting from the enforcement of judicial decisions against hospitals in E. The following measures are necessary to ensure that the medical staff of the National Health Service, their decentralised units and the National Health Insurance Fund (NCHA), are paid by means of money orders issued by the bodies concerned, after a subsidy from appropriations in the State budget".

36. Article 2 of PD 412/1998 is repealed.

37. The applications of doctors submitted between 3.8.2010 and 2.3.2011 for a speciality other than the one originally selected, among the specialities of Psychiatry, Neurology and Child Psychiatry, will be recorded in the priority files as follows. b) doctors who have completed less than half of the required training time for the final stage of the specialty will be recorded together with doctors for whom an application for the second stage of the specialty was pending on 2.8.2010; c) doctors who have completed less than half of the required training time for the final stage of the specialty will be recorded together with doctors for whom an application for the second stage of the specialty was pending on 2.8.2010. The criterion for ranking these doctors in cases (a) and (b) will be the date of submission of their application for the previous stage of specialty and they will be proposed for appointment to temporary posts after completion of the placement of the previous doctor in the order of priority.

38. At the end of subsection 3 of section 67 of Act No. 3918/2011 (A 31), the following subsections shall be added:

"The applications of doctors to obtain priority ranking that have been submitted out of time and until the entry into force of this provision shall be entered in the priority ranking according to the criteria of the transitional provisions above and at the end of each category. Applications of doctors who were appointed or recognised at one of the stages of specialisation listed before 2.8.2010 and which were submitted after 2.8.2010 shall be valid and shall be entered in the priority ranking according to the criteria laid down in the above transitional provisions.

39. Doctors appointed in accordance with the provisions of paragraph 8 of Article 25 of Law 25. 3868/2010 (A 129), to posts that became vacant after 3.8.2010 and until 2.3.2011, the date of entry into force of Law no. 3918/2011 (A 31), for preliminary or principal placement in the specialties of Psychiatry, Neurology, Pediatrics and Physical Medicine and Rehabilitation, in Nursing Institutes approved for partial or full training in these specialties, will be placed in temporary posts for the duration of the training provided by the Hospital and required for the specialty of doctor, if they have not been placed, at the time of publication of this Law, in accordance with the provisions of Article 67 of Law No. 3918/ 2011.

40. At the end of subparagraph b of paragraph 2 of Article 2 of Act No 3868/2010 which replaced paragraph 2 of Article 21 of Act No 3580/2007 (A134), the following subparagraph shall be added "In the event that in some specialties there is no interest in filling the posts of auxiliary doctors and there is no auxiliary doctor already in service whose contract can be extended in accordance with

paragraph d of this Article, the exclusive period of fifteen (15) days shall not apply, but the notice shall remain open until the posts provided for in the list of auxiliary doctors are filled."

41. Stand-alone chronic haemodialysis units operating outside hospitals and clinics may double their capacity if they also operate as a holiday unit, particularly for foreign patients.

They can also have an X-ray and microbiological laboratory to serve the patients of HMOs without any additional financial burden on them or the insurance institutions.

All this is, of course, subject to the legal obligations and conditions set out in Decree-Law No. 225/2000.

42. At the end of letter b of paragraph 2 of Article 2 of Law No. 3868/2010, the following is added:

"In the event that in certain specialty units in arid and problematic regions, as well as in island regions, there is no interest in filling the posts of auxiliary physicians and there is no auxiliary physician already serving in these units, whose contract may be extended in accordance with paragraph d of this Article, the exclusive period of fifteen (15) days shall not apply, but the notice shall remain open until the posts provided for in the list of auxiliary physicians are filled.

If the institution to which the said doctors are to render their services is unable to cover the cost of their fees, such cost shall be borne by the Health Region to which the institution belongs."

Article 67

The following annex is annexed to this document and forms an integral part of it:

ANNEX

ORGAN AND DONOR CHARACTERISATION

SECTION A - Minimum information package

Minimum information for organ characterisation

The minimum information for organ and donor characterisation to be collected for each donation, in accordance with Article 16(1) and without prejudice to Article 16(2), is as follows paragraph 2 is as follows:

The hospital where the removal is carried out and other

General data

Type of donor

Blood group

Gender

Cause of death

Date of death

Date of birth or estimated age

Weight

Height

History of intravenous drug abuse (past or present)

History of malignant neoplasia (past or present) History of other communicable diseases (present)

Testing for HIV/AIDS, hepatitis C and hepatitis B virus Basic information for assessing the patient's health status

the functioning of the donated organ

SECTION B- Supplementary information package

Information for the characterisation of organs and structures

The following information shall be collected in addition to the minimum information specified in Part A, at the discretion of the medical team, taking into account the relevance of this information and the specific circumstances of the case, in accordance with Article 16(2):

A. General information

Detailed contact details of the procurement organisation where the procurement takes place, necessary for the coordination, allocation and traceability of organs from donors to recipients and vice versa.

B. Donor information

Human demographic and geographic data necessary to ensure adequate compatibility between donor/organ and recipient.

C. Donor medical history

Medical history of the donor, in particular medical conditions that may affect the suitability of the organs for transplantation and that may pose a risk of disease transmission.

D. Pathological and clinical data

The data from the clinical examination necessary to assess the pathological and anatomical state of the potential donor, as well as any findings indicating conditions not detected during the examination of the donor's medical history that may affect the suitability of the organs for transplantation and that may represent a risk of disease transmission.

E. Laboratory parameters

Data needed to assess the functional characterisation of the organs and to identify potentially transmissible diseases and possible contraindications to organ donation.

F. Imaging tests

Imaging tests necessary to assess the anatomical condition of the organs to be transplanted.

Z. Treatment

Therapeutic treatments administered to the donor that are relevant for the assessment of the functional status of the organs and the suitability for organ donation, in particular the use of antibiotics, inotropic support or transfusion therapy.

Article 68

Positive list of medicinal products subject to medical prescription

1. The first and second paragraphs of letter c of para. 2 of Article 12 of Act No. 3816/2010 (A 6) shall be replaced by the following:

"By a decision of the Minister of Health and Social Solidarity, published in the Official Gazette, a list of medicinal specialties for the treatment of the serious diseases referred to in paragraph 2 shall be approved on the recommendation of the National Organization of Medicines (EOF). According to the same procedure, the list shall be reviewed, completed or amended in separate lists at least once a year."

2. Point (d) of paragraph 2 shall be deleted. 2 of Article 12 of Law No 3816/2010 is hereby repealed.

3. Case b of paragraph 1 of Article 12 of Act No. 3816/2010 is deleted. 3816/2010 shall be replaced by the following:

"b. For the establishment, revision and completion of the list of prescription drugs, a system of reference prices for each therapeutic category of pharmaceutical preparations shall be established. The reference price for each therapeutic class shall constitute the maximum price for reimbursement by social security institutions for medicinal products in the whole therapeutic class. If the difference between the prices of the pharmaceutical preparations and the reference price is positive, the pharmaceutical companies will reimburse the social security institutions, provided that the companies have previously declared in their application that they agree to be included in the list and the reimbursement scheme. If the pharmaceutical companies do not submit such an application, their proprietary medicines are automatically excluded from the positive list. The procedure for implementing the reference price system is specified in a decision of the Ministers of Health and Social Solidarity and Labour and Social Security and is published on the website of the National Organisation for Medicines (EOF). In particular, this decision defines the way in which the therapeutic categories are established, the way in which the reference price of each therapeutic category is determined, the bodies responsible for communicating the reference prices, the bodies

and the procedure for calculating, certifying and collecting the amounts of reimbursement to the social security bodies, and any other relevant issue. In any case, the above rules shall apply irrespective of the provisions of Article 35 of Law No 3918/2011 (A 31)."

4. In case c of paragraph 1 of Article 12 of Law No 3816/2010 the words "by joint decision of the Ministers of Labour and Social Security, Health and Social Solidarity and Economy, Competitiveness and Navigation" shall be replaced by the words "by joint decision of the Ministers of Health and Social Solidarity and Labour and Social Security".

Article 69

Provisions on the pricing of pharmaceutical products

1. Paragraphs 1 and 2 of Article 17 of Law No. 96/1973 (A 172) shall be replaced by the following:

"1. The maximum prices for wholesale, hospital, retail and any other special sales of pharmaceutical products shall be determined by means of price bulletins issued by the Minister of Health and Social Solidarity following an opinion of the Pharmaceutical Price Committee. The price lists come into force after their publication on the website of the Ministry of Health and Social Solidarity and do not require publication in the Official Gazette. The deadline for submitting objections begins on the day following the date of publication on the Internet.

2. The Pharmaceutical Pricing Committee and the Pharmaceutical Pricing Division may request the assistance of the EMEA on matters relating to products under its responsibility which are considered necessary for the pricing procedure.

2. Cases (c) and (d) of Paragraph 5 of Article 17 of Act No 96/1973 (A 172), as replaced by Paragraph 1 of Article 14 of Act No 3840/2010 shall be replaced by the following:

"(c) The prices of original pharmaceutical products shall, after certification by any appropriate means of the expiry of the first national or European patent for the active ingredient in the respective products, be reduced by at least thirty percent (30%).

The prices of pharmaceutical products of the same active ingredient and pharmaceutical form shall be set at a maximum of ninety percent (90%) of the selling price of the corresponding prototype of the pharmaceutical product for which the first national or European patent for the active ingredient has expired, as that price is determined in accordance with the provisions in force. The procedure for determining the prices of pharmaceutical products pursuant to the preceding paragraphs shall be applied ex officio by the Drug Pricing Department of the Division of Drugs and Pharmacies of the Ministry of Health and Social Solidarity.

(d) The price of each pharmaceutical product manufactured or packaged or imported into the country shall be based on the average of the three lowest equivalent prices of the pharmaceutical product in the Member States of the European Union (EU) for which official data are available and communicated by the competent authorities of these countries. The price is determined taking into account the price at which the medicinal product is sold to wholesalers and/or the wholesalers' price in the Member States where the medicinal product is marketed, for which official data are available and communicated by the competent authorities of these Member States. The price of each pharmaceutical product is determined by the Pharmaceutical Pricing Department of the Directorate for Medicines and Pharmacies of the Ministry of Health and Social Solidarity, which determines the price of each pharmaceutical product twice a year. For pharmaceutical products that are not marketed in three Member States, the method for calculating the price is determined by the average of the prices in the two Member States in which a price was recorded. If the medicinal product is only marketed in another Member State, the lower of the current price and the price in the other Member State is taken. By decision of the Minister of Health and Social Affairs and Social Solidarity will determine this matter further".

3. Case h of par. 5 of Article 17 of Act No 96/1973 (A 172), added by par. 4 of Article 15 of Act No 3557/2007 (No 100) shall be replaced by the following read as follows:

"Applications submitted to the Pricing Section shall be

Applications submitted to the Pharmaceutical Pricing Department of the Directorate of Drugs and Pharmacies of the Ministry of Health and Social Solidarity for the determination of prices of pharmaceutical products shall be accompanied by a fee, which shall be set at: a) three hundred (300) euros, if it is a matter of setting the price of a new medicine, per NOP code; b) one hundred and fifty (150) euros, if it is a matter of increasing the price of a medicine on the market, per NOP code. The revenue from the filing of fees shall be paid to the State budget. The amounts of the fees referred to in this paragraph may be adjusted by joint decision of the Ministers of Health and Social Solidarity and Economy.

4. Para. 2 of Article 13 of Act No. 3408/2005 (A 272), as replaced by Para. 2 of Article 14 of Act No. 3840/2010 shall be replaced by the following:

"2. 2: a) provide the competent authority with the data and information, including the price of their product, requested by the competent authority, so that the latter can determine the initial price of each pharmaceutical product and the adjustment of the price of the pharmaceutical product already in circulation, b) notify the Pharmaceutical Pricing Department of the Directorate of Pharmaceuticals and Pharmacies of the Ministry of Health and Social Solidarity of the date of entry into force of the first national or European patent for the active ingredient of their products. A company that omits or refuses to provide or provides inaccurate or untrue data and information shall be fined ten times the difference between the price resulting from the data submitted by the pharmaceutical company and the price determined by the Department, multiplied by the quantity of the pharmaceutical product sold and for as long as the approved price was in force. The imposition of the fine under this paragraph shall be independent of the claim of the insurance funds for compensation for the loss they suffered as a result of the aforementioned difference in the price of the pharmaceutical product. The legal representative of a pharmaceutical company who is found to have concealed or refused to provide or provided untruthful or inaccurate data and information shall be punished by imprisonment of at least six months. A decision of the Minister of Health and Social Solidarity shall determine the bodies, procedure and any other relevant matters for the imposition of the fine, which shall constitute State revenue and be collected in accordance with the provisions of the Public Revenue Code."

5. Para. 3 of Article 14 of Act No. 3840/2010 (A 53) shall be replaced by the following:

"3. A decision of the Minister of Health and Social Solidarity will determine all the above details of the implementation of the above provisions".

Article 70

Provisions relating to pharmacies

1. The last two subparagraphs of para. 3 of Article 36 of Act No. 3918/2011 (A 31) shall be replaced by the following:

"Within the boundaries of the Region of Attica and the Thessaloniki regional unit, as defined in Law No 3852/2010 (A 87), and in municipalities with a population exceeding 100 000 inhabitants, the above ratio of inhabitants per pharmacy shall be determined at the level of municipalities on the basis of the last census.

2. Para. 4 of Article 36 of Act No. 3918/2011 (A 31) shall be replaced by the following:

"4. The relocation and establishment of pharmacies shall be permitted, with the exception of the provisions of Paragraph 1 of this Article, near public hospitals with a capacity of more than one hundred and fifty (150) beds and at a maximum distance of one hundred (100) meters on both sides of the central outer door of the hospital and on both (2) building lines of the road on which the door is located. The number of new pharmacies may not exceed the number of pharmacies already operating in the area defined in the preceding paragraph at the time of publication of this Law."

Article 71

Miscellaneous Provisions

1. The last subsection of para. 1 of Article 38 of Act No. 3918/2011 (A 31) shall be replaced by the following:

"The net price of the manufacturer or importer shall be defined as the wholesale price of the pharmaceutical product minus 5.12 %".

2. The last subparagraph of paragraph 5.5. 2 of Article 38 of Act no. 3918/2011 (A 31) shall be replaced by the following

"The net price of the manufacturer or importer shall be defined as the wholesale price of the pharmaceutical product minus 7.24 %".

3. The penultimate and last subparagraphs of paragraph 3 of Article 39 of Act No 3918/2011 (A 31) shall be replaced by the following:

"The Department of Pharmaceutical Pricing shall be composed of one (1) employee of the Faculty of Informatics, two (2) employees of the Faculty of Informatics, one (1) employee of the Faculty of Finance, two (2) employees of the Faculty of Administration and two (2) employees of the Faculty of Pharmacy. The Department of Pharmaceutical Pricing shall be headed by an employee of the Department of Pharmacy or Informatics or Administration or Economics."

4. At the end of the case and of Paragraph 3 of Article 17 of Act No. 96/1973 (A 172), as replaced by Paragraph 5 of Article 39 of Act No. 3918/2011 (A 31), the words "with his deputy" shall be inserted.

5. In section 39 of Act No 3918/2011 (A 31), the following paragraph 6a shall be added

"6.α. By decision of the Minister of Health and Social Solidarity, a regulation of the Prices and Medicines Committee shall be established" and paragraph 7 of the same Article shall be renumbered as paragraph 8".

6. Para. 3 of Article 63 of Act No. 3918/2011 (A 31) shall be amended as follows:

"3. By a decision of the Minister of Health and Social Solidarity, issued on the basis of a proposal of the EOF Council, the manner of printing, on the remaining outer packaging and after detachment of the packaging, shall be determined.

the movable stem of the authenticity strip, the "EAN" bar codes, the serial number of the strip and the EMEA code of the pharmacy in such a way that they remain indelible".

7. Case c of paragraph (c) is deleted. 13 of Article 3 of Act No 1316/1983 (A 3), as replaced by paragraph 1 of Article 63 of Act No 3918/2011 (A 31) is replaced by the following:

"c. By a decision of the Minister of Health and Social Solidarity, issued on the proposal of the EOF Council, the type of films, the manner of their distribution, the manner of their cancellation, their use and any other relevant matters shall be determined."

Article 72

Regulation of E.O.P.Y. matters

1. Article 11 of Law No. 2768/1999 (A 273), paragraphs 6, 7, 8 and 9 shall be added as follows:

"6. The measures provided for in paragraph 1 of this Article and Article 19 of Act No 3918/2011 (A 31) shall be deducted from wages or pensions and, together with the employer's contribution, shall be paid into an OPAD bank account by the end of the following month of wages or retirement. From the 1st of the following month, if they are not paid, these contributions become due and are subject to additional charges at the rate laid down in Article 9(1) of the Staff Regulations. 6 of Act No 3232/2004 (A 48), as in force from time to time.

7. The Directorate of Administration and Finance of the OPAD Central Office shall be responsible for the collection of contributions, their certification, control, imposition of additional charges and all other related matters.

8. By decision of the Minister of Labour and Social Welfare, upon the proposal of the Board of Directors of OPAD, the Rules of Financial and Accounting Organisation of the Agency are approved.

9. The insurance contributions provided for sickness benefits in OPAD and the Health Sector of Municipal and Community Employees of OPAD shall be collected by the Health Sectors of Public Sector Employees and the Health Sector of Municipal and Community Employees pursuant to Article 25 par. 4, subparagraph 3 of Article 25(4) of Law No 3918/2011 and after the inclusion of OPAD and TYDKY for health benefits in kind in the Hellenic Health Insurance Fund. The Financial Management - Accounting Department of the Administrative - Financial Department of the Central Office of OPAD is responsible for the collection of insurance contributions. The sixth paragraph of Article 25 establishes the distribution of contributions between the National Social Security Fund and the OPAD sections.

2. Paragraph 2. 1 of Article 17 of Act No 3918/2011, in the fourth line after the sentence "which", the following sentence shall be added: "is a social security institution and".

3. In paragraph 4 of Article 17, the word "director" shall be replaced by the word "president".

4. At the end of paragraph 4, the first sentence shall be replaced by the words "the President". 2 of section 19 of Act No 3918/ 2011, the following paragraph shall be added at the end of section 19 of Act No 3918/ 2011:

"The individual monthly contribution to the health sector of members of the Organisation of Liberal Professions (OAEE) at the rate of 7,65 % shall be distributed as follows

5. After Article 19 of Law No 3918/ 2011, the following Article 19 A shall be added

Article 19 A

Establishment of accounts for cash benefits

1. From the beginning of the operation of the E.O.P.Y., the following shall be established

a. At IKA-ETAM, an account called "Cash Benefits Account", with full accounting and financial autonomy. The purpose of the account is to grant cash benefits to the Institute's insured persons and to those who take out insurance with the Institute. The granting of these benefits continues to be governed by the provisions of the IKA-ETAM Sickness Benefits Regulations and A.No. 1846/1951 (A 179), which remain in force even after the integration of the Institution's Health Insurance Fund into IKA-ETAM, as far as benefits in kind are concerned, and which are amended by a decision of the Minister of Labour and Social Security, on the proposal of the IKA-ETAM Board of Directors, and the members of the Account are served by the IKA-ETAM Health Committees. The resources of the Account are:

(aa) The income of the IKA-ETAM Sickness Branch from contributions for cash benefits, namely: aaa) a contribution of the insured and the employer for a total rate of 1.20%, which is calculated on the insured's benefits of any kind and distributed at 0.40% for the insured and 0.80% for the employer; bb) 1% as an employer's contribution according to Art. 38 para. 1 of Act. 1846/1951, as in force, for insured bricklayers; cg) 0.40% of the income from the State contribution for the insurance of insured persons after 1 January 1993,

(bb) revenue accruing from the State's contribution to the financing of the special reserve for maternity protection costs in the IKA - ETAM,

(cc) receipts from grants, advances on immovable property, annuities and any other receipts arising from the operation of the account or provided for in individual provisions.

β. In the OAEE, an account called 'Cash Benefits Account', with full accounting and financial autonomy. The purpose of the account is to provide cash benefits to those insured by the Agency and to those who become insured by the Agency. The provision of cash benefits continues to be governed by the provisions of the OAEE Health Benefits Regulation, which remains in force for these benefits even after joining the Hellenic Health Insurance Fund. of the Agency for Health with regard to benefits in kind, and is amended by a decision of the Minister of Labour and Social Security, upon proposal of the OAEE Board of Directors, and the members of the Account are served by the Health Committees of the Hellenic Health Insurance Fund. The resources of the Account are:

(aa) The revenues of the OAE Health Branch from contributions, i.e.: aaa) 0.50 % of the amount of 4 a-

(b) 0,50 % of the amount of the fourth insurance category for the old insured (up to 31.12.1992), (bb) 0,50 % of the insurance category to which the insured are assigned after 1.1.1993, (cg) 0,40 % of the income from State participation in the insurance of the insured after 1.1.1993, and (bb) income from subsidies, income from real estate, yields and any other income derived from the operation of the account or provided for in individual provisions.

c. In the OGA, an account named "Cash Benefits Account", with full accounting and legal autonomy. The purpose of the account is to provide cash benefits to members of the OASI and to those who become members of the OASI. The provision of cash benefits continues to be governed by the provisions of the Regulation on Hospital Care for DG insured persons, which remains in force for these benefits even after accession to the NHIF. of the health branch of the OGA with regard to benefits in kind, and is amended by decision of the Minister of Labour and Social Security, on the proposal of the OGA Board of Directors, and the insured persons covered by the account are served by the health committees of the OGA. The resources of the account are:

(aa) OGA health revenues from contributions: aaa) 0.20 % of the insurance category to which the insured persons belong; and

(bb) Income from grants, annuities, returns and any other income arising from the operation of the account or provided for in individual provisions.

2. The provisions of paragraph 2 of Article 19 of these Regulations shall apply to the collection of contributions to the above mentioned accounts.

3. The contribution of each account to the administrative costs shall be determined by decision of the Minister for Labour and Social Security, acting on a proposal from the boards of directors of the institutions concerned.

4. The accounting organisation, management, preparation of budgets, budgets, accounts, purchases and investments of the Account shall be governed by the provisions in force for the individual institutions."

6. Case A of paragraph 1 of Article 23 of Law No 3918/2011 shall be replaced by the following:

"A. The Central Office shall be structured as follows:

1. General Directorate of Health Services and Market Management
2. General Directorate for Planning and Development of Health Services
3. H.E.D.H.F.S.A.

The General Directorate for Health Services Management and Market consists of the following units

α. Directorate for the Management of Human Resources

β. Directorate for Financial Services and Procurement

c. Directorate for the Organisation and Supervision of Health Services of the Hellenic Health Organisation.

δ. Directorate of Information Technologies

ε. Legal Affairs Directorate

f. Independent Department for Services to Citizens.

The General Directorate for Planning and Development of Services

The General Directorate for Planning and Development of Health Services consists of the following units

α. Directorate for Planning and Development of Health Services and Development of Health Care: a.

Directorate for Planning and Development of Health Services

β. Planning Directorate: Planning Directorate

c. Directorate for Pharmaceuticals

δ. Directorate of Benefits and International Insurance Relations.

Services reporting to the President

(α) Independent Press and Public Relations Office (b) Independent Secretariat Office

(c) Independent Crisis Management Department.

7. At the end of subparagraph c of paragraph

B of paragraph (b) 1 of Article 23 of Act 23. 3918/2011 the following shall be added:

"Γ. A Regional Directorate shall be established in each prefecture of the country, which shall be subordinate to the General Directorate for the Management and Procurement of Health Services, which shall be part of the administrative structure of the National Health Service, as it shall be defined by the Para. 5 of Article 17 of Law no. 3918/2011.

Until the adoption of the Statute of the Hellenic Health Service, this Directorate will constitute an organisational unit per prefecture of the Regional Services of the Hellenic Health Service, whose seat will be chosen by decision of the President of the Agency.

This Directorate is divided into the following departments:

(a) Sickness Benefits Department

(b) Accounting Department

(c) Secretarial Department.

The Directorate is responsible for recognising, identifying, processing and

The Directorate is responsible for recognising, recording and authorising the payment of expenses for all National Health Insurance Fund services by county.

8. 8. 1 of Article 25 of Act No. 25. 3918/ 2011 shall be transferred as case c of par. 2 of the same Article, and case c of par. 2 shall be repealed.

9. Case a of par. 2 of Article 25 of Act No 3918/2011 is transferred as case c of par. 1 of the same Article.

10. The "Planning and Evaluation Directorate" of Case b of Paragraph 2 of Article 25 of Act No. 3918/2011 is subdivided as follows:

a. Planning Directorate

The Planning Directorate is responsible for:

(aa) Planning the necessary promotional actions

(a) Planning the necessary health promotion activities in cooperation with national and international bodies.

(bb) Planning cooperation between the institutions belonging to the National Health Service and the National Health Service that make up the primary health care network.

(c) Determining the needs of regional services for medical practices of various specialities.

(d) The study, evaluation and transfer of biomedical technologies to the health services of the Organisation.

b. Evaluation and Quality Assurance Directorate

The Evaluation and Quality Assurance Directorate is responsible for:

(a) Aa) Monitoring the effectiveness of the operation of the

(aa) Monitoring the effectiveness of the functioning of the Agency's health units by administrative region and identifying necessary interventions.

(Bb) Monitoring services provided and evaluating the effectiveness of systems used by health care providers to serve Agency members.

11. Case d of Paragraph 2 of Article 25 of Act No. 3918/2011 "Insurance - Direction of Benefits", with its organisational structure, shall be replaced by the following:

"d. Directorate of Benefits and International Insurance Relations.

The Directorate of Benefits and International Insurance Relations shall be responsible for:

(aa) the study, elaboration and application of the provisions of the Uniform Rules of the Organization concerning health benefits in kind, their scope, amount, method and procedure of granting, the determination of the beneficiaries of such benefits and the manner in which expenses shall be covered and (a) The study, elaboration and application of the provisions of the Uniform Rules of the Organization concerning health benefits in kind, their scope, amount, method and procedure of granting, the determination of beneficiaries of such benefits and the manner in which expenses incurred are to be covered.

(bb) The management of health care procedures, both by the National Health Service services and by external providers.

(c) The monitoring and implementation of general health care legislation that has an impact on the implementation of the Health Services Regulation.

D) Coordination of social security schemes relating to benefits in kind for sickness, accidents at work or occupational diseases, as well as safeguarding patients' rights in the framework of EU, bilateral or multilateral agreements on cross-border healthcare.

12. At the end of Paragraph 2 of Article 25 of Act No 3918/2011, Paragraph 3 is added as follows:

"3. Services under the authority of the President of the Organisation

α) The Press and Public Relations Office The Press and Public Relations Office is responsible for monitoring the media and the Internet, informing the Directorate and the relevant departments, informing the public about the Agency's objectives and activities, drafting and promoting the Agency's communications, and

managing all types of events organised by the Agency.

b) Office of the Independent Secretariat

The Office of the Executive Secretariat is responsible for assisting the Chairperson and Vice-Chairpersons in their work, conducting correspondence, gathering necessary information, organising communication with services, staff, associations, public and private bodies and the general public.

(c) Independent Crisis Management Unit

The Independent Crisis Management Unit is responsible for managing emergency situations within the health services, in cooperation with the competent bodies, and for managing civil protection issues in accordance with the provisions in force.

provisions in force".

13. Paragraphs 3, 4, 5 and 6 of Article 25 of v. 3918/2011 are renumbered 4, 5, 6 and 7 respectively.

14. The tenth and eleventh subparagraphs of paragraph 4 of Article 25 of Act No. 3918/2011, renumbered 5, a-

shall be replaced by the following:

"The services of OPAD shall be established at the level of.

They are organised at the level of the General Directorate, are divided into Central and Regional Directorates and are structured as follows:

A. Central Service

1. Administrative - Financial Directorate

α) Human Resources Management Department

b) Financial Management - Accounting Department

(c) Procurement Department - Resource Management

2. Insurance Directorate

(α) Health Care Department

(b) Regional Services Department

(c) Office of the Independent Secretariat'.

15. In the third line of paragraph B of subsection 15. 4

of Article 25 of Act no. 3918/2011, renumbered 5, the word "services" shall be replaced by the word "employees".

16. In Article 25 of Act No. 3918/2011, the following paragraph 8 shall be added:

"8. 8. 2503/1997, upon the proposal of the Minister of Labour and Social Welfare, after the opinion of the OPAD Board of Directors, the OPAD Organisation shall be established".

17. Para. 6 of Article 25 of Act No. 3918/2011, renumbered 7, shall be replaced by the following:

"7. 7. 5 of Article 17 of Law no. 3918/2011, the further structure of the services of the Hellenic Health Insurance Fund, the more specific responsibilities of its services and of OPAD, the branches from which the heads of their organisational units come, and any other necessary details shall be determined by a joint decision of the Ministers of the Interior, Decentralisation and Electronic

Government, Labour and Social Security and Health and Social Solidarity, after consulting the Board of Directors of E.O.P.Y. or OPAD".

18. Article 25 of Law No. 3918/2011, paragraph 9 is added as follows:

"9. By joint decision of the Ministers of Labour and Social Security and of Health and Social Solidarity and on the proposal of the Board of Directors of the National Health Insurance Fund, responsibilities may be transferred between the Directorates of the Agency's Central Service."

19. The last two paragraphs of para. 1 of Article 26 of Law No. 3918/2011 shall be replaced by the following:

"The procedures currently underway by the institutions for which the relevant approval has been granted for the assignment of work to doctors, dentists and pharmacists and the filling of posts of medical and health personnel shall be continued by the National Health Insurance Fund. The staff recruited and the corresponding posts shall be transferred to the Hellenic Statistical Office.

20. In para. 6 of Article 26 of Law No. 3918/2011, in the second line, the number "6" shall be replaced by the number "5".

21. The following paragraph 9 shall be added at the end of Section 26 of Act No. 3918/2011:

"9. Doctors, dentists, pharmacists and health personnel employed by the IKA-ETAM, the OAEE, the OGA and the OPAD shall be automatically transferred on the date on which these health branches become part of the E.O.P.Y., under the conditions laid down in this Article."

22. At the end of Paragraph 1 of Article 28 of Act No. 3918/2011, the following subparagraphs shall be added:

"By way of exception:

(α) The immovable property of IKA-ETAM, with the exception of the property of the Personal Insurance Sector-DEH (OAP-DEH) and the property referred to in par. 3918/2011 shall become the property of the Foundation's social insurance branch.

(b) The property of the sickness insurance branch of the former Hotel Employees' Insurance Fund (TAXY), which was incorporated into IKA-ETAM in accordance with the provisions of Article 4 of Law No. 3655/2008 (A 58), shall be transferred automatically to the National Health Service Delivery Organisation (NPSO).

(c) The properties of IKA-ETAM, in which the Health Services, the Health Units, the Centre for Diagnostic Medicine at Work and any other health service of the Institution are housed or co-located, as well as the mechanical, computer and other equipment used for the organisation and provision of health services, from the beginning of the operation of the National Health Service Provider Organisation (NPSO). The use is granted free of charge to the Agency, which undertakes to pay the relevant taxes, fees, bills, maintenance and corresponding costs of any necessary operational updates.

23. Article 28 of Law No. 3918/2011, paragraphs 7, 8 and 9 are added as follows:

"7. The competent departments of the insurance organisations IKA-ETAM, OGA, OAEE and OPAD shall be required to submit to the National Health Insurance Organisation all the information necessary for keeping a register of insured persons, pensioners and members of their families, and employers.

8. As a social security institution, the National Health Insurance Fund will have access, through EDIKA S.A., to the information systems of the organisations mentioned in the previous paragraph, for the purpose of collecting, comparing and statistically evaluating data on health benefits and expenses.

9. The National Health Insurance Fund may, by decision of its Board of Directors and with the approval of the Ministers of Labour and Social Security and of Health and Social Solidarity, and in accordance with the provisions in force, entrust the following tasks to natural or legal persons of public or private law

(α) the study, registration, evaluation, assessment and submission of proposals for the use of their assets.

(b) the administrative and financial organisation of their departments.

(c) The closing of budgets and accounts and general accounting information.

(d) The entry and processing of data in their computer programmes.

(e) The control of health expenditure.

24. At the end of paragraph 2 of Article 32 of Act No 3918/2011, the following paragraph is added "Personnel from the nursing-midwifery branch of IKA-ETAM who are transferred to the host institutions under this Act may, after their transfer to the nursing branch of IKA-ETAM, be enrolled within one month of submitting an application for preference, provided that they have worked in any employment relationship with IKA-ETAM, hold a diploma in midwifery and have provided nursing services for at least eight years prior to their transfer. Those not classified as above shall be classified in the category of midwives.

25. Para. 4 of Article 32 of Act No. 3918/2011 is replaced by the following:

"4. Ownership and all other real rights over all movable and immovable property of IKA - ETAM, which had been assigned by the latter to serve the purpose of its Hospital Support Services, shall automatically pass to the host institutions referred to in paragraphs 1 and 2 of this Article without any form, deed or contract and without consideration. By 31.12.2011, the board of directors of the host institutions concerned shall make an inventory and draw up a report on all movable and immovable property which comes into its ownership or over which it has rights in rem. An extract of the inventory report describing the immovable property and the real rights acquired on it is entered free of charge in the relevant registers of the land register or the land registry. The inventory report of movable property shall be entered in the relevant books of the receiving agencies.

26. The governors and chairpersons of all social security institutions under the responsibility of the Ministry of Labour and Social Security, with the exception of the Social Security Fund, shall be selected by the procedure stipulated in Rule 49A of the Rules of Parliament, without any other procedure, and shall be appointed by decision of the Minister of Labour and Social Security for a term of three years.

For the appointment of the Governor of IKA-ETAM and the President of IKA-ETAM to the National Organisation for the Provision of Health Services (E.O.P.Y.), the provisions in force for each of these institutions shall apply.

The qualifications required to fill the post of director or president shall be, as far as the National Health Service is concerned, those provided for in subsection (1) of this article. 2 of Article 20 of Act No 3918/2011 (A 31), and for the other institutions, those defined by the provisions of the second subparagraph of case a of paragraph 1 of Article 134 of Act No 134. 3655/2008 (A 58).

From the entry into force of this Act, any provision that regulates the issue of the selection of the governor or president of social security institutions in a different manner shall be abolished.

27. Para. 6 of Article 33 of Act No. 3918/2011 shall be replaced as follows:

"6. 6.

28. Article 33 of Law No. 3918/2011, Paragraph 11 is added as follows:

"11. For the period from 1.6.2011 to 31.12.2011, all staff employed in the integrated hospital support services of IKA-ETAM in accordance with paragraph 1 of Article 32 of this Article shall continue to receive from IKA-ETAM all types of remuneration they were receiving before the transfer. This expenditure shall be borne for the above-mentioned period by the IKA-ETAM budget and shall be offset by hospital fees collected from patients admitted to the integrated units. A joint decision of the Ministers of Finance, Labour and Social Security and Health and Social Solidarity will regulate the method and procedure of compensation and any other matter relating to compensation."

Article 73

Entry into force

This Law shall enter into force upon its publication in the Government Gazette, unless otherwise specified by a special provision.