

A BILL
entitled

AN 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.

BE IT ENACTED by the President, by and with the advice and consent of the House of Representatives, in this present Parliament assembled, and by the authority of the same, as follows:-

ARRANGEMENT OF ACT

	Articles	
Part I	General Provisions	1 - 3
Part II	Directorate for Policy in Health	4 - 5
Part III	Directorate for Health Services	6 - 7
Part IV	Directorate for Health Regulation	8 - 9
Part V	Provisions Common for all Directorates	10 - 16
Part VI	Council of Health	17 - 21
Part VII	Healthcare Benefits and Entitlement	22 - 27
Part VIII	Patients' Rights and Safety	28 - 30
Part IX	Miscellaneous	31 - 32

PART I

General Provisions

1. The short title of this Act is the Health Act, 2013. Short title and commencement.
- (2) The provisions of this Act shall come into force on such date as the Minister may establish by notice in the Gazette, and different dates may be established for different provisions of this Act.
2. In this Act, unless the context otherwise requires - Interpretation.
- "Advisory Committee" means the Advisory Committee on Healthcare Benefits established by article 23;
- "Council" means the Council of Health established under article 17;
- "insured person" means a person included in the list established by article 25;
- "Member State" means a State party to the Treaty as defined by the European Union Act; Cap. 460
- "Minister" means the Minister responsible for Health, and "Ministry" shall be construed accordingly;
- "patient" means a person who is receiving, or has received, medical attention, care, or treatment, whether in a healthcare setting or otherwise.
3. This Act intends to establish and ensure a health system based on the principles of 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. Scope.

PART II

Directorate for Policy in Health

4. (1) There shall be established a Directorate 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 Directorate for Policy in Health.

C 188

care services.

(2) The Head of this Directorate shall be a Director General who shall also be, *ex officio*, the Chief Medical Officer to Government.

Functions and duties of the Directorate.

5. The Directorate 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.

PART III

Directorate for Healthcare Services

Directorate for Health Services.

6. (1) There shall be established a Directorate 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.

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

Functions of the Directorate.

7. The Directorate 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.

PART IV

Directorate for Health Regulation

Directorate for Health Regulation.

8. (1) There shall be established a Directorate 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.

(2) The Head of this Directorate shall be a Director General, who shall also be, *ex officio*, the Superintendant of Public Health.

Functions of the Directorate.

9. The Directorate 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.

PART V

Provisions Common for all Directorates

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

Appointment of Directors General.

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

Juridical representation.

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 Directorates shall be the responsibility of the Directors General.

Directors General to be responsible for officers, etc.

13. Without prejudice to the provisions of this Act, any function of a Directorate may be exercised through an authorised person or contractor after an agreement to that effect has been reached:

Exercise of functions through third parties.

Provided that no such agreement with third parties shall be entered into unless:

(a) the exercise of that particular function or functions through an authorised person or contractor is for the benefit of the Directorate; and

(b) the estimated amount for the exercise of that particular function or functions does not exceed that sum established, from time to time, by the Minister or the Permanent Secretary, and the special reason for such an agreement has been approved by the Minister after consultation with the Minister responsible for finance; and

(c) a call for tenders has been issued for such purpose.

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

Exchange of information between the Directorates.

(2) A Directorate shall have access to all information which another Directorate or other entity, established by or under this Act, may possess, and is entitled to request and obtain all data it may require from patients, relatives, personnel and professionals, and from public and private healthcare providers, and such data shall be given

C 190

to it within a reasonable time from the date of request.

(3) Every Directorate 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.

Respect for the diversity of health institutions.

15. Without prejudice, and subject to, their functions, the Directorates 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.

16. (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

Establishment and composition of Council of Health.

17. (1) There shall be established a 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.

Duties of the Council of Health.

18. (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.

(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.

Powers of the Council.

19. (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.

(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.

20. 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 Government, the Council may decide by a majority of the members present.

21. 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

22. 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.

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

S.L. 458.31

(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

C 192

Advisory Committee at the first available opportunity.

Powers of the
Committee.

24. (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 its advice, the Committee 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.

25. (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) For the purpose of this Act, an insured person means:

(a) a national of a Member State or of the European Economic Area, or a Swiss citizen, or a long term resident in terms of the Status of Long-Term Residents (Third Country Nationals) Regulations, whose primary residence is in Malta and who is:

S.L. 217.05

Cap. 318

(i) actively covered by social insurance in terms of the Social Security Act; or

Cap. 318

(ii) deemed to be covered for healthcare in terms of the Social Security Act irrespective of their social security contribution status, but excluding persons who would otherwise only be deemed to be so insured by virtue of the European Convention on Social and Medical Assistance and Protocol thereto; or

(iii) in possession of a health insurance cover by the competent authority of another Member State in terms of the Community Regulations on the application of social security schemes in force; or

(b) a citizen of a country which has a reciprocal healthcare agreement in force with Malta, in respect of such care and treatment to which such citizen would be entitled under the terms of such agreement or any understanding or agreed minutes subsequent thereto; or

(c) a person covered by the Refugees Act or any regulations made thereunder, but only in respect of such care and treatment to which such persons would be entitled under the terms of regulations, administrative policies or agreements subsequent thereto; or

(d) dependants of persons mentioned in paragraphs (a) to (c).

(2) The Minister may, from time to time, determine through regulations made under this Act that certain healthcare benefits may be restricted to certain categories of insured persons.

26. (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.

Public
healthcare fees.

(2) The fees and, or costs, 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.

C 194

Healthcare fees
levied by
private
healthcare.

27. Without prejudice to any other law or regulations relating to consumer protection in force at any time, all healthcare providers, both public providers where the patient or customer is not an insured person, and private providers in all instances, shall be obliged to apply the same scale of fees for the services offered to patients in comparable medical situations, irrelevant of the country of which they are nationals.

PART VIII

Patients' Rights and Safety

Patients rights.

28. It shall be the right of every patient:

(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;

Cap. 440.

(d) to access his medical records in accordance with the Data Protection Act, provided this is not to the detriment of his overall wellbeing;

Cap. 440.

(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;

Cap. 490.

(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.

Patients'
responsibilities.

29. 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.

30. (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.

Charter of
Patients' 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

31. 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:

Powers of the
Minister.

(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;

(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.

32. (1) With effect from the coming into force of this Act, the provisions of the Department of Health (Constitution) Ordinance shall be repealed. For the avoidance of doubt, parts of that Ordinance may be repealed at different dates on the coming into force of a corresponding Part or Article of this Act.

Repeal and
saving.
Cap. 94.

(2) Any regulations or orders made under the provisions of the said 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.

(3) 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.

C 198

SCHEDULE A

[Article 16(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 17(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 Attorney General or his representative;
 - (d) the Chief Medical Officer to Government;
 - (e) a person representing the healthcare professionals;
 - (f) a person representing public health;
 - (g) a person representing private healthcare providers;
 - (h) a person nominated by associations representing the patients;
 - (i) any other officer who the Minister may deem, from time to time,

fit to appoint on this Board; and

(j) 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.

SCHEDULE C

[Article 23(3)]

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

(a) the Permanent Secretary in the Ministry, as Chairman;

(b) the Director General Healthcare Services, as Deputy Chairman;

(c) the Clinical Chairperson of the Department of Medicine in the Ministry;

(d) the Clinical Chairperson of the Department of Surgery in the Ministry;

(e) a pharmacist;

(f) a person who has the warrant to practice as advocate in Malta representing the Ministry;

(g) a representative of the Minister responsible for Finance;

(h) a representative of the Consumer Protection Department;

(i) any other officer who the Minister may deem, from time to time, fit to appoint on this Board; and

(j) 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.

C 200

Objects and Reasons

The Objects and Reasons of this Bill are to provide, in lieu of the Department of Health (Constitution) Ordinance, for an updated law on the running and administration of the department involved in the provision of services connected with public health, in line with the exigencies of today's requirements.

The Bill also aims to regulate the entitlement to, and the quality of, healthcare services in Malta, and to provide for the rights of patients.

