
HEALTH ACT**ARRANGEMENT OF ACT**

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CHAPTER 528

HEALTH ACT

To regulate the entitlement to, and the quality of, healthcare services in Malta, to consolidate and reform the Government structures and entities responsible for Health and to provide for the rights of patients.

25th October, 2013*

ACT XI of 2013, as amended by Act VII of 2017 and Legal Notice 102 of 2018.

PART I

General Provisions

- | | |
|-----------------|---|
| Short title. | 1. The short title of this Act is the Health Act. |
| Interpretation. | <p>2. In this Act, unless the context otherwise requires -</p> <p>"Advisory Committee" means the Advisory Committee on Healthcare Benefits established by article 22;</p> <p>"Council" means the Council of Health established under article 16;</p> <p>"insured person" means a person included in the list established by regulations made under this Act;</p> <p>"medical records" means all the documents containing data, assessments and information of any kind on a patient's situation and clinical development throughout the care process;</p> <p>"Member State" means a State party to the Treaty as defined by the <u>European Union Act</u>;</p> <p>"Minister" means the Minister responsible for Health, and "Ministry" shall be construed accordingly;</p> <p>"patient" means a person who is receiving, or has received, medical attention, care, or treatment, whether in a healthcare setting or otherwise;</p> <p>"relatives" means relatives as defined under article 30 of the <u>Social Security Act</u>, but also every person who maintains a close personal relationship with the patient.</p> |
| Cap. 460 | |
| Cap. 318. | |
| Scope. | <p>3. This Act intends to establish and ensure a health system based on the principles of equity, accessibility, quality and sustainability by regulating the entitlement to, and the quality of, healthcare services in Malta, consolidating and reforming the Government structures and entities responsible for health and by providing for the rights of patients.</p> |

PART II

Department for Policy in Health

*see article 1(2) of the Act as originally enacted, and Legal Notice 386 of 2013.

4. (1) There shall be established a Department for Policy in Health whose mission shall be, in general, to act as the chief adviser to the Minister on all matters related to the Government's health policies and particularly to advise the Minister on the development of policy and co-ordination of strategic plans, on the design and implementation of action plans, and on the evaluation of outcomes in order to contribute to the sustainability of public health and health care services.

Department for
Policy in Health.

(2) The Head of this Department shall be the Chief Medical Officer to Government.

5. The Department for Policy in Health shall in general exercise those functions and fulfil all the duties and responsibilities emanating from law, and in particular, those functions and duties which the Minister may, from time to time, establish by regulations.

Functions and
duties of the
Department.

PART III

Department for Healthcare Services

6. (1) There shall be established a Department for Healthcare Services whose mission shall be to ensure the effective and efficient operation and delivery of healthcare services with an emphasis on clinical and corporate governance, service delivery and quality review within an established framework of controlled decentralization and autonomy involving user participation.

Department for
Health Services.

(2) The Head of this Department shall be a Director General.

7. The Department for Healthcare Services shall in general exercise those functions and fulfil all the duties and responsibilities emanating from law, and in particular, those functions and duties which the Minister may, from time to time, establish by regulations.

Functions of the
Department.

PART IV

Department for Health Regulation

8. (1) There shall be established a Department for Health Regulation whose mission shall be to safeguard public health, licence, monitor and inspect the provision of healthcare services in order to ensure their quality and safety, and to recommend the standards to be met by healthcare providers and advice the Minister on matters relating to public health.

Department for
Health Regulation.

(2) The Head of this Department shall be the Superintendant of Public Health.

9. The Department for Health Regulation shall in general exercise those functions and fulfil all the duties and responsibilities emanating from law, and in particular, those functions and duties which the Minister may, from time to time, establish by regulations.

Functions of the
Department.

PART V

Provisions Common for all Departments

Appointment of
Heads and Director
General.

10. The Heads and Director General shall be appointed by the Prime Minister for a period of three years which may be renewed for a further period or periods, after a call for applications under article 92 of the Constitution of Malta, and under such terms, conditions, functions and responsibilities as may be stated in the respective letter of appointment.

Juridical
representation.

11. The legal and juridical representation of the Departments shall be vested in the respective Heads and Director General, or in any other person appointed and acting on their behalf.

Heads and Director
General to be
responsible for
officers, etc.

12. Without prejudice to the provisions of this Act, the executive management, the administration and the administrative control of the officers and employees of the Departments shall be the responsibility of the Heads and Director General.

Exchange of
information
between the
Departments.

13. (1) Every Department may request, collect and verify any information, data and statistics, as may be required for the performance of its functions.

(2) A Department shall have access to all information which another Department or other entity, established by or under this Act.

(3) A Department may request all information from patients, relatives, personnel, and professionals, and from public and private healthcare providers, and such data shall be given to it in cases of emergency, for reasons of public health and to safeguard the vital interest of the patient or a third person. In all other cases the informed consent of the patient shall be required.

(4) Every Department shall have access to other statistics and data of an economic and social nature as required in order that it may perform its functions according to this Act.

(5) The preceding sub-articles of this article shall be without prejudice to any data protection legislation in force in Malta.

Respect for the
diversity of health
institutions.

14. Without prejudice, and subject to, their functions, the Departments shall respect the diversity of healthcare entities, services and programmes, and dialogue and collaborate with other entities, institutions and agencies, both public and private, local and foreign, about policies, initiatives and projects in order to ensure that the whole system operates effectively within the country.

Health Policy and
Strategy Board.

15. (1) There shall be established a Board to be known as the Health Policy and Strategy Board, presided by the Minister, to discuss and evaluate the policy, strategy developments and direction in the health sector and to monitor and follow the implementation of the health policy and strategy adopted by the Government.

(2) The Board shall be composed as provided for in Schedule A, and the Minister may by regulations amend the said Schedule, and provide for any other matter or procedure he may deem necessary for the better implementation of the functions of the Board.

PART VI

Council of Health

- 16.** (1) There shall be established a Council of Health. Establishment and composition of Council of Health.
- (2) The Council shall be composed as provided for in Schedule B, and the Minister may by regulations amend the said Schedule, and provide for any other matter or procedure he may deem necessary for the better implementation of the functions of the Council.
- 17.** (1) It shall be the duty of the Council to, whenever so requested, advise Government on any matter affecting all matters related to health in Malta. Duties of the Council of Health.
- (2) Without prejudice to the generality of the above, it shall be the duty of the Council, in particular, to advise on any matter with regards to which the law provides that the advice of the Council shall be sought.
- 18.** (1) The Council shall have the power to appoint sub-committees and to co-opt thereon members who are not members of the said Council when discussing specific items on its agenda. Powers of the Council.
- (2) The Council shall also have the power to recommend any such measures, enquiries or scientific investigations as, in its opinion, are useful in the interests of the public health.
- 19.** It shall not be lawful for the Council to transact any business unless there are at least five of its members present: Meetings of the Council and quorum.
- Provided that, if the Council is convened to consider any matter upon which its advice is urgently required by the Minister, the Council may decide by a majority of the members present.
- 20.** Without prejudice to the powers of the Minister under article 31 to make regulations to give effect to any of the provisions of this Act, the Minister may make, vary or revoke regulations for the proper conduct of the business of the Council. Power of the Minister to make regulations.

PART VII

Healthcare Benefits and Entitlement

- 21.** The Minister shall establish the healthcare benefits that are to be provided directly or indirectly by the public healthcare system, after considering the advice of the Advisory Committee on Healthcare Benefits established in article 23. Healthcare benefits.
- 22.** (1) There shall be established an Advisory Committee on Healthcare Benefits. Advisory Committee on Healthcare Benefits.
- (2) The Advisory Committee on Healthcare Benefits may set up sub-committees to deal with different and specific categories of benefits as it may deem necessary. Without prejudice to the generality of the foregoing, the Government Formulary List Advisory Committee established by the [Availability of Medicinal Products within the Government Health Services Regulations](#) shall S.L. 458.31

be deemed to be one of the aforementioned sub-committees.

(3) The Advisory Committee shall be composed as provided for in Schedule C, and the Minister may by regulations amend the said Schedule, and provide for any other matter or procedure he may deem necessary for the better implementation of the functions of the Advisory Committee.

(4) The Advisory Committee shall meet as often as necessary and shall regulate its own procedures:

Provided that in the case of urgent vitally necessary treatment, the Chief Medical Officer may authorise the provision of such healthcare benefits and duly report to the Minister and the Advisory Committee at the first available opportunity.

(5) The Advisory Committee shall retain the right to advise the Minister to restrict any form of entitlement on the basis of protocols.

Powers of the
Committee.

23. (1) It shall be the duty of the Committee to recommend the healthcare benefits to be provided directly or indirectly by the public healthcare system and to maintain a publicly accessible list of such benefits regularly updated.

(2) In formulating the list, the Committee shall primarily base its consideration on the impact of such benefits on the patient and subsequently shall be guided by the following:

- (a) international evidence;
- (b) health technology assessments;
- (c) consultation with relevant stakeholders;
- (d) capacity within the public health system;
- (e) social and epidemiological considerations;
- (f) affordability and sustainability.

Entitlement to free
healthcare benefits.

24. (1) Without prejudice to any other provision of any other law, only an insured person may qualify for free healthcare benefits provided by, or on behalf of, the public healthcare system.

(2) The Minister shall, from time to time, determine through regulations made under this Act who shall be deemed to be an insured person for the purposes of this article.

Public healthcare
fees.

25. (1) There shall be established a Register, to be kept by the Permanent Secretary of the Ministry for Health, which shall include all the benefits, services, interventions and treatments provided by the public healthcare system, and the cost and, or fees corresponding to each such benefit, service, intervention and treatment. This register shall be updated on an annual basis, or before, as the Minister may from time to time determine.

(2) All the information referred to in sub-article (1) shall be made publicly available.

(3) Without prejudice to any other law or regulations, the established fees and, or costs, shall be construed as the maximum reimbursement possible should a person opt for any form of cross-

border healthcare under any form of agreement which Malta may be a party to, irrespective of the actual fees and, or cost incurred in pursuance of such cross-border healthcare.

(4) Any person, not being an insured person as defined under this Act, shall be subjected to pay the full fees and, or costs for benefits, services, interventions or treatments as they result from the register established in sub-article (1).

(5) Without prejudice to sub-article (4) or to any other law or regulation, the Minister may approve for the partial, or full, waiver of fees and, or costs due by any person, not being an insured person, in exceptional circumstances and, or on humanitarian grounds.

26. Without prejudice to any other law or regulations relating to consumer protection in force at any time, all private healthcare providers shall be obliged to apply the same scale of fees for the services offered by them to patients, independently of the Member State of which these patients are nationals, in so far as these are in comparable medical situations.

Healthcare fees
levied by private
healthcare.

PART VIII

Patients' Rights and Safety

27. (1) It shall be the right of every patient:

Patients rights.
Amended by:
VII. 2017.2.

- (a) to receive healthcare in accordance with the provisions of this Act;
- (b) to receive information concerning the state of his health and the health services and treatments available;
- (c) to be provided in advance with clear information on the treatment options available and to be involved in discussions and decisions about the treatment to be given;
- (d) to access his medical records in accordance with the [Data Protection Act](#), provided this is not to the detriment of his overall wellbeing;
- (e) to have his medical data processed in conformity with the [Data Protection Act](#);
- (f) to refuse treatment that is offered to him, provided such refusal is endorsed by his signature;
- (g) to be seen and treated without excessive or undue delay;
- (h) to file a complaint about services received and be informed of the outcome of the investigation of his complaint in a timely manner;
- (i) to appeal in respect of any decision taken under this Act to the Administrative Review Tribunal in accordance with the provisions of the [Administrative Justice Act](#) and any applicable regulations made thereunder.

Cap. 586.

Cap. 586.

Cap. 490.

Persons who are sixteen years of age.

(2) Without prejudice to the provisions of sub-article (1) and notwithstanding the provisions of any other law, a person who has attained the age of sixteen years shall have the right to consent to, or refuse, medical attention, care or treatment if the medical practitioner is of the opinion that such person has sufficient maturity and understanding to so consent or refuse:

Provided that where the medical practitioner is of the opinion that the said person lacks the maturity and understanding to consent to or to refuse treatment, the consent of the person having parental or other legal authority over such person shall be required:

Provided further that where the medical practitioner is of the opinion that the said person has sufficient maturity and understanding to consent to treatment but refuses such treatment, the treatment may still be given if the medical practitioner is of the opinion that the treatment is urgently required in the best interest of the said person.

Cap. 464.

(3) For the purposes of sub-article (2), after a medical practitioner shall have certified that a person as referred to in the said sub-article has sufficient maturity and understanding to consent to treatment, other healthcare professionals regulated by the Health Care Professions Act shall be considered to be authorised to participate in the medical attention, care or treatment and in the healthcare plan decided by the medical practitioner by offering and administering those services, benefits, interventions and treatments required by the said person without the need for any further authorisation in that respect.

Patients' responsibilities.

28. Without prejudice to anything provided in this Act and, or any other law, whilst health care providers are expected to provide services based on the respect for human dignity, users are expected to make use of the services available in a responsible manner and to show respect to professionals, employees and also for the property.

Charter of Patients' Rights and Responsibilities.

29. (1) The Minister shall, within two years of the coming into force of this Part, publish a document to be known as the Charter of Patient Rights and Responsibilities.

(2) The Charter shall set out a summary of the rights and responsibilities of patients and other relevant persons as existing at the time of publication.

(3) The Charter shall be updated on a regular basis to reflect contemporary trends and issues.

PART IX

Miscellaneous

Powers of the Minister.

30. The Minister may, subject to the provisions of this Act, make regulations to give effect to any provisions of this Act or to regulate or otherwise provide about anything in respect of the functions and the activities which affect the provision of healthcare, and may in particular, but without prejudice to the generality of the aforesaid, make regulations for any of the following purposes:

(a) to regulate any matter connected with, or incidental to,

the implementation of the functions, operation and administration of all healthcare entities;

- (b) to prescribe such data, reports and statements of accounts which have to be sent to the Minister and to the Directors General by the Principals and, or the Chief Executive Officers, and such other officers and persons relating to healthcare as the Minister may deem necessary to request, and in such manner, form, time and on such subjects as he may specify in the regulations;
- (c) to establish any fee and, or payment which may be due by, or under this Act, or for any service given in compliance with the provisions of this Act;
- (d) to provide about any form or procedure which may be required or expedient, and about which there would be no specific procedure in this Act;
- (e) to establish rules by means of which the Government may ratify and give effect to international conventions relating to health and which have already been ratified by the Government of Malta; or in order to achieve compliance with any international obligation pertaining to the Government of Malta or with European Union Directives on any matter or area concerning health;
- (f) to establish the functions and duties of the directorates and departments established by, or through this Act;
- (g) in order to ensure the provision of health services in a full and continuous process throughout life, to establish those healthcare entities in such manner as it may from time to time appear to be necessary in the Maltese Islands and, unless otherwise provided in this Act or in any other law, to establish also statutes and rules to regulate the mission, scope, functions, powers and duties, financial accountability or otherwise, and any other procedure which has to be followed, performed or observed by any entity so established by or under this Act;
- (h) to establish, unless otherwise provided in this Act or in any other law, statutes and rules to regulate the mission, scope, functions, powers and duties, financial accountability or otherwise, and any other procedure which has to be followed, performed or observed by any Council, Committee or Board established by or under this Act;

Cap. 490.

- (i) to afford, subject also to the provisions of any other law, to a person aggrieved by the decision of any entity, body or organisation established by or under this Act, means and procedures either to lodge his complaints and aggravation about a decision or to contest or appeal from such a decision to the Administrative Review Tribunal in accordance with the provisions of the [Administrative Justice Act](#) and any applicable regulations made thereunder, and to be satisfied if that aggravation is upheld;
- (j) to establish anything which is due to be, or may be established under this Act, and to provide on any other matter as may be deemed to be appropriate;
- (k) to establish the fines for any contravention or breach of any provision of any regulation made under this Act, or for non-compliance with any provision or any requirement imposed under such provision:
Provided that any regulations made under this paragraph may provide differently for different aims or circumstances, for different classes or types of entities, and for different classes of patients;
- (l) to establish the framework of the national health policy for public and private healthcare providers, and it shall be the duty of all such providers to implement this policy according to the potential and the various needs of patients attending thereat;
- (m) to establish, in the paramount interest of health in Malta, any possible exceptions to any provision contained in any law;
- (n) to regulate any matter related to indemnity insurance in the healthcare sector;
- (o) to regulate any matter connected with patients rights and safety;
- (p) to regulate any matter related to the licensing connected with the provision of healthcare services.

Saving.
Cap. 94.

31. (1) Any regulations or orders made under the provisions of the Department of Health (Constitution) Ordinance* and still in force on the commencement of this Act, or the relevant Part or article, shall, until provision is made by or in virtue of this Act, continue to remain in force and have effect as if made under this Act.

(2) Any licence, permission or other authorisation granted under any provision of the aforesaid Ordinance shall continue to have effect as if it were a licence, permission or other authorisation granted under the authority of this Act.

*Repealed by this Act.

SCHEDULE A

[Article 15(2)]

The Health Policy and Strategy Board shall be composed as follows:

- (a) the Minister, as Chairman;
- (b) the Permanent Secretary in the Ministry, as Deputy Chairman;
- (c) the three Directors General established under this Act, *ex officio*;
- (d) the financial controller of the Ministry, and in his absence, the highest ranking officer responsible for the financial administration of the Ministry;
- (e) a Minister's consultant;
- (f) any other officer who the Minister may deem, from time to time, fit to appoint on this Board; and
- (g) an officer appointed by the Minister to act as secretary.

SCHEDULE B

[Article 16(2)]

(1) The Council of Health shall be composed as follows:

- (a) the Minister, as Chairman;
- (b) the Permanent Secretary in the Ministry, as Deputy Chairman;
- (c) the legal officer of the Ministry;
- (d) the Superintendent of Public Health;
- (e) a person representing the healthcare professionals;
- (f) a specialist in public health medicine;
- (g) a person representing private healthcare providers;
- (h) a person nominated by associations representing the patients;
- (i) trade-unionism expert in health matters;
- (j) a member of the academic staff on Health Sciences of the University of Malta; and
- (k) an officer appointed by the Minister to act as secretary.

(2) The members referred to in paragraph (1)(e), (f), (g), (h), (i) and (j) shall be appointed by the Minister for such term as the Minister shall, from time to time, decide.

*Amended by:
L.N. 102 of
2018.*

SCHEDULE C

[Article 22(3)]

(1) The Advisory Committee on Healthcare Benefits shall be composed as follows:

- (a) the Permanent Secretary in the Ministry, as Chairman;
- (b) the Chief Medical Officer to Government, as Deputy Chairman;
- (c) the Lead Chairperson of the Chairpersons Committee;
- (d) a nurse;
- (e) a pharmacist;
- (f) an allied healthcare professional;
- (g) a person who has the warrant to practice as advocate in Malta representing the Ministry;
- (h) a representative of the Minister responsible for Finance;
- (i) a representative of the Consumer Protection Department;
- (j) a representative of the Central Procurement and Supplies Unit within the Ministry for Health; and;
- (k) an officer appointed by the Minister to act as secretary.

(2) The members referred to in paragraph (1)(d),(e), (f), (g), (h), (i) (j) and (k) shall be appointed by the Minister for such term as the Minister shall, from time to time, decide.
