

REPUBLIC



OF CYPRUS

1(I)/2005

**THE SAFEGUARDING AND PROTECTION OF THE
PATIENTS' RIGHTS LAW, 2004**

*(English translation prepared and
issued by the Office of the Law Commissioner)*

ΓΕΝ (Α) – L.76

NICOSIA

PRINTED AT THE PRINTING OFFICE OF THE REPUBLIC OF CYPRUS

Price:

(Advance copy)

Number 1(I)/2005

**A LAW TO PROVIDE FOR THE SAFEGUARDING AND
PROTECTION OF THE PATIENTS' RIGHTS AND FOR RELATED
MATTERS**

Preamble.

Whereas the protection of the patients' rights derives from international and european treaties and other legal acts and, in particular, from the international treaties ratified from time to time by the Republic of Cyprus, from the Declaration on the Promotion of Patients' Rights in Europe of the World Health Organization and the European Charter of Patients' Rights, as well as the European Charter of Fundamental Rights, which was incorporated in the Constitutional Treaty signed on 29 October 2004,

And whereas human rights in the field of health care and, in particular, the right to life, the right to physical and mental integrity and security, the right to respect of private life and to dignified treatment in the provision of health services, the right to protection of health through proper measures of prevention of deceases and health care, are not regulated by law,

And whereas the protection of human rights in the field of health care constitutes an essential factor of ensuring the level of health care for the citizens,

And for purposes of legal safeguarding of the patients' rights and the establishment of an effective mechanism to monitor the respect of these rights,

The House of Representatives enacts as follows:

PART I – INTRODUCTORY PROVISIONS

Short title. **1.** This Law may be cited as the Safeguarding and Protection of the Patients' Rights Law, 2004.

Interpretation. **2.** In this Law, unless the text otherwise requires -

“Board of the Pancyprian Medical Association” means the Board functioning under the Medical (Associations, Discipline and Pension Fund) Laws, 1967 to 2002;

16 of 1967
4 of 1970
28 of 1976
32 of 1977
90 of 1985
50 of 1987
208(l) of 2002.

“competent authority” has the meaning assigned to this term by the Pubic Service Law, for the time being in force;

“Emergency Department” means the department of a medical institution intended for the provision of any emergency health care and is designated as such by the said institution;

“genetic data” means all data, of whatever type, concerning the hereditary characteristics of an individual or concerning the pattern of inheritance of such characteristics within a related group of individuals;

“health care” means any form of medical, dental, paramedical, laboratory, pharmaceutical or nursing service for prevention, diagnosis, treatment or promotion of health, including mental health.

“health care services” means any form of health care service in the public or private sector provided to a person as a patient;

“health care services provider” means a doctor, a dentist, a pharmacist, a nurse, a midwife and a member of paramedical personnel, registered or licensed under the relevant law, or, if the profession in question is not regulated by law, is recognized as such, as well as administrative personnel which provides or is involved in the provision of, health care services;

“life-threatening situation” means a situation threatening immediate danger to life or severe, irreversible, disability if medical care is not provided;

“medical emergency” means an incident threatening immediate danger to life or severe irreversible disability, if medical care is not provided urgently;

“medical institution” means any premises where health care services are provided, either by an individual or a group of individuals, and includes a hospital, a medical care institution, a health center and any place where health care services are provided, belonging to, or controlled by, the Republic or any public corporate or unincorporate body, or local authority, as well as any private medical care institution, as defined by the Private Medical Care Institutions (Control of Establishment and Operation) Law, 2001, including a diagnostic center, a private practice, a clinical laboratory and a pharmacy of the private sector;

90(I) of 2001.

“medical practitioner” means any person registered as a medical practitioner under the Medical Registration Law, and includes specializing and pre-registration doctors;

Cap. 250.
30 of 1959
30 of 1961
53 of 1961
79 of 1968
114 of 1968
14 of 1974
18 of 1979
72 of 1991
66(I) of 1995

112(I) of 1996

102(I) of 2004.

“medical records” means any records compiled in written, electronic, or any other form, comprising information relating to the physical or mental health or condition of a patient whose identity may be determined thereby, and which are compiled by or on behalf of a person who by profession provides health care services;

“Minister” means the Minister of Health;

“patient” means a natural person suffering from any disease or illness, or any person seeking or provided with health care;

“patients' rights” means the rights provided by this Law and which refer to a person as a patient;

“relevant law” means a law regulating a profession referred to in the term “health care services provider”;

“State hospital” means a hospital owned or controlled by the Republic;

“unfavourable discrimination” means a violation of the principle of equal treatment on the basis of, inter alia, sex, sexual orientation, religion, racial or ethnic origin, color, philosophical, political convictions and religious beliefs, age, health status, special needs and social-financial status.

Scope of
this Law.

3. The provisions of this Law are complementary to the rights deriving from international treaties relating to the protection of human rights, ratified by the Republic and of the rights deriving from other laws which have special provisions relating to specific human rights.

PART II –PATIENTS' RIGHTS

Right to health care
and treatment.

4.–(1) Every patient shall have the right to health care, appropriate to the needs of his health to be provided within a reasonable time appropriate to those needs:

Provided that, in the case of a medical emergency the patient shall have the right to receive urgent health care unconditionally.

(2) The patient shall have the right to receive good quality health care, characterized by high technical standards as well as human relations between the patient and the health care services provider.

(3) The decision for choosing between different kinds of treatment and care shall be taken by the health care services provider and shall be primarily related to the patient's interest.

(4) The patient shall have the right to uninterrupted continuation of health care and to expect the cooperation between all health care services providers and medical institutions involved in the diagnosis, treatment and care related to him.

(5) (a) The patient shall have an inalienable right to choose and to change the medical institution or health care services provider providing health care to him, (provided that this is compatible with the functioning of the health care system).

(b) The medical institution or the health care services provider shall give the patient every reasonable facility for the exercise of the right referred to in paragraph (a), (provided that this is compatible with the functioning of the health care system).

(6) (a) When there is no longer a medical reason for a patient to remain in a medical institution, the patient shall have the

right to be fully informed before he is discharged or transferred to another institution, if this is deemed expedient, as the case may be:

Provided that, a transfer to another institution may be made, only if the administration of such other institution has agreed to accept the said patient.

- (b) When the patient is discharged and, if his condition so requires, community and home services shall be provided, provided that this is compatible with the functioning of the health care system.

(7) Notwithstanding the above, a medical practitioner shall have a duty to operate in accordance with the Medical Professional Ethics Regulations of the Board of the Pancyprian Medical Association and on the basis of the relevant professional obligations and standards.

Dignified
treatment.

5.-(1) The patient shall have the right to be treated with dignity during health care provision, which shall be rendered with appropriate respect for his cultural values.

(2) The patient shall have the right during the provision of health care, to enjoy the support of his family, relatives and friends and continuous spiritual support, including religious as well as psychological support and guidance, if needed:

Provided that, a patient admitted to a medical institution shall have the right to receive visitors at such times and according to the arrangements, determined by the administration of the said institution, on the basis of the requirements of the patient's health care and the proper functioning of the institution.

(3) The patient shall have the right to be relieved from pain and suffering, in accordance with the available scientific knowledge and the Medical Professional Ethics Regulations of the Board of the Pancyprian Medical Association, in force for the time being, within the limits of the law and legitimate procedures.

(4) The patient shall have the right to health care and respect of his dignity all through the final stage of his life, within the limits of the law and legitimate procedures.

Access to health care services.

6. Health care services must always be available and accessible, in accordance with the capacity of the existing Health Care System and the available financial, human and material resources of the state.

Prohibition of unfavourable discrimination.

7.-(1) Health care shall be provided to all equally and without unfavourable discrimination.

(2) Where as a matter of fact, a choice must be made between patients for the provision of a particular health care service, this should be made without discrimination, in a fair manner and on the basis of objective scientific/professional criteria.

Health care in a medical emergency or in a life threatening situation.

8.-(1) Where a medical institution or a medical practitioner or other competent health care services provider is requested to provide health care to a patient in circumstances prima facie, constituting a medical emergency or a life threatening situation, he shall examine and treat the patient, the soonest possible, to the best of his ability or the capacity of the institution.

(2) Where in the cases mentioned in subsection (1), the medical institution or the medical practitioner or other competent health care services provider is unable to provide health care to a patient, he shall refer him to another medical institution or health care services provider

where it is reasonably expected to receive more appropriate health care and shall ensure to the maximum extent possible that the patient is transferred to such an institution. In such a case, where there is a choice between equally suitable institutions, the patient's wishes shall be taken into account.

(3) The administration of the medical institution shall make appropriate arrangements for the implementation of the provisions of this section.

Medical
examination in
an Emergency
Department.

9.—(1) A patient applying or transferred to an Emergency Department shall have the right to a medical examination by a competent health care services provider within a reasonable time.

(2) In case the competent health care services provider finds that the patient needs urgent care, he shall give the patient such care:

Provided that, if the patient requires further care which cannot be provided in the said Department, the competent health care services provider shall refer the patient to a suitable department of the same or another medical institution and shall ensure to the maximum extent possible, that the patient is transferred to such a department. In case of a referral to another medical institution, where there is a choice between equally suitable institutions, the patient's wishes shall be taken into account.

(3) The administration of a medical institution having an Emergency Department shall make appropriate arrangements for the implementation of the provisions of this section.

Right
to information.

10.—(1) Every person shall have the right to be informed about the patients' rights. Sufficient information on health services, as well as the ways to better utilize them, must be available to the public, in accordance with the provisions of the following subsections.

(2) The patient shall have the right to a complete medical information.

(3) Information may be withheld from the patient only in exceptional cases, when there is valid reason to believe that this information may cause serious harm to the patient's mental or physical health.

(4) The patient is not considered to have disclaimed the right to information, unless he has so requested in writing.

(5) The patient shall have the right to choose whether another person should be informed on his behalf.

(6) The information shall be given to the patient or to the person he has chosen to be informed on his behalf, in a comprehensible manner, refraining from using as far as possible technical terminology.

(7) The patient shall have the right, if he so wishes, to receive a second medical opinion, in which case he shall have the right, subject to the provisions of section 18, to be supplied with a copy of his medical record, including the medical report and biological substances and to be given all possible assistance to this effect.

(8) (a) When the patient is admitted to a medical institution, he shall be informed of the identity and professional position of every person providing health care to him, as well as the regulations regarding the conditions and procedures of stay and provision of health care in the said institution.

(b) The Minister, after a consultation with the Board of the Pancyprian Medical Association shall issue directions as to the manner of providing the information mentioned in paragraph (a).

(9) The patient, at his discharge from a medical institution, shall have the right to request and receive, a written report of the diagnosis, treatment and condition of his health, subject to the provisions of section 18.

(10) The patient shall have the right to request and receive, a reasonable analytical estimate of charges, if any, at any stage of the health care:

Provided that, the provision of such reasonable estimate shall not preclude the health care services provider from exceeding the estimate or making additional charges based on changes in the patient's condition or treatment needs, provided that he has previously informed the patient, if this is reasonably possible.

Health care with the consent of the patient.

11.-(1) A prerequisite for the provision of health care is the patient's consent given after complete medical information, which is provided by the health care services provider to the patient, in due time, and in a comprehensible to the patient manner, so that the latter may understand the information provided and make a free and independent choice:

Provided that, if the patient has exercised the right pursuant to subsection (5) of section 10, the provisions of this subsection shall apply, mutatis mutandis, in relation to the person the patient has chosen to be informed on his behalf, who shall decide on behalf of the patient:

Provided further that, the health care services provider, may, in exceptional cases, withhold certain information from the patient concerning his medical condition, if he deems that, the provision of such information may cause serious harm to the patient's mental or physical health. In such a case information not provided to the patient, shall be provided to the spouse, father, mother and descendants

thereof or to whomever of the above is reasonable under the circumstances, who shall act accordingly in their discretion.

(2) The consent of the patient or the person acting on his behalf, pursuant to subsection (5) of section 10, may be given in writing or orally, provided that such consent is put in writing as soon as possible, if feasible.

(3) In case of innovative treatment, subject to the provisions of subsection (5) of section 10 and subsection (1) of this section, the patient shall be appropriately informed accordingly and his written consent shall be ensured:

Provided that, in case of subsection (5) of section 10 and subsection (1) of this section, the representative shall be appropriately informed and his written consent shall be ensured.

(4) The consent of the patient is required for the use of all substances of the human body. Consent may be presumed, when the substances are to be used in the current course of diagnosis, treatment or care of the patient, for which consent has already been given.

(5) The consent of the patient is necessary for participation in clinical teaching.

Medical
information.

12. For the purposes of sections 10 and 11, "medical information" includes the following:

- (a) the diagnosis of the patient's medical condition and, if possible, its prognosis;
- (b) a description of the purpose, anticipated benefit and likelihood of success of the proposed treatment;

- (c) the risks entailed in the proposed treatment, including side-effects, pain and discomfort;
- (d) the likelihood of success and the risks of various forms of treatment or non-treatment.

Health care without the consent of the patient.

13.—(1) Where the patient is in no position, due to his mental or physical state, to express his will and the provision of medical care is urgently needed, the consent of the patient may be presumed, unless it is obvious, from previously expressed wishes that he would have refused.

(2) Where due to the patient's physical or mental state a person is or should have been, appointed by law, whose consent is required and the provision of health care is urgently needed, such health care may be provided, if it is not possible to obtain in time such consent, unless it is obvious that, in the circumstances the said person would have refused:

Provided that, when the consent of the person appointed by law is required, the patient shall be involved in the process to the extent that his capacity and circumstances allow.

(3) Where, according to the law, a minor does not have capacity to consent to his receiving health care, health care may only be provided with the authorization of his parent or another person, who according to the law may provide such authorization and the provisions of subsection (2) shall apply, *mutatis mutandis*:

Provided that, the opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his age and degree of maturity.

(4) If the person appointed by law or, in the case of a minor, his parent or another person, pursuant to subsection (3), refuses to give

consent and the health care/services provider believes that health care is in the best interest of the patient, the matter, if time allows, is referred to a court or to another body, as may be, from time to time, prescribed by the law:

Provided that, in case of a medical emergency, the health care services provider shall act in his judgment to the patient's best interest.

(5) In any case where proper consent is impossible to be obtained—

- (a) any health care imposed as urgent may only be provided if the health care services provider deems it to be to the benefit of the patient's health or conducive to the patient's best interest;
- (b) any previously expressed wishes of the patient concerning health care shall be taken into consideration.

Participation of the patient in scientific research or experimental treatment.

14.—(1) Subject to the provisions of any law in force for the time being, the participation of a patient in scientific research or experimental treatment shall be allowed only in the following circumstances:

- (a) there is no alternative solution of comparable effectiveness;
- (b) the risks which may be incurred by that patient are not disproportionate to the potential benefits of the research;
- (c) the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research and multi-disciplinary review of its ethical acceptability;
- (d) the patient has been informed of his rights prescribed by this law;

- (e) the necessary written consent of the patient provided for under section 13, has been given specifically and in writing after a complete medical information.

(2) Where the patient is not able to consent, research may be undertaken only if the following conditions are met:

- (a) the conditions mentioned in paragraphs (a) to (d) of subsection (1);
- (b) the results of the research have the potential to produce real and direct benefit to his health;
- (c) research of comparable efficiency cannot be carried out on individuals capable of giving consent;
- (d) the necessary authorization provided for in section 13 has been given specifically and in writing, and
- (e) the person concerned does not object.

Confidentiality.

- 15.-(1)(a)** Subject to the provisions of subsection (2), all information about the patient's medical condition, diagnosis, prognosis and treatment, as well as any other personal data shall be kept confidential even after the death of the patient and shall not be disclosed to any person or authority.
- (b) The competent health care services provider or any person working in a medical institution shall not disclose any information regarding a patient which comes to his knowledge in the course of his duties or his work.
 - (c) The administration of a medical institution or the competent health care services provider shall make the necessary arrangements to ensure that persons working under their direction shall not disclose such information.

(2) The medical institution or the competent health care services provider may disclose medical information to a third person if –

- (a) the patient has given his written consent. The patient's consent may be presumed, where disclosure is to a person involved in the patient's treatment;
- (b) the disclosure is for the purpose of the patient's treatment by another health care services provider;
- (c) the information is disclosed to the medical institution providing health care to the patient or to a member of its staff for the purposes of processing, or filing the information, or for notification required by law;
- (d) the disclosure of information is for the purpose of publication in medical journals or for research or teaching purposes, provided that all information identifying the patient is not disclosed;
- (e) there is a legal obligation to this effect;
- (f) the Board of the Pancyprian Medical Association has decided, after giving both the medical practitioner and the patient an opportunity to express their views, that the non-disclosure of the information could possibly cause serious harm to other persons' health or physical integrity or have serious impact to the society as a whole:

Provided that, information shall be disclosed to the extent that the case requires making every effort to keep the identity of the patient:

Provided further that, each person receiving information, pursuant to this section, shall be subject to the provisions of subsection (1) of this section.

(3) All information and data that may possibly reveal the identity of the patient should be protected.

Protection of the patient's privacy.

16.—(1) There can be no intrusion into a patient's private and family life, unless with the patient's consent and if this is deemed necessary for his diagnosis, treatment or care.

(2) Health care shall only be provided with appropriate respect for the patient's private life and shall, as a rule, be given in the presence only of those persons who are necessary for the provision of health care.

(3) A patient admitted to a medical institution shall be entitled to facilities or arrangements which ensure the protection of his privacy, particularly when the medical or nursing staff is providing personal care or carrying out medical tests or other treatment.

Keeping medical records.

17.—(1) The competent health care services provider has a duty to keep medical records showing the course of the treatment of the patient. These records shall include detailed data identifying the patient and the competent health care services provider, as well as medical information on the treatment received by the patient, his previous medical record, as far as known, the diagnosis of his current medical condition and the treatment currently provided:

Provided that, personal notes of the health care services provider shall not form part of the medical record.

(2) The administration of a medical institution or the health care services provider, as the case may be, shall have responsibility to keep and safeguard regular and updated medical records, in accordance with the Processing of Personal Data (Protection of Individuals) Laws, 2001 and 2003.

138(I) of 2001
37(I) of 2003.

Rights of the patient regarding medical records.

Official Gazette, Supplement III(I): 8.11.2002.

18.—(1) The patient shall have the right to be informed of, to have access to and to object to, data relating to him, which is contained in the medical records and, in the exercise of these rights, the provisions of sections 11 to 14 of the Processing of Personal Data (Protection of Individuals) Laws, 2001 and 2003 and of the Processing of Personal Data (Licenses and Fees) Regulations, 2002, shall apply, *mutatis mutandis*.

(2) Without prejudice to the provisions of subsection (1), the patient's right of access to his medical records shall enable him, directly or indirectly through his legal representative, to receive information contained in these records, or a copy or extract thereof. This right includes the rectification of this information, their erasure and the blocking of the records by reason of inaccuracies and shortages:

Provided that, the right of access may be limited, rejected or suspended by the person for the time being responsible for keeping such medical records if—

- (a) this information is likely to cause serious harm to the patient's health, in which case the provisions of the second proviso to subsection (1) of section 11, shall apply, *mutatis mutandis*; or
- (b) information on third parties may be disclosed and it is impossible to prevent access to such information; or
- (c) in the case of genetic data, this information is likely to cause serious harm to consanguine or uterine kin or to a person who has a direct link with this genetic line.

Right of representation.

19. The patient shall have the right of appropriate representation, through the duly registered pancyprian representative bodies, representing groups of patients, in institutional organs, for the purpose

of expressing views, with regard to programming, formation and implementation of policy in matters of health.

Payment of health care services provider.

20. Nothing in this Law shall affect the right of a health care services provider or a medical institution to payment.

PART III – CONTROL MECHANISMS

Exercise of the rights pursuant to this Law.

21.–(1) This Part shall apply for the purpose of exercising the patients' rights pursuant to this Law:

Provided that, in cases of exercising the rights of section 18 the provisions of the Processing of Personal Data (Protection of Individuals) Laws 2001 and 2003, shall apply.

(2) The enjoyment of the rights provided by this Law must be ensured without any unfavourable discrimination.

(3) The enjoyment/exercise of the rights provided by this Law shall be subject only to regulation compatible with international treaties on human rights.

(4) If the patient cannot himself exercise the rights mentioned in this Part, such rights shall be exercised by his legal representative or the person whom the patient has appointed to this effect. In the absence of such representative, other reasonable measures shall be taken for the effective exercise of the patients' rights.

(5) Subject to the provisions of the proviso to subsection (1), the patient shall have the right to have access to information and advice enabling him to exercise the rights prescribed in this Part. There shall be provided to the patient any information and/or assistance for the process of submitting his complaints.

(6) The patients' complaints shall be fully examined without delay, in accordance with the provisions of the following sections and the patient shall be informed of the reasoned outcome of the examination immediately after the issue thereof.

Patients' Rights Officer for the safeguarding of the patients' rights in a State hospital.

22.—(1) Every State hospital shall have a duty to designate a person to be responsible for the safeguarding of the patients' rights (hereinafter referred to as "Patients' Rights Officer"), whose duties are the following:

- (a) to give advice and assistance to the patients for the purpose of safeguarding of the rights provided under this Law;
- (b) to receive and handle complaints of patients which require, in his judgment, immediate handling, otherwise to refer them to the Complaints Examination Committee established pursuant to section 23;
- (c) to guide and inform the medical, paramedical, nursing and administrative personnel of the institution on all matters relating to the provisions of this Law:

Provided that, nothing in this section shall give competence to

- (i) examine matters concerning medical expert evidence, or medical negligence or a claim for compensation; or
- (ii) take disciplinary measures for any matter for which the Disciplinary Board of the Pancyprian Medical Association and/or the competent authority have competence.

(2) Duties of the Patients' Rights Officer are assigned to a civil servant or other appropriate person by the Minister of Health, in collaboration with the Minister of Finance, in accordance with the applied procedure in force for the time being. The Patients' Rights

Officer must be independent from the health care services providers of the state hospital in for which he is assigned duties and is accountable to the general administration of the Ministry of Health.

(3) In case where the Patients' Rights Officer is unable to perform his duties mentioned in subsection (1), his representative, to whom those duties are assigned in the same manner and who has the same responsibilities as the Patients' Rights Officer, may perform such duties.

(4) The Patients' Rights Officer, pursuant to subsection (1), or his representative, pursuant to subsection (3), shall have an obligation to perform the said duties impartially and shall try to procure the best possible solution, always having in mind the best possible, under the circumstances, manner of safeguarding the patients' rights.

(5) The administration of the State hospital shall take all appropriate measures in order to comply with the obligations imposed thereto pursuant to this section.

Complaints
Examination
Committee.

23.-(1) There shall be established a Complaints Examination Committee (hereinafter referred to as the "Committee"), one per district, with competence—

(a) with respect to the medical institutions falling within the provisions of section 22—

(i) to examine complaints of patients referred to it by the Patients' Rights Officer; and

(ii) to examine at second instance any complaints of patients, who have not been satisfied by the decision of the Patients' Rights Officer, pursuant to section 22 or by a decision pursuant to subparagraph (i).

(b) with respect to the medical institutions not falling within the provisions of section 22–

- (i) to examine at first instance complaints of patients; and
- (ii) to examine at second instance complaints of patients who have not been satisfied by a decision, pursuant to subparagraph (i)

Provided that, nothing in this section shall give competence to–

- (i) examine matters concerning medical expert evidence, or medical negligence or a claim for compensation; or
- (ii) take disciplinary measures for any matter for which the Disciplinary Board of the Pancyprian Medical Association and/or the competent authority have competence, in which case the provisions of subsection (8), shall apply.

(2) (a) The Committee shall consist of five members appointed as such by the Minister for a term of office of four years. Three members shall form a quorum.

- (b) (i) The Chairman of the Committee, at least, must be independent from the health care services providers and the medical institutions seated in the relevant district;
- (ii) a member of the Committee examining a particular complaint must be independent from the health care services provider and/or the medical institution to whom the complaint relates and, in any case, where there may be an impediment, the member must declare the impediment.

(3) The Committee shall have its seat in the largest state medical institution in the district for which it is appointed. The Ministry of Health shall provide secretarial services and all the facilities for the proper and efficient functioning of the Committee.

(4) (a) With regard to the exercise of the competence mentioned in subparagraph (i) of paragraph (a) and in subparagraph (i) of paragraph (b) of subsection (1), the complaints of the patients shall be examined by one member of the Committee.

(b) With regard to the exercise of the competence mentioned in subparagraph (ii) of paragraph (a) and in subparagraph (ii) of paragraph (b) of subsection (1), the complaints of the patients shall be examined by the Committee.

(5) The Committee shall examine the complaint referred to it without delay and shall decide on the matter within a reasonable time and in particular–

(a) a complaint falling within subparagraph (i) of paragraph (b) of subsection (1), must be examined and a decision must be issued, at the latest, within 48 hours from the submission of the complaint;

(b) a complaint falling within subparagraph (i) of paragraph (a) of subsection (1), must be examined and a decision must be issued at the latest, within 15 days from the referral of the complaint to it;

(c) a complaint falling within subparagraph (ii) of paragraph (a) and subparagraph (ii) of paragraph (b) of subsection (1), must be examined and a decision must be issued, at the latest, within a month from the referral of the

complaint to the Committee for examination at second instance.

(6) The Committee's decision in accordance with subsection (5) shall be notified to the patient and the affected health care services provider and/or medical institution who shall be obliged to take it seriously into consideration.

(7) The minutes of the Committee's meetings, all the preparative material for the Committee's meetings submitted before it and the conclusions of the Committee's meetings shall be confidential.

(8) In case where the Committee deems that there is a prima facie case for taking disciplinary measures, it shall inform the competent for the health care services provider to whom the complaint relates, professional body and/or authority, as the case may be.

Obligation to inform patients for submission of complaints.

24.-(1) The administration of a medical institution or the health care services provider shall have an obligation to poster at a conspicuous place and/or inform the patient of the names of the persons comprising the competent Committee mentioned in subsection (1) of section 23, and to provide more specific information whether the particular Committee has competence over the particular institution or the particular health care services provider, as the case may be, to hear complaints under paragraph (a) or paragraph (b) of subsection (1) of section 23 and the way to contact the members of the Committee.

(2) The administration of a State hospital shall, in addition to the provisions of subsection (1), have an obligation to poster at a conspicuous place and/or inform the patient in time of the name of the Patients' Rights Officer and his representative, appointed pursuant to subsections (1) and (3) of section 22, respectively.

PART IV – FINAL PROVISIONS

Offences and penalties.

25. A health care services provider who contravenes any of the provisions of section 17 shall be guilty of an offence and the provisions of sections 25 and 26 of the Processing of Personal Data (Protection of Individuals) Laws, 2001 and 2003 shall apply mutatis mutandis:

Provided that, in order to constitute an offence pursuant to this subsection, proof of intent or professional negligence shall not be required.

Regulations.

26.–(1) The Council of Ministers has the power to make Regulations to be published in the Official Gazette of the Republic in relation to any matter which shall or may be prescribed and generally for the better carrying into effect of the provisions of this Law.

(2) Without prejudice to the generality of subsection (1), Regulations made thereunder, may provide–

- (a) for the manner of informing patients regarding the rights regulated by this Law and the exercise thereof;
- (b) for the manner of transferring a patient to an appropriate medical institution;
- (c) for the manner in which a patient may nominate another person to receive medical information on his behalf;
- (d) for the manner in which decisions shall be taken by the Patients' Rights Officer pursuant to section 22;
- (e) for the composition, functioning and any other matter regarding the Complaints Examination Committee pursuant to section 23;
- (f) for the manner of informing patients about the Patients' Rights Officer and the Complaints Examination Committee, pursuant to section 24.

(3) Regulations made under this Law shall be laid before the House of Representatives for approval or rejection within sixty days of their laying. If the House of Representatives approves the Regulations or the period of sixty days so expires, the Regulations shall be published in the Official Gazette of the Republic and shall come into force as from the date of their publication.

Entry into force of
this Law.

27. This Law shall come into force within three months from the day of its publication in the Official Gazette of the Republic.*

* Law 1(I)/2005 was published in the Official Gazette of the Republic on 7.1.2005.