

LAW WHICH SHALL PROVIDE FOR ELECTRONIC HEALTH
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The Electronic Health Law of 2019 is issued by publication in the Official Gazette of the Republic of Cyprus in accordance with Article 52 of the Constitution.

Number 59 (I) of 2019

LAW WHICH SHALL PROVIDE FOR ELECTRONIC HEALTH

The House of Representatives enacts as follows:

Short
Title

1. This Law shall be cited as the Electronic Health Law of 2019.

PART I

INTRODUCTORY AND INTERPRETATIVE PROVISIONS

Interpretation.

2. In this Law, unless the context requires otherwise:-

"Acceptable integration profiles" means the sets of acceptable specifications for the procurement of health information systems;

"Authority" means the National e-Health Authority established under Article 4 of this Law;

"Core set of health data" means the set of a citizen's health data registered by healthcare providers in the e-Health Record and stored electronically in the Bank in accordance with the provisions of Article 19 of this Law;

"Health data" means the entirety of stored biomedical data of any form, diagnoses, assessments, biosignals, laboratory results, imaging, other diagnostic and therapeutic interventions, medical prescriptions and information of any kind, in relation to each citizen's condition and health development from birth to death and includes records drawn up by the provider in writing, electronically or otherwise;

"Republic" means the Republic of Cyprus;

"System operator" means the natural or legal person who undertakes to maintain and provide security for the citizen's health managed by the provider;

"Extensive set of health data" means the minimum mandatory registered health data set for a citizen, registered and stored electronically by healthcare providers in accordance with the provisions of Article 27 at any point of health services provision, in any way, by using monitoring technologies and/or short and long-term health care;

"Single e-Health Records Bank" or "SeHRB" means a bank established under Article 28 of this Law;

"Printed Records" means health data kept in paper form;

125 (I) of 2018.

"Processing" has the meaning assigned to it in Article 2 of the Law providing for the Protection of Natural Persons with regard to the Processing of Personal Data and for the Free Movement of such Data;

"e-Health Record" means an electronic file containing the data specified in Article 19 of this Law;

E.U.Official
Journal L.119,
4.5.2016,
p.1

"Regulation (EU) 2016/679" means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) ;

"Legal representative" means a person authorized by a citizen to enter data in his/her electronic health record in paper or electronic form;

89 (I) of 2001
134 (I) of 2002
101 (I) of 2004
62 (I) of 2005
74 (I) of 2017.

"Health Insurance Organization" or "HIO" means the Organization established under the provisions of the General Health Care Law;

73 (I) of 2017
32 (I) of 2018.

"State Health Services Organisation" or "SHSO" means the Organization established under the provisions of the Establishment of State Health Services Law;

"Provider" means a healthcare provider;

"Healthcare provider" means any natural or legal person or other entity who is legally providing health services in the Republic;

"Citizen" means a natural person who has his/her permanent or habitual residence in the areas controlled by the Republic or a natural person who has no permanent or habitual residence in the areas controlled by the Republic and is a visitor to the areas controlled by the Republic or intends to visit them;

"Disease prevention and health promotion" means the planning and actions taken by healthcare providers and/or competent authorities and services for the primary or secondary prevention of diseases at individual or national level and the promotion of the citizens' health and wellbeing;

"Telemedicine" means the provision of health services in cases where there is physical distance between a patient and the provider of such services and which may take place under specified conditions and with the use of technological infrastructures;

"Bank" means the Single Electronic Health Records Bank;

"Health Data Bank" includes the Single Electronic Health Records Bank and Provider Banks;

"Provider Bank" means the infrastructure and electronic equipment of the provider so that the provider performs the functions specified in Article 27 of this Law;

"Minister" means the Minister of Health;

70 (I) of 2001
83 (I) of 2002
35 (I) of 2004
78 (I) of 2004
100 (I) of 2004
263 (I) of 2004
13 (I) of 2005
28 (I) of 2005
97 (I) of 2005
122 (I) of 2005
20 (I) of 2006
75 (I) of 2006
104 (I) of 2006
20 (I) of 2007
76 (I) of 2007
25 (I) of 2010
116 (I) 2010
92 (I) of 2011
63 (I) of 2012
209 (I) 2012
121 (I) 2013
146 (I) 2013
114 (I) 2014
142 (I) of 2017.

"Medicinal product" has the meaning assigned to it in Article 2 of the Medicinal Products for YHuman Use (Quality Control, Supply and Pricing) Law;

"Users" means providers and citizens.

Purpose and scope of the provisions of this Law

3. The purpose of this Law is to establish a framework for the use of electronic health for the prevention of disease, the promotion of health and the effective and safe provision of health services to citizens through the establishment of a National e-Health Authority, the implementation of the e-Health Record system, the regulation of the storage and use of biomedical information and telemedicine.

PART II NATIONAL AUTHORITY FOR ELECTRONIC HEALTH

National e-Health Authority

4. - (1) An Authority is established under the name "National e-Health Authority", which is a legal person of public law, has all the qualities of a legal person and is governed by the provisions of this Law.

(2) The Authority shall exercise the duties, powers and authorities conferred upon it by the provisions of this Law.

(3) The Authority is managed by and acts through a seven-member board, which manages its assets and resources and carries out its duties, powers and authorities.

(4) The Chairman of the Administrative Board of the Authority shall be an independent person of recognized standing and honesty, holding a university degree and having a minimum of 10 years of experience in one of the following fields:

- (a) Public administration or business administration;
- (b) Economics;
- (c) Computer Science and/or engineering;
- (d) Health Sciences;
- (e) Law

and who has further demonstrated knowledge in one or more of the above fields.

(5) The members of the Administrative Board of the Authority shall be comprised of six (6) persons of high ethical and professional level, of which:

- (a) Five (5) members should hold a university degree and have experience in one of the following fields and have further demonstrated knowledge in one or more of the following areas:
 - (i) Public administration or business administration;
 - (ii) Economics;
 - (iii) Computer Science and/or Engineering;
 - (iv) Health Sciences;
 - (v) Law

Provided that among the five (5) members of the Administrative Board of the Authority, at least one member should hold a university degree in Public Administration or Business Administration, at least one member should hold a university degree in Economics, at least one member should hold a university degree in Computer Science and/or Engineering, at least one member should hold a university degree in Health Sciences, at least one member should hold a university degree in Law; and

- (b) one member is proposed to the Minister by the Cyprus Federation of Patients and Friends Associations.

(6) Subject to the provisions of this article, the Administrative Board of the Authority shall be appointed by the Council of Ministers upon the recommendation of the Minister and the first appointment shall take place by decision of the Council of Ministers within two (2) months after the entry into force of the provisions of this Law.

(7) Political party officials cannot be appointed as members of the Board of the Authority.

(8)(a) Any person, either himself or his/her spouse, who has any personal, direct, indirect or conflicting interest in undertakings related to the activities of the Authority or has a relative up to the fourth (4th) degree of relation that deals with professionally or holds shares in excess of ten percent (10%) of the share capital of or has any other direct, indirect or conflicting interest in undertakings related to the activities of the Authority, cannot be appointed or maintain his post as chairman or a member of the Board of the Authority.

(b) In order to ensure compliance with the provisions of paragraph (a), the Chairman and the members of the Administrative Board of the Authority shall, upon assuming their duties, make a declaration to the Council of Ministers of any interest in any undertakings that they maintain which are related to the activities of the Authority.

(c) The Chairperson or any member of the Administrative Board of the Authority shall not attend any meeting where there is discussion and/or in the decision-making regarding any matter in which they or their relatives up to the fourth (4th) degree have a direct or indirect interest:

It is understood that the persons referred to in this paragraph are not entitled to sign any agreement, settlement, contract or document that will initiate transaction procedures or activities relating to the subject for which they have declared an interest.

(d) In the event that the Chairman or any member of the Board of the Authority has a direct or indirect interest in any matter discussed or to be discussed and/or for which a decision has been or will be taken, he/she must disclose the nature of such interest in a board meeting and he/she shall not engage in subsequent discussions and/or decisions on this matter.

(e) The disclosure of interest is recorded in the minutes.

(f) A person who makes a false declaration in breach of the provisions of paragraphs (a), (b), (c) and (d) is guilty of an offense and, if convicted, is punished by imprisonment not exceeding one (1) year or with a fine not exceeding forty thousand euros (€ 40,000) or by both penalties.

(9) The Chairman and members of the Board of the Authority and any person serving with the Authority shall not be liable for any act or omission during the performance of their duties and responsibilities under the provisions of this Law, unless it is established that the act or the omission was made in bad faith.

(10) The Chairman and any person appointed as members of the Board of the Authority shall elect the Vice-Chairman among themselves.

Term of office of the Authority's Administrative Board Members

5. The term of office of the Chairman, the Vice-Chairman and the members of the Administrative Board of the Authority shall be five years and may be renewed for a second consecutive term in accordance with the provisions of this Part.

Terms of service, remuneration of the Chairman and remuneration of the Members of the Administrative Board

6. - (1) The terms of service and the remuneration of the Chairman of the Board of the Authority shall be determined by the Council of Ministers.

(2) The Vice-Chairman and the members of the Board of Directors of the Authority shall be compensated, per the specifications of the Council of Ministers.

(3) The expenditure for the payment of the Chairman's remuneration and the remuneration of the Vice-Chairman and the other members of the Administrative Board of the Authority shall be charged to the Authority's annual budget.

Vacancy of the post of the Chairman, Vice-Chairman and members of the Authority

7. The post of the Chairman, Vice-Chairman or any member of the Administrative Board of the Authority shall be vacant in the event of one of the following:

(a) His/her death,

(b) His/her written resignation submitted to the Council of Ministers, or

(c) His/her termination by the Council of Ministers in accordance with the provisions of Article 8.

Termination of the Chairman, Vice-Chairman and members of the Board of the Authority

8. The Chairman, Vice-Chairman or any member of the Administrative Board of the Authority Council of Ministers shall be terminated by the Council of Ministers, if he/she:

(a) declares bankruptcy or comes to an arrangement with his creditors, in accordance with the laws in force in the Republic,

- (b) becomes mentally incompetent, under the laws in force in the Republic,
- (c) is unable to perform his or her duties because of physical disability or illness,
- (d) acquires a financial or other interest that may affect the impartiality of his/her judgment and does not submit his/her resignation,
- (e) abuses his/her position and as a result, if his/her term of office continues it shall be detrimental to the public interest and does not submit his/her resignation,
- (f) upon recommendation by the Authority, if he or she is unjustifiably absent from office or after an unjustified absence from the meetings of the Authority for three (3) consecutive times; or
- (g) if he/she is convicted of a criminal offense involving a lack of honesty or moral disgrace.

Vacancy of a member of the Authority

9. The members of the Administrative Board of the Authority shall exercise the powers, duties and authorities of their post, regardless of the temporary vacancy of a member's post.

Annual Budget

10. - (1) Four (4) months before the beginning of the new financial year, the Authority shall prepare and submit a budget, through the Minister, to the Council of Ministers for approval.

194 of 1987
318 of 1987
52 of 1988
69 of 1989
186 of 1991
19 (I) of 2001
35 (I) of 2012.

(2) When the budget of the Authority is approved by the Council of Ministers, it shall be submitted to the House of Representatives in accordance with the provisions of the Public Legal Entities (Vote on Budget) Law.

(3) Until the approval of the Authority's first budget, provision is made in the budget of the Ministry of Health for the expenditure required to carry out its responsibilities.

Financial Year

11. The Authority 's financial year shall begin on 1st January and end on 31st December of the same year.

Office and staff of the Authority

12. - (1) The Authority shall be housed in suitable premises temporarily assigned or leased by the Ministry of Health until the Authority acquires its own office.

(2) The structure, departments and functions of the Authority shall be determined by Regulations issued by the Council of Ministers.

(3) The Authority has its own staff:

It is noted that if the immediate recruitment of staff is not possible and until recruitment, the Authority may use staff seconded by the public service.

73 (I) of 2016.

(4) The Authority may enter into contracts with natural or legal persons, on such terms and conditions as it may determine, which are deemed necessary for the effective performance of its functions and the performance of its tasks, in accordance with the provisions of the Regulation of Public Procurement Procedures and Other Related Matters Law.

Keeping Accounts.

13. - (1) The Authority keeps full and accurate accounts which are audited by the Auditor General of the Republic or an approved private house and submitted to the Minister.

53 (I) of 2017
171 (I) of 2017.

(2) (a) The Auditor General of the Republic may, at his discretion, entrust the audit or designate the delegation of the audit of the Authority's accounts to auditors or audit offices that have obtained authorization and have been entered in the relevant register kept under of the provisions of the Auditors Law.

(b) The Attorney General of the Republic may at any time carry out at his discretion additional accounting or other financial control.

Annual Report
and Financial
Statements

20 of 2014
123 (I) of 2016
133 (I) of 2016
159 (I) of 2017.

14. - (1) Within four (4) months from the end of the financial year, the Authority shall draw up and submit to the Minister a financial report, including the final balance sheet of the budget year in accordance with the provisions of the Fiscal Responsibility and Budget Framework Law.

(2) The financial report and financial statements are signed by the Chairman of the Authority and before being submitted to the Minister are audited by the Auditor General of the Republic.

Meetings of the
Authority,
quorum and
decision-making

15. - (1) The Chairman of the Administrative Board of the Authority shall preside over the Board, convene its meetings and sign the minutes and any other important document.

(2) The Chairman of the Administrative Board of the Authority shall ensure the execution of the decisions and the exercise of the Authority's powers and represent the Authority before judicial or other authorities.

(3) The Chairman shall convene a Board meeting whenever he/she sees fit, but at least once a month and, if requested in writing by at least three (3) members of the Board, who shall consequently determine the issues to be discussed, shall convene a meeting as soon as possible.

(4) The invitation to a meeting is done in writing and is addressed to all members of the Administrative Board of the Authority, at least five (5) days before the date set for the meeting:

It is noted that, in extraordinary and justified cases, the invitation can be given to the members of the Authority twenty four (24) hours before the date set for the meeting.

(5) The agenda shall be drawn up by the Chairman of the Board and will be communicated along with the invitation to the meeting:

It is noted that, if the Authority so decides, in an extraordinary and justified case an item outside the agenda may be introduced for discussion by the Chairman or a member of the Authority.

(6) The Chairman or the Vice-Chairman and at least three (3) Board members attending a meeting shall constitute a quorum.

(7) The decisions of the Authority shall be taken by a majority of the votes of the Board members and in the event of a tie the Chairman shall have a casting vote.

(8) The Chairman presides over the meetings of the Board chairman and, in the event of his absence or temporary impediment, the Vice-chairman takes his/her place.

(9) In the event of the simultaneous absence of the Chairman and the Vice-Chairman, the Administrative Board shall not convene.

(10) At each meeting of the Board minutes are kept, which are signed by the Chairman or in his absence, by the Vice-Chairman.

Responsibilities

16. The Authority's responsibilities are as follows:

(a) The drawing up of:

(i) Regulations which are submitted to the Council of Ministers through the Minister and submitted to the House of Representatives for approval; and

(ii) internal regulations and issuing decisions;

(b) the issue of binding and mandatory instructions to holders and operators of Health Data Banks and their authorized representatives for the obligations and rights of providers arising from the provisions of this Law;

(c) to perform the proper technical inspections and monitoring of the Health Data Banks in order to ascertain that their operation complies with the provisions of this Law and the Regulations, Internal Regulations and Directives issued thereunder;

- (d) drawing up proposals to the Minister and other stakeholders on the strategic vision, priorities and objectives of e-Health and setting up a Roadmap for actions to maintain an electronic health system at national level;
- (e) defining the operating standards and specifications, the operating framework, financing and setting up of the Single e-Health Records Bank, which keeps and manages citizens' electronic health records;
- (f) to study, undertake and promote actions for the implementation of:
 - (i) interoperable e-Health applications with other Member States, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare,
 - (ii) common identification and authentication measures with other Member States to facilitate transferability of data in cross-border healthcare and actions to ensure the interoperability of eHealth systems through the use of acceptable integration profiles installed or to be installed to healthcare providers and their compliance with the relevant European Union law and relevant standards but also with the national eHealth objectives;
- (g) setting standards and specifications for the operation of telemedicine services and submitting proposals to the Minister, the Health Insurance Organization and other stakeholders for their funding models;
- (h) cooperation and exchange of information with other Member States of the European Union or third countries, as well as with the national authorities and institutions of the European Union responsible for electronic health;
- (i) monitoring, at European and international level, the developments in the field of eHealth and submitting proposals to the Minister for actions which the Republic must and is required to undertake;
- (j) monitoring of European and other co-funded programmes relating to eHealth and submission of proposals to the Minister for the actions to be taken to reinforce the effective participation of the Republic in these programmes, in the light of the national strategy for development, research, technology and innovation;
- (k) the management of revenue generated by the economic exploitation of anonymous databases;
- (l) the promotion and application of the principles and methods of e-Health in the scientific communication, the undergraduate, postgraduate and lifelong education of health professionals, as well as informing the citizens;
- (m) the provision of specialized consultants to the Minister on issues pertaining to the Authority's responsibilities, as well as suggestions for the adoption of laws relating to these responsibilities;
- (n) inviting experts to assist with the Authority's work by providing specialized advice or opinions or know-how and, where appropriate, specific training to its members and / or staff;
- (o) issuing guidelines regarding the eHealth Applications Certification Framework so that the framework is compatible with international standards, the minimum equipment, minimum necessary staffing and minimum qualifications required for the operation of such applications in healthcare facilities;
- (p) the operation of the National e-Health Contact Point, as defined in Article 17 of this Law;
- (q) the establishment and maintenance of Registers;
- (r) the establishment of technical committees:
 - (i) by persons from other bodies and organized groups to provide any other suggestions to the Authority on matters falling within its responsibilities;
 - (ii) for purposes of monitoring and inspecting the quality and safety of the services provided by healthcare providers; and

(s) the performance of any other responsibility arising from the provisions of this Law.

National e-Health
Contact Point

17. - (1) The Authority, acting as the National e-Health Contact Point with other Member States, shall ensure the continuation of cross-border healthcare and patient safety by providing cross-border electronic services.

(2) The responsibilities of the National e-Health Contact Point are as follows:

- (a) To establish the appropriate data security and data protection systems for the purposes of complying with cross-border e-services requirements and all applicable national requirements
- (b) To take all reasonable measures to ensure data security, including confidentiality of data, integrity, authenticity, availability and non-discouragement;
- (c) To implement a proper health data control route to and from Member States which will allow authorized official bodies to properly monitor established mechanisms for collection, processing, translation and transmission of data.

Record keeping

18. - (1) The Authority shall keep:

- (a) a Register of e-health record holders; and
- (b) a register of healthcare providers.

(2) The data contained in the e-health record holders Register shall be determined by a decree of the Minister, upon recommendation by the Authority.

PART III CITIZENS' ELECTRONIC HEALTH RECORD

Creation and
Contents of an e-
Health Record

19. - (1) At each point of providing health care services in any way through the use of health monitoring and health care technologies closely and remotely, the Electronic Health Record is available to allow safe diagnosis, treatment and follow-up during scheduled or non-scheduled healthcare provision.

(2) The Electronic Health Record contains:

- (a) The citizens' core set of health data; and
- (b) health data registered by the citizen himself or his legal representative.

(3) Each provider is required to enter health data in the core set of health data:

It is noted that the first input of health data in the core set of health data is made only by the personal physician of the e-health record holder or his/her authorized representative.

(4) The input of health data by the citizen in the Electronic Health Record is optional.

149 (l) 2013
82 (l) of 2015.

(5) The contents of the core set of health data shall be determined by a decree of the Minister on the recommendation of the Authority and in accordance with the provisions of Article 36 of the Implementation of Patients' Rights in the context of Cross-border Health Care Law.

(6) Health data shall include records drawn up by the provider in writing, electronically or otherwise and shall contain:

- (a) Information detailing the identity of the patient and the provider and medical information regarding the treatment received by the patient, his/her previous medical history, to the extent known, the diagnosis of his/her current medical condition and treatment provided;
- (b) other information relating to the physical or mental health or condition of the patient who can be identified by this information.

E-Health Record
Holders

20. - (1) An electronic health record holder is any citizen of the Republic who,

- (a) He/she is registered in the Register of e-health record holders;

(b) has not been excluded from registration in the Register of e-health record holders due to his or her objection to participate in it.

(2) The exclusion of a citizen from the Register of e-health record holders may be made at any time in the premises or at the offices for objection filing purposes specified by a decree of the Minister, upon recommendation by the Authority.

(3) Any person who objects to holding an e-health record, either for himself or for his/her minor children, shall send his/her objection either in writing or electronically.

(4) Where a citizen chooses, either for himself or his children, not to hold an e-health record or requests that he/she or his/her children be removed from the Bank, the Authority shall inform the citizen in writing of any consequences it may have with regard to the future provision of health services both at national and cross-border level.

(5) The Authority keeps a register of excluded citizens for the purpose of informing the Ministry of Health in case the Ministry deems it necessary to know about the protection of all citizens.

(6) The manner and regulations for the operation of the premises or offices for objection filing purposes shall be determined by the Authority's internal regulations

(7) The authenticity of the identity and statement of the citizen who does not wish to hold an e-health record is inspected by the Authority.

How to Obtain an e-Health Record

21.- (1) Every citizen of the Republic and his/her minor children are registered either at the Citizen Service Centers (CSC) or online on the Ariadni Government Gateway Portal or other certified applications to obtain their Electronic Health Record.

(2) (a) The registration of a citizen's minor children is made by the citizen himself.

(b) When a child is born in the Republic, an e-health Record is automatically created in the Single e-Health Records Bank.

(3) Where a citizen is legally or physically incapacitated and has no legal capacity, his legal representative may apply the procedure referred to in subsection (1) for the purpose of obtaining an e-health record in his place.

How to Access e-Health Records
E.U.Official
Journal L.257,
28.8.2014,
p. 73.

22. Subject to the provisions of Regulation (EU) 910/2014 of the European Parliament and of the Council of 23 October July 2014 on electronic identification and trust services for electronic transactions in the Internal Market, access to the Electronic Health Record is made via the Ariadni Government Gateway Portal and/or other certified applications.

Right of access to the e-Health Record

23.- (1) The following have a right to access the health data in the Electronic Health Record:

(a) The citizen who is the holder of the e-health record;

(b) the healthcare provider who treats the citizen and to whom he has granted authorization in accordance with the provisions of paragraph (c) of Article 25;

(c) the legal representative of the electronic health record holder to whom the citizen has granted authorization in accordance with the provisions of paragraph (c) of Article 25;

(d) the National Contact Point for e-Health;

(e) a person duly authorized by the Authority;

(i) for administrative, insurance, judicial or similar proceedings;

(ii) to verify the legitimacy of access by users.

(2) The persons authorized, in accordance with the provisions of this Article, to have access to the health data of the electronic health record shall ensure the confidentiality and privacy of the health data assigned to them for access and processing purposes and shall maintain confidentiality during their service, as well as following its termination, in accordance with the provisions of the Law providing for the Protection of Natural Persons with regard to the Processing of Personal Data and for the Free Movement of such Data and Regulation (EU) 2016/679.

(3) The persons referred to in subsection (2) shall be provided with specific access codes other than those provided to the holders of e-health records.

Rights of e-Health Record Holders

24. - (1) E-health Record Holders are entitled to:

- (a) access and receive electronic information about their health data from their Electronic Health Record or following a letter sent to the Commissioner for the Supervision of E-health Records;
- (b) information by providers regarding the health data included in the extensive set of health data maintained by the Provider's Bank;
- (c) set the authorization levels for providers by specifying the person who will be partially or totally authorized to access the Electronic Health Record from the Bank's electronic operating system by sending a letter to the Authority in accordance with the decisions issued by the Authority on the activation of the specific rights of the citizen;
- (d) lock specific health data and render this data inaccessible to the healthcare provider;
- (e) voluntarily include health data in the e-health record which are not included in the core set of health data;
- (f) correct and delete existing non-medical information that they have not registered themselves.

It is understood that the holders of the Electronic Health Records have the rights provided for in Regulation (EU) 2016/679.

(2) (a) In the event that the e-health record holder has locked his/her health data in his/her electronic record, he/she assumes full responsibility for the fact that the healthcare provider cannot take them into account when providing health services.

(b) If the provider is informed of the existence and nature of locked health data in the e-health record, he/she cannot be informed of their content without prior authorization by the citizen.

Rights and obligations of Health Service Providers

25. The healthcare provider has the following rights and obligations:

- (a) To ensure the effective, uninterrupted and automatic updating of the core data set of the citizen through its electronic connection to the Electronic Health Record;
- (b) To have the necessary infrastructure to register, identify and connect to the Electronic Health Record as well as the necessary infrastructure to process and record health data related to his/her expertise and provision of healthcare to the citizen;
- (c) To access the Electronic Health Record only if-
 - (i) he/she is authorized by the e-health record holder, and
 - (ii) his/her identity, role and access code have been confirmed;
- (d) Not to modify the health data which have been stored into the e-health record and in the event of a change in circumstances which may essentially affect the course of healthcare provision, then additional updated health data shall be stored in the record;
- (e) To ensure that the storage, processing and filing of health data in the Electronic Health Record is in accordance with the provisions of the Law providing for the Protection of Natural Persons

with regard to the Processing of Personal Data and for the Free Movement of such Data and Regulation (EU) 2016/679;

- (f) The provider and his/her employees should keep in full confidence the health data contained in the Electronic Health Record and which have been disclosed to them as a result of their employment, without prejudice to any other legitimate obligations of confidentiality.

PART IV HEALTH DATA BANKS

Establishment of a Provider Bank

- 26.** Each provider shall create a Provider Bank within a deadline specified by the Authority.

Basic functions of the Data Bank

- 27.** - (1) The following key functions are performed at the Provider Bank:

- (a) The registration, maintenance and electronic storage of the core set of health data of the citizen;
- (b) The registration, maintenance and electronic storage;
- (i) of the extensive health data set
- (ii) any other health data other than those listed in the core and extensive health data sets (optional for every citizen).

It is noted that for the health data maintained in the Provider Bank, the provider shall ensure that the security measures maintained by the Bank, as defined in Article 33 of this Law, are observed proportionately;

- (c) The processing of health data.
- (d) Keeping a backup of the health data in his/her Provider Bank:
- It is noted that any data recovery from backups is recorded so that the nature and extent of any loss of data as a result of any interruption of the Provider Bank's system and software operation can be assessed.
- (e) Making available to the citizen and his/her legal representative the health data relating to him/her.
- (f) Interoperability with other e-Health systems for the purpose of informing others about the better provision of healthcare to the citizen.

(2) The contents of the extensive set of health data referred to in sub-paragraph (i) of paragraph (b) of subsection (1) shall be determined by a decree of the Minister upon recommendation of the Authority.

(3) The provider and his/her employees should keep in full confidence the health data contained in the Provider Bank and which have been disclosed to them as a result of their employment, without prejudice to any other legitimate obligations of confidentiality.

(4) The functions referred to in this Article are the minimum set of functions performed in the electronic management system of the Provider Bank.

Establishment of a Single e-Health Records Bank

- 28.** The Authority establishes and operates the Single Electronic Health Records Bank where the Citizen's Electronic Health Record is created and stored.

It is understood that the Authority may entrust the design, development, maintenance and operation of the Single Bank to a contractor following a public tender.

General principles applied by the Single e-Health Records Bank

- 29.** - (1) The Authority shall ensure that the following general principles apply to the maintenance of the Single e-Health Records Bank:

- (a) The principle of security, which ensures the privacy, confidentiality and integrity of health data whenever that data is altered, registered or read by users.
 - (b) The principle of interconnectivity, which ensures the possibility of distributing and exchanging data at semantic level, in order to allow both the readability of the health data by users and the automated processing of data by other systems.
 - (c) The principle of range and comprehensiveness, which provides the ability to support many types of health data and support for data input in structured form, as well as in free text format.
 - (d) The principle of transfer, according to which the health data is transferable and user-friendly, irrespective of the hardware, software and national language used by each person.
 - (e) The principle of evolution, which provides the ability to support the Electronic Health Record for long periods of time, through the compatibility of processing it from previous and consecutive versions of software systems in such a way as to maintain the possibility of data recovery by the Bank over time regardless of any upgrades or changes to its software or hardware.
 - (f) The principle of availability and recoverability, which ensures that there is a uninterrupted function for providing health data to the user.
- (2) The technical specifications determining the application of the above general principles are specified and updated by instructions issued by the Authority.

Basic functions of the Single e-Health Records Bank

30. - (1) The Authority shall ensure that the following basic functions are performed in the Single e-Health Records Bank:

- (a) The creation, maintenance and electronic storage of the e-Health Record for every citizen of the Republic;
- (b) The processing the Health Data included in the e-Health Records and their conversion into anonymous databases so that they can be used by anonymous biomedical information banks that may be created:

It is understood that the export of health data from the Single e-Health Records Bank may carried out only when a citizen consents to include his or her personal data in anonymous databases;
- (c) The electronic communication and provision of health data to the authorized users of the e-Health Record; and
- (d) To ensure the interoperability of the e-Health Record with other e-Health systems.

(2) The functions referred to in subsection (1) are the minimum set of functions that the Bank may perform.

(3) The e-Health Record Bank keeps and stores data in e-Health Records within the territory of the Republic and an encrypted and updated copy of each Record is kept in a secure location at least twenty (20) kilometres from the main repositories in the territory of the Republic.

(4) The encrypted databases are kept and stored in a place authorized by the Authority outside the territory of the Republic and within the territory of the European Union.

(5) When data is retrieved from backups this retrieval is recorded in the e-Health Record so that the nature and extent of any loss of data as a result of any disruption of the system and software of the Bank can be assessed.

(6) The exchange of data for access and updating purposes takes place in accordance with international and accepted integration profiles.

Revenue from the exploitation of anonymous databases

31. Any revenue received from any conversion of health data included in the e-Health Record into anonymous databases and from the disposal of such data from anonymous databases to third parties shall be deposited with the fixed treasury of the Republic and part thereof shall be assigned to the Authority for the management and disposal for the benefit of the citizen.

Key information of each input into the e-Health Record by the Bank

32. Any access in the e-Health Record is recorded and the input contains at least the following:

- (a) Date and time of access;
- (b) the unique transaction log number;
- (c) the type of data processing;
- (d) the access code of the person having access;
- (e) the unique identification code of the data used;
- (f) the search criteria; and
- (g) any error messages for searches that result in error.

Security measures maintained by the Bank

33. - (1) In order to deal with the interception of information when transmitting the message, the tampering with the information or with the identity of the recipient and / or the sender and the changes made to or termination of the Bank's software, the Authority shall ensure that the following security measures are upheld:

- (a) The authenticity of a user's identity when exchanging data;
 - (b) the authorized user access and the prohibition of access to unauthorized persons;
 - (c) the confidentiality of health data in accordance with the provisions of the Protection of Individuals with regard to the Protection of Natural Persons with regard to the Processing of Personal Data and for the Free Movement of such Data and Regulation (EU) 2016/679;
 - (d) the availability of health data only to authorized users;
 - (e) the encryption of all health data stored in the Bank's repositories and in the back-up areas;
 - (f) ensuring the integrity of health data so that they cannot be altered;
 - (g) the ability to monitor the person and the time when that person has modified or processed the data;
 - (h) assigning responsibility for the input, access or modification of each data to each user;
 - (i) documenting the processing operations so that they can be monitored;
 - (j) keeping back-up, as laid down in Article 30.
- (2) The Authority shall ensure that,
- (a) Any change in existing data or the input of new data into the e-Health Record is clearly marked along with the date and time it has been made; and
 - (b) the date and time of the Bank's software is correct.

PART V VARIOUS PROVISIONS

Administrative penalties

34. Anyone who, personally or via an employee or by representative,

- (a) Infringes the provisions of this Law,
- (b) gains access to an e-Health Record without the consent of the citizen,

shall be subject to an administrative penalty by the Authority.

Investigation of infringements

35. (1) The Authority shall investigate, upon complaint or on its own initiative, whether any person, personally or via an employee or by representative, has committed an offense referred to in Article 34.

(2) Where the Authority, in accordance with the investigation under subsection (1), finds that there has been an infringement of any provision referred to in the above subsection, it has the power, depending on the nature, duration and gravity of the infringement, to take all or any of the following actions:

- (a) To order or recommend to the offender that, within a specified time limit, he/she should terminate the infringement and not repeat it in the future or, if the infringement has ended before the Authority's decision has been taken, to confirm the infringement by decision.
- (b) To impose an administrative fine, depending on the nature, gravity and duration of the offense, up to ten thousand euros (€ 10,000) per case.
- (c) To impose an administrative penalty of up to two hundred euros (€ 200) in the event of a continuation of the infringement for each additional case of such an infringement, depending on its gravity and / or
- (d) To impose an administrative penalty of ten thousand euros (€ 10,000) per e-Health Record.

(3) The Authority must duly justify its decision in relation to the exercise of any of the powers provided for in subsection (2).

Imposition of administrative penalties

36. (1) The administrative penalties provided for in subsection (2) of Article 35 shall be imposed on the infringer by a justified written decision of the Authority confirming the offense, after giving the offender the opportunity to make written clarifications within fifteen (15) days from the notification of that decision.

(2) The amount of the administrative penalty shall be collected by the Authority when the time limit of seventy-five (75) days from the notification of the Authority's decision to impose a monetary penalty or in case the appeal has expired before the Administrative Court, following the issuance of a non-annulment judgment.

(3) In the event of failure to pay the penalties imposed by the Authority in accordance with this Law, the Authority shall take legal action and collect the amount due as a civil debt owed to the Republic.

Issuance of Regulations

37. (1) The Council of Ministers, upon recommendation of the Authority, may issue Regulations for the better implementation of the provisions of this Law, which are submitted through the Minister to the Council of Ministers for approval.

(2) Regulations issued pursuant to the provisions of this Law shall be submitted to the House of Representatives and if, within 60 days of their submission, the House of Representatives does not amend or annul them in whole or in part, they shall immediately be published in the Official Gazette of the Republic after the expiry of the aforesaid deadline.

(3) If the House of Representatives resolves upon the amendment of the regulations in force, in whole or in part, pursuant to the provisions of this Law, the amended regulations shall be published in the Official Gazette of the Republic as amended and in force from the date of their publication.

(4) Without prejudice to the generality of subsection (1), the Regulations referred to therein shall regulate the following matters:

- (a) The structure, departments and operation of the Authority
- (b) the establishment of a Treasury for the Authority
- (c) any matter for which this Law provides for the adoption of Regulations.

Transitional provisions

38. - (1) Healthcare providers shall update the Citizen's Electronic Health Record with information that they have kept for the last three (3) years showing the history of the patient's therapies within a period of twenty-four (24) months from a date specified by the Authority.

(2) For the period until the establishment and operation of the Bank by the Authority, which expires upon notification of the Authority in the Official Gazette of the Republic, the Authority shall cooperate with the Health Insurance Organization (HIO) and the State Health Services Organisation (SHSO), so that the IT systems used can interoperate.

Entry into force
of the provisions
of this Law.

39. This Law shall enter into force on a date to be determined by notification of the Council of Ministers published in the Official Gazette of the Republic, which may set different dates of entry into force for different provisions of this Law.

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