Overview of the national laws on electronic health records in the EU Member States and their interaction with the provision of cross-border eHealth services

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Overview of the national laws on electronic health records in the EU Member States

National Report for Greece

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Executive Summary

1. Stage of development of EHRs in Greece

In 2000, the Greek government, in accordance with the European Union recommendations for the Information Society, procured an operational program for implementing the information society strategy for Greece in a coherent and integrated way. During the period 2000-2006, in the frame of the 3rd Community structural assistance programme, Greece started developing Integrated Information Health Systems for the majority of the –at that time- seventeen Regional Health Directorates. 83 out of the 132 hospitals of Greece were covered by the programme and got Integrated Information Systems through the Regional Health Directorate they belonged to. The great value of the Integrated Information Health Systems is that they allow the distributed collection of medical and clinical data as part of the work processes and efficient access to the EHR. However, as the development of the Integrated Information Health System for each Regional Health Directorate was procured separately, they resulted in different systems without interoperability among the regions.

In February 2014 Law 4238/2014 on the Primary National Health Network placed the responsibility for primary care under the auspices of the Ministry of Health. Following that law, and the transposition of the Patients' Rights Directive in Greece in December 2013, Greece has set the legislative framework for the adoption of an EHR system. Law 4238/2014 provides in Article 51(4) for the creation of Electronic Health Records for all Greek citizens. A common national sample – prototype for an Electronic Health Record will be issued via a Decision of the Minster of Health and after a proposal of the National Council of Electronic Health Governance (Εθνικό Συμβούλιο Διακυβέρνησης Ηλεκτρονικής Υγείας). The decision will specify the content, the way of creation, the identification of patients and the access to medical information, in accordance with Law 2472/1997 and Law 3471/2006.

In a first phase, the Ministry of Health is going to launch a pilot system of Patient Summaries, based on the epSOS patient summary[1] and in compliance with the Guidelines on minimum/non-exhaustive patient summary dataset for electronic exchange in accordance with the cross-border directive 2011/24/EC[2] that has been adopted by the EU eHealth Network. The aim is to present the pilot at the eHealth Forum that will take place in Athens on 12-14 May 2014. At this moment the pilot platform is being built using the CDA of epSOS. Hospitals are going to feed the platform with information on a daily basis (parallel to the maintenance and updating of their own systems). In a second phase the creation of the full EHR will follow, following extensive consultation with stakeholders.

2. Summary of legal requirements applying to EHRs

Article 51(4) of Law 4238/2014 established the creation of an electronic health record for all Greek citizens. An EHR contains a short medical history of every citizen, as part of the medical record, as well as data, predictions and information of any kind relating to the conditions and the clinical progress of a patient throughout the treatment. A number of Ministerial Decisions will specify the content, the way of creation, the identification of patients and the access to medical information, as well as application of EHRs. Such decisions have not been issued yet.

The Ministry of Health, via its designated services, is assigned as the National Authority for issues relating to Electronic Health and has the full responsibility for the coordination of actions for the realization of the national strategy for Electronic Health, in collaboration with the competent stakeholders. The private law legal person "Social Insurance eGovernance – IDIKA" (Ηλεκτρονική

[1] http://www.epsos.eu/epsos-services/patient-summary.html
[2] http://ec.europa.eu/health/ehealth/docs/guidelines_patient_summary_en.pdf

Διακυβέρνηση Κοινωνικής Ασφάλισης – ΗΔΙΚΑ)[3] has been assigned with the development of the system of patient summaries and is planning to develop the system within two years.

Since 2009 the Social Security Number (AMKA) has been established obligatorily as the employment and social security identification number of all citizens in Greece. It has been used in the ePrescription System and will be used in the EHRs.

The EHR is created by the family doctor or the medical staff of a health unit, which follows the patient. The family and other doctors are obliged to maintain and to update the EHR of patients with all information that is necessary for the monitoring, therapy and the rehabilitation of patients. The EHR data are property of the patient and are safely stored, under the responsibility of the Ministry of Health, in accordance with the Data Protection legislation.

Consent for the processing of health data has to always be given in writing. As in Greece there is currently no infrastructure for electronic signatures, electronic consent cannot be given. The processing of sensitive data is allowed after a permit of the Greek DPA only for the grounds that are mentioned in Article 7(2) of Law 2472/1997 (e.g. consent, for research and scientific purposes, protection of public health etc). The processing of sensitive personal data is also allowed when it is foreseen in a law that provides for the necessary safeguards. Patients have a right to access their health data and receive copies of their files. Medical secrecy cannot be raised when the patient wishes to get informed or receive copies.

Currently there is a legal gap in relation to medical liability for advice provided in distance. In Greece medical advice from a distance (i.e. telecare, eHealth, etc) is not reimbursable. This means that such services are not recognized as standard health services. A 2009 draft law for the organization and functioning of the Primary National Health Network[4] included under the concept of primary health care, the provision of medical advice from a distance and services with the use of advanced technologies and infrastructures, especially through special telemedicine system and open communication line (Art. 1(2)(h) of the 2009 draft law). Such services were not included in the list of services of Primary Health Care listed in Art. 1(5) Law 4238/2014. Moreover if a doctor does not register information in the patient file (e.g. about an allergy), they do not have any liability if something goes wrong (neither civil, nor criminal). There is no legal obligation for the doctor to consult the medical information that is in the ePrescription system.

The system of ePrescriptions in Greece is built in such as way to allow for the inclusion of relevant information in the EHR. The ePrescription system allows the entry of diseases in the system using ICD10 and the use of DRGs in order to facilitate and control the reimbursement of health-related expenses. The authentication of health professionals to the EHR system will be done based on the system that already exists in the ePrescription system. Doctors have to be certified to the ePrescription system and are given access to the system via a username and password.

3. Good practices

The Social Security Number (AMKA) has been established as the employment and social security identification number of all citizens in Greece. It has been used in the ePrescription System and will be used in the EHRs. The use of the Social Security Number (AMKA) in the existing Integrated Information Systems for the Regional Health Directorates facilitates the linking of patient information.

[3] www.idika.gr

[4] Draft law for the organization and functioning of the general Primary National Health Network (Σχέδιο νόμου για την οργάνωση και λειτουργία του γενικού συστήματος πρωτοβάθμιας φροντίδας υγείας), available on the website of the Greek Ministry of Health at: http://www.moh.gov.gr/articles/newspaper/nomothesia-kanonismoi/194-isxyoysa-nomothesia?fdl=317 (only in Greek).

The Greek DPA dealt with the issue of security related obligations in relation to electronic medical records of employees and specified as a minimum the specifications of the online application that is used by the occupational health doctor during the processing of the medical file of the patient. The main points relate to the encryption of the sensitive data of the employees, the strict access limited only to the occupational health doctor and their assistants that are subject to the obligation of professional secrecy or relevant codes of conduct, the secure identification and authentication mechanisms of the users, the security in the systems development and the network that hosts the application, the application of log files, the existence of policy for the creation of security back-ups, the secure destruction of personal data, the physical measures for the security of the computer systems and finally the information of the employees for the processing of their personal data and the way to exercise their right of access[5]. These recommendations of the Greek DPA with regard to the medical records of employees can be used as a good practice for the legislator in relation to EHRs.

The use of ICD10 codification and DRGs, already used in the ePrescription system, is very important for the development of the EHR system.

Currently there is no law that provides for compliance to specific standards in relation to healthcare systems. However, in practice compliance with the HL7 standard (Health Level Seven) for exchanging information between health applications is required. HL7 Hellas is promoting a Memorandum of Understanding for the compliance to the HL7 standard.

4. Legal barriers

Law 3235/2004 on the primary health care already established the legal framework for the development of EHR system in Greece. However, the law conditioned its application on Ministerial decisions that were never adopted. The application of Law 4238/2014 also depends on several Ministerial Decisions, which leads to uncertainty.

The patient summary that has been developed by the epSOS project will be used in the first pilot phase of the EHR, while in the full EHR more information will be added, including lab tests and medication summary. However, as there is currently no legal obligation for physicians and hospitals to have an electronic record of their patients, parts of the patients' records are kept at this moment in legacy systems and in non-digital form (paper or film) which is often scanned and indexed.

For the creation of the EHR system, consultation with all interested stakeholders will take place, which will require time. Crucial will be the issue of what data are going to be included in EHRs, as consensus seems to be difficult with the medical community.

The Greek system of ePrescription does not rely on patients consent and does not offer for the possibility to opt-out. Each doctor in order to get access to the file of a specific patient has to indicate that the consent of the patient has been obtained, but no verification of this action is required. Such a choice also for EHR system may not be in line with the respect of fundamental rights of patients, especially their right to privacy and data protection. As in Greece there is currently no infrastructure for electronic signatures, electronic consent cannot be given.

The system of accessing patient information has to be optimised for the development of the EHR system. Currently any physician that is certified with the ePrescription system and knows the Social Security Number (AMKA) of a person can get access to the medical prescriptions and examinations of the patient by ticking a check box saying that the consent of the patient has been acquired. However,

[5] Permission for processing of the Greek DPA (Protocol number: ΓΝ/ΕΞ/6301/03-10-2012), as cited in the 2012 Annual report, available only in Greek at: http://www.dpa.gr/pls/portal/docs/PAGE/APDPX/ANNUALREPORTS/AR2012/ARXH%20PROSTASIAS%20APOLOGISMOS%202012_%20WEBUSE.PDF.

no actual consent verification mechanism exists.

The ePrescription system covers only medicines that can be prescribed and reimbursed and are imported by pharmaceutical companies. It leaves out medicines that are offered by the Institute of Pharmaceutical Research and Technology, medicines that belong to the negative list (medicine provided with medical prescription but not reimbursed by EOPYY), orthopedic devices, etc. Moreover a number of medical treatments are not prescribed in ePrescription, leaving out for example logotherapy. As the ePrescrption system is going to be used as the basis for the creation of the EHR system, these limitations need to be taken into account and addressed from the beginning.

The authentication of health professionals to the EHR system will be done based on the system that already exists in the ePrescription system. Doctors have to be certified to the ePrescription system and are given access to the system via a username and password. Additional safeguards may be required given the sensitivity of data included in EHRs.

The Greek ePrescription system is using the ICD10 codification for diseases in primary care. ICPC-2[6] classifies patient data and clinical activity in the domains of General/Family Practice and primary care and should be used together with ICD10, taking into account the frequency distribution of problems seen in these domains. There is currently no codification for medical devices, but there are committees that are trying to resolve this issue.

Currently there is a legal gap in relation to medical liability for advice provided in distance. In Greece medical advice from a distance (i.e. telecare, eHealth, etc) is not reimbursable. This means that such services are not recognized as standard health services. There is no legal obligation for the doctor to consult the medical information that is in the ePrescription system, which can be justified due to the scope of the ePrescription system. However this needs to be revisited if the ePrescription system will be linked to EHRs. Moreover, the national ePrescription system has included some medical protocols, i.e. medical guidelines for medical treatments. However a broader problem (not only relevant for Greece) is that there are not many standardised medical protocols and guidelines.

Interoperability between the existing Integrated Information Systems of the Greek Regional Health Directorates could be achieved through the use of middleware. However it is difficult to see how the relevant costs could be covered at this moment.

The legal framework for public procurement needs to be simplified. Currently even for the maintenance of systems (i.e. EHR systems) there is a need for public procurement.

The creation of EHR system is expensive and financial issues are a main barrier in Greece at this moment.

[6] http://www.who.int/classifications/icd/adaptations/icpc2/en/

Contents

List of abbreviations

AMKA	Social Security Number
Art.	Article
CDA	Clinical Document Architecture
CME	Code of Medical Ethics
DPA	Data Protection Authority
DRG	Diagnosis Related Group
EHR	Electronic Health Record
EOPYY	National Organization for the Provision of Healthcare Services (Εθνικός Οργανισμός Παροχής Υπηρεσιών Υγείας)
ESY	National Health System (Εθνικό Σύστημα Υγείας)
HCR	Health Care Region
IDIKA	Social Insurance eGovernance (Ηλεκτρονική Διακυβέρνηση Κοινωνικής Ασφάλισης – ΗΔΙΚΑ)
GG	Government Gazette
NA	Not Available

1. General context

1.1. EHR systems in place

In 2000, the Greek government, in accordance with the European Union recommendations for the Information Society, procured an operational program for implementing the information society strategy for Greece in a coherent and integrated way. During the period 2000-2006, in the frame of the 3rd Community structural assistance programme, Greece started developing Integrated Information Health Systems for the majority of the –at that time- seventeen Regional Health Directorates. 83 out of the 132 hospitals of Greece were covered by the programme and got Integrated Information Systems through the Regional Health Directorate they belonged to. The great value of the Integrated Information Health Systems is that they allow the distributed collection of medical and clinical data as part of the work processes and efficient access to the EHR. However, as the development of the Integrated Information Health System for each Regional Health Directorate was procured separately, they resulted in different systems without interoperability among the regions. Moreover, a local Patient Register Number was created for each patient that could be used only in the system of each specific Directorate, making difficult the exchange of information about a patient. The Integrated Information Systems allowed hospitals to maintain the medical records of their patients in an electronic format. However, the information that is contained in the records is not harmonised and homogeneous. In 2008 Greece adopted a law regulating a Social Security Number (AMKA) for all Greek citizens, a number that is today broadly used in healthcare and on which the ePrescription system was based, which became operational in Greece in 2009. The use of AMKA is now used in all healthcare related transactions and is part of all records of hospitals in addition to the local patient register number.

A core hindrance in the development of EHR has been the fact that until recently the Healthcare system in Greece was fragmented, as it was partly a responsibility of the Ministry of Health and partly a responsibility of the Ministry of Labour and Social Security. In February 2014 a law reforming the primary care in Greece was adopted (see next subsection) placing the responsibility for primary care under the auspices of the Ministry of Health. Following that law, and the transposition of the Patients' Rights Directive in Greece in December 2013, Greece has set the legislative framework for the adoption of an EHR system.

In a first phase, the Ministry of Health is going to launch a pilot system of Patient Summaries, based on the epSOS patient summary[7] and in compliance with the Guidelines on minimum/non-exhaustive patient summary dataset for electronic exchange in accordance with the cross-border directive 2011/24/EC[8] that has been adopted by the EU eHealth Network. The aim is to present the pilot at the eHealth Forum that will take place in Athens on 12-14 May 2014. At this moment the pilot platform is being built using the CDA of epSOS. Hospitals are going to feed the platform with information on a daily basis (parallel to the maintenance and updating of their own systems). In a second phase the creation of the full EHR will follow, following extensive consultation with stakeholders.

Health information about patients that will feed the EHR can be collected from existing sources: First, the hospital administrative information through the hospital discharge, where information about DGRs, diagnosis, medical examinations, medication etc is mentioned. Second, the ePrescription system, where information about diagnosis and prescription of medication and medical examinations is kept. Currently all Greek hospitals are obliged to send to the National Organization for the Provision of Healthcare Services (Εθνικός Οργανισμός Παροχής Υπηρεσιών Υγείας – EOPYY) for financial control purposes administrative information about ambulance services, as well as the hospital

[7] http://www.epsos.eu/epsos-services/patient-summary.html
[8] http://ec.europa.eu/health/ehealth/docs/guidelines_patient_summary_en.pdf

admission and discharge of patients. All hospitals send this information in a standardized way to EOPYY. The patient summary can collect information from this platform.

The patient summary that has been developed by the epSOS project is a subset of the information that can facilitate the exchange of information about patients. In the EHR more information will be added, including lab tests and medication summary. Parts of the patients' records are kept at this moment in legacy systems and in non-digital form (paper or film) which is often scanned and indexed. This makes it difficult to create a homogeneous EHR.

The Ministry of Health (at that time Ministry of Health and Social Solidarity) developed the ESY.net system that is a business intelligence system which, among others, collects aggregated information about patients. In the relevant web application of ESY.net, authorized personnel of Hospitals and Health Care Centres is required each month to upload the necessary operational and financial data, data that is verified by its overseeing Health Care Region (HCR) administration.

1.2. Institutional setting

Until recently the Healthcare system in Greece was fragmented, as it was partly a responsibility of the Ministry of Health and partly a responsibility of the Ministry of Labour and Social Security. In February 2014 a law reforming the primary care in Greece was adopted (see next subsection) placing the responsibility for primary care under the auspices of the Ministry of Health. Following that law, and the transposition of the Patients' Rights Directive in Greece in December 2013, Greece has set the legislative framework for the adoption of an EHR system.

More concretely in relation to EHR, **the Ministry of Health**, via its designated services, is assigned as the National Authority for issues relating to Electronic Health and has the full responsibility of the coordination of actions for the realization of the national strategy for Electronic Health, in collaboration with the competent stakeholders (Art. 13(1) Law 4213/2013).

In Greece the creation of the EHR system will commence with the deployment of patient summaries. The private law legal person "Social Insurance eGovernance – **IDIKA**" (Ηλεκτρονική Διακυβέρνηση Κοινωνικής Ασφάλισης – ΗΔΙΚΑ)[9] has been assigned with the development of the system of patient summaries and is planning to develop the system within two years. As a patient summary is not the full health record of the patient, there will be additional information added at a later stage in order to create full EHRs following extensive consultation with stakeholders. IDIKA's mission is, among others, to facilitate the Ministry of Health in the realization of its goals and to provide consultation services to insurance organizations. IDIKA has developed the Integrated Information Systems of 15 major hospitals in Greece and has in-house expertise on the ePrescription system. At this moment it functions as the de-facto leader in the development of the patient summary system and the future EHR system in Greece, something that is expected to be confirmed by ministerial decision soon.

The Directorate of International Insurance Relations of the National Organization for the Provision of Healthcare Services (Εθνικός Οργανισμός Παροχής Υπηρεσιών Υγείας – ΕΟΠΥΥ) is specified as the National Contact Point (NCP) for cross-border healthcare and is assisted in its function by the Health Directorates of Greece (Art 6(1) Law 4213/2013.

A number of public bodies and Ministries are involved in either the development of EHR solutions and systems or in the specification of guidelines, regarding e.g. interoperability (Ministry of Administrative Reform and e-Governance), standardization (e.g. Hellenic Organization for Standardization - ELOT), etc.

The **Greek Data Protection Authority** is an independent public authority with the task to supervise

[9] www.idika.gr

the implementation of the Greek data protection legislation and all other regulations pertaining to the protection of individuals from the processing of personal data as well as to the exercise of the duties assigned to it each time. The processing of sensitive data is allowed after a permit of the Greek DPA only for the grounds that are mentioned in Article 7(2) of Law 2472/1997 (e.g. for research and scientific purposes, protection of public health etc), so the role of the DPA is very important in relation to the processing of health data.

1.3. Legal setting and future legal development

The discussion for the development of a system of electronic medical records started in Greece more than a decade ago and in 2004 the required legal framework for the creation of electronic medical records was adopted. However, the actual application and execution of the law was dependent on the adoption of a Decision of the Minister of Health and Welfare (Ministry of Health today), which was never issued. More concretely, Art. 9(5) of **Law 3235/2004[10] on the primary health care** foresaw the creation of electronic medical insurers' records (ηλεκτρονικός ιατρικός φάκελος ασφαλισμένου). The law conditioned the specification of the necessary infrastructure and the type and content of the electronic medical insurers' records upon the adoption of a Decision of the Minister of Health and Welfare, which was never issued. More specifically Art. 9 of law 3235/2004 stipulated that an electronic medical record would be established for every Greek citizen and would consist of medical information about them created by any entity providing healthcare services. Every Health Centre would get a full infrastructure for the maintenance and updating of elements of the electronic medical file and for the access to information that would be maintained in other entities providing healthcare services. Similar infrastructure should be available at the offices or private family or personal doctors, that are certified with health insurance organisations. The family and private doctor would have to inform the electronic medical files of insurers with information produced by them. Paragraph 4 of Art. 9 would also introduce the electronic health card for citizens for the facilitation of access to health services and for ensuring the direct provision of necessary information and data relating to the health of the card holder. As mentioned above Art. 9(5) stated that a Decision of the Minister of Health and Welfare (as the Ministry of Health was called in 2004) would specify the necessary infrastructure, the type and content of the electronic medical insurers' records, the security requirements of the system, the basic information to be contained in the electronic health card, as well as any other necessary information. Such a Ministerial Decision was never adopted and therefore the relevant provisions for **eHealth of Law 3235/2004 were never applied.**.

In October 2011, the Ministry of Health sent **guidelines for the realisation of an Electronic Health Record system based on clinical documents**[11] to all Hospitals of the National Health System (ESY). Although these guidelines were only partially realised, they can be a good starting point for the creation of an EHR system.

Recently Greece succeeded in passing a law for the reform of the National Health System via **Law 4238/2014[12] on the Primary National Health Network**. The law is restructuring the primary healthcare system in Greece, establishing Health Centres that will encompass the existing Health Centres and the polyclinics. According to Article 3 of Law 4238/2014 "The Statute (Οργανισμός) of Health Centres will specify […] the content and the storage process of the patients' personal file". These Statutes will be issued upon common Ministerial Decisions of the Ministers of Health, Administrative Reform & e-Governance and Finance, following a recommendation of the relevant Regional Health Administration (Δ.Υ.Πε.) and the Central Board of Regional Health (ΚΕ.ΣΥ.Πε). This law provided in Article 51(4) for the creation of Electronic Health Records for all Greek citizens.

[10] Law 3235/2004 on Primary Health Care, G.G. A'53/18.02.2004 (Πρωτοβάθμια Φροντίδα Υγείας), available in Greek at http://tinyurl.com/kkuff9f.
[11] http://www.moh.gov.gr/articles/hlektronikes-efarmoges-e-s-y/831-hlektronikos-fakelos-asthenwn
[12] Law 4238/2014 on the Primary National Health Network, GG A' 38/17.02.2014 (Πρωτοβάθμιο Εθνικό Δίκτυο Υγείας (Π.Ε.Δ.Υ.)).

This will eventually lead to the creation of a unique Electronic Health Record for each citizen, covering both primary and secondary health care. The Electronic Health Record will be created by the family doctor or by medical staff of the health unit where the patient is being monitored. A common national sample – prototype for an Electronic Health Record will be issued via a Decision of the Minster of Health and after a proposal of the National Council of Electronic Health Governance (Εθνικό Συμβούλιο Διακυβέρνησης Ηλεκτρονικής Υγείας). The decision will specify the content, the way of creation, the identification of patients and the access to medical information, in accordance with Law 2472/1997[13] and Law 3471/2006[14]. According to Article 5(3)(e) of Law 4238/2014 on family doctors "a Ministerial Decision of the Minister of Health will specify the details of the application of electronic health records".

Law 4213/2013[15] transposed the Patients' Rights Directive. According to Article 3(13) a medical record is defined as "all the documents that contain data, predictions and information of any kind relating to the conditions and the clinical progress of a patient throughout the treatment". This definition will be crucial in the realization of the EHR system in Greece, together with the aforementioned provisions of Law 4238/2014 and the expected Ministerial Decisions.

Although not directly referring to EHRs, the **Code of Medical Ethics (CME)**[16] [Law 3418/2005] will be very important for the development of the EHR system in Greece, as several of its provision will probably be extended to EHRs, at least in the first phase of its development. The CME specifies that doctors are obliged to maintain medical records, in electronic form or other, which contains data that are inextricably or causally linked to the disease or the health of their patients, respecting the legislation on the protection of personal data (Art.14(1) CME). The medical records have to contain the name and last name, the father's name, the gender, the age, the occupation, the address of the patient, the dates of visits, as well as any other important information that is related to the provision of care to the patient, such as for example and depending on the specialisation of the doctor, the health related complaints, the primary and secondary diagnosis or the followed treatment (Art.14(2) CME). The clinics and hospitals keep in their medical records the results of clinical and paraclinical examinations, as well (Art.14(3) CME).

Issues relating to data protection are regulated via **Law 2472/1997**[17] **on the processing of personal**

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[13] Law 2472/1997 on the Protection of Individuals with regard to the Processing of Personal Data (*Νόμος 2472/1997 «Προστασία του ατόμου από την επεξεργασία δεδομένων προσωπικού χαρακτήρα»*), Government Gazette, A' 50/10.04.1997, available online in Greek at http://tinyurl.com/oec7m2b. An unofficial translation in English of the consolidated version of the Data Protection Law, including the latest amendments of Law 3783/2009 is available on the website of the Greek DPA at http://www.dpa.gr/pls/portal/docs/PAGE/APDPX/ENGLISH_INDEX/LEGAL%20FRAMEWORK/LAW%202472-97-APRIL010-EN%20_2_.PDF

[14] Law 3471/2006 "Protection of personal data and privacy in the electronic communications sector and amendment of law 2472/1997" GG A'133/28.06.2006, available online at http://tinyurl.com/kdxdkyp (*Νόμος υπ' αριθ. 3471/2006 «Προστασία δεδομένων προσωπικού χαρακτήρα και της ιδιωτικής ζωής στον τομέα των ηλεκτρονικών επικοινωνιών και τροποποίηση του ν. 2472/1997»)*. An unofficial translation in English is available online on the website of the Hellenic DPA: http://www.dpa.gr/pls/portal/docs/PAGE/APDPX/ENGLISH_INDEX/LEGAL%20FRAMEWORK/LAW%203471-2006-EN.PDF.

[15] Law 4213/2013 "adaptation f the national legislation to the provisions of Directive 2011/24/EC of the European Parliament and the of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (L88/45/4.4.2011) and other provisions", G.G. A'261/09.12.2013 (Προσαρμογή της εθνικής νομοθεσίας στις διατάξεις της οδηγίας 2011/24/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 9ης Μαρτίου 2011 περί εφαρμογής των δικαιωμάτων των ασθενών στο πλαίσιο της διασυνοριακής υγειονομικής περίθαλψης (L88/45/4.4.2011) και άλλες διατάξεις), available in Greek at http://tinyurl.com/o2fe8p4.

[16] Law 3418/2005 Code of Medical Ethics, GG A. 287/28.11.2005 (Κώδικας Ιατρικής Δεοντολογίας), available in Greek at http://tinyurl.com/ng298s6.

[17] Law 2472/1997 on the Protection of Individuals with regard to the Processing of Personal Data (*Νόμος 2472/1997 «Προστασία του ατόμου από την επεξεργασία δεδομένων προσωπικού χαρακτήρα»*), Government Gazette, A' 50/10.04.1997, available online in Greek at http://tinyurl.com/oec7m2b. An unofficial translation in English of the consolidated version of the Data Protection Law, including the latest amendments of Law 3783/2009 is available on the website of the Greek DPA at http://www.dpa.gr/pls/portal/docs/PAGE/APDPX/ENGLISH_INDEX/LEGAL%20FRAMEWORK/LAW%202472-97-APRIL010-EN%20_2_.PDF

data and **Law 3471/2006**[18] **on personal data and privacy in the electronic communications sector** (whenever applicable). Health data are sensitive data (Art. 2b Law 2472/1997). When the processing relates to health matters it should be carried out by a health professional subject to the obligation of professional secrecy or relevant codes of conduct, provided that such processing is necessary for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services. The **Greek DPA** may issue an opinion on EHRs, if so requested by the competent legislative bodies.

In accordance with **Law 3850/2010**[19]**,** the **medical record of employees** can be stored with in paper or electronic format.

[18] Law 3471/2006 "Protection of personal data and privacy in the electronic communications sector and amendment of law 2472/1997" GG A'133/28.06.2006, available online at http://tinyurl.com/kdxdkyp (*Νόμος υπ' αριθ. 3471/2006 «Προστασία δεδομένων προσωπικού χαρακτήρα και της ιδιωτικής ζωής στον τομέα των ηλεκτρονικών επικοινωνιών και τροποποίηση του ν. 2472/1997»)*. An unofficial translation in English is available online on the website of the Hellenic DPA: http://www.dpa.gr/pls/portal/docs/PAGE/APDPX/ENGLISH_INDEX/LEGAL%20FRAMEWORK/LAW%203471-2006-EN.PDF.

[19] Law 3850/2010 "Ratification of the Code of laws on the health and safety of employees, GG 84 A'/02.06.2010 (Κύρωση του Κώδικα νόμων για την υγεία και την ασφάλεια των εργαζομένων), available only in Greek at http://www.eoppep.gr/teens/images/thematikoi_katalogoi/N_3850_2010.pdf.

2. Legal requirements applying to EHRs in Greece

2.1. Health data to be included in EHRs

2.1.1. Main findings

Article 51(4) of Law 4238/2014 establishes the creation of an electronic health record for all Greek citizens. Art. 51(4)(2) specifies that an EHR contains a short medical history of every citizen, as part of the medical record, as well as the information mentioned in Art. 3(13) of Law 4213/2013, which transposed the Patient's Rights Directive into Greece. According to Article 3(13) of Law 4213/2013 a medical file is defined as "all the documents that contain data, predictions and information of any kind relating to the conditions and the clinical progress of a patient throughout the treatment". A Ministerial Decision of the Minister of Health will specify the details of the application of EHR. **This decision has not been issued yet**.

The entry of diseases in the system of **ePrescription** using the International Statistical Classification of Diseases and Related Health Problems 10 (**ICD10**) became obligatory gradually from the 21st of June 2013. The ePrescription system introduced the use of DRGs (Diagnosis Related Groups) in order to facilitate and control the reimbursement of health-related expenses. In September 2011 the correlation between DRGs (Κλειστά Ενοποιημένα Νοσήλεια – KEN) and ICD10 was completed. Moreover the ePrescription system already includes a small number of therapeutic protocols, which can be expanded for the needs of the EHR system.

The Social Security Number (AMKA) has been established as the employment and social security identification number of all citizens in Greece. It has been used in the ePrescription System and will be used in the EHRs.

2.1.2. Table on health data

Questions	Legal reference	Detailed description
Are there specific rules on the content of EHRs? (or regional provisions, agreements, plans?)	Art. 51(4)(2) of Law 4238/2014	Art. 51(4)(2) of Law 4238/2014 specifies that an EHR contains a short medical history of every citizen, as part of the medical record, as well as the information mentioned in Art. 3(13) of Law 4213/2013, which transposed the Patient's Rights Directive into Greece. It should be highlighted that the content of the EHR with regard to the a short medical history of citizens should be common at national level and obligatory (Art. 51(4)(3). A **Ministerial Decision** of the Minister of Health will specify the details of the application of EHR.
	Art. 3(13) of Law 4213/2013	Pursuant to Art. 3(13) of Law 4213/2013, a medical file is defined as "all the documents that contain data, predictions and information of any kind relating to the conditions and the clinical progress of a patient throughout the treatment".
	Art. 14 Code of Medical Ethics/Law 3418/2005 (for doctors' medical records, that can also be kept electronically)	The Code of Medical Ethics specifies that doctors are obliged to maintain medical records, in electronic form or other, which contains data that are inextricably or causally linked to the disease or the health of their patients, respecting the legislation on the protection of personal data (Art.14(1) CME). The medical records have to contain the name and last name, the father's name, the gender, the age, the occupation, the address of the patient, the dates of visits, as well as any other important information that is related to the provision of care to the patient, such as for example and depending on the specialisation of the doctor, the health related complaints, the primary and secondary diagnosis or the followed treatment (Art.14(2) CME). The clinics and hospitals keep in their medical records the results of clinical and paraclinical examinations, as well (Art.14(3) CME).
Are these data restricted to purely medical information (e.g. physical or mental health, well-being)?		Please see above.
Is there a definition of EHR or patient's summary provided in the national legislation?	Art. 51(4)(2) of Law 4238/2014	An EHR contains a short medical history of every citizen, as part of the medical record, as well as the information mentioned in Art. 3(13) of Law 4213/2013, i.e. all the documents that contain data, predictions and information of any kind relating to the conditions and the clinical progress of a patient throughout the treatment. A **Ministerial Decision** of the Minister of Health will specify the

Questions	Legal reference	Detailed description
	Article 3(13) of Law 4213/2013	details of the application of EHR. Pursuant to Art. 3(13) of Law 4213/2013, a **medical file** is defined as "all the documents that contain data, predictions and information of any kind relating to the conditions and the clinical progress of a patient throughout the treatment". Patient summary is defined in line with the definition of the epSOS project: "The epSOS Patient Summary is a standardized set of basic medical data that includes the most important clinical facts required to ensure safe and secure healthcare. […]The epSOS Patient Summary contains the following data: - General information about the patient (e.g. name, birth date, gender). - A medical summary consisting of the most important clinical patient data (e.g. allergies, current medical problems, medical implants, or major surgical procedures during the last six months). - A list of the current medication including all prescribed medicines that the patient is currently taking. Information about the Patient Summary itself e.g. when and by whom the Patient Summary was generated or updated. This data is also used for protocol and security purposes."[20].
Are there any requirements on the content of EHRs (e.g. detailed requirements on specific health data or general reference to health data)?	Art. 51(4)(2) of Law 4238/2014	Art. 51(4)(2) of Law 4238/2014 specifies that an EHR contains a short medical history of every citizen, as part of the medical record, as well as the information mentioned in Art. 3(13) of Law 4213/2013, i.e. all the documents that contain data, predictions and information of any kind relating to the conditions and the clinical progress of a patient throughout the treatment. A **Ministerial Decision** of the Minister of Health will specify the details of the application of EHR.
Are there any specific rules on the use of a common terminology or coding system to identify diseases, disorders, symptoms and others?	Art. 3(3) Law 3892/2010 on ePrescription	Pursuant to Art. 3(3) Law 3892/2010 on ePrescription, the doctors are allowed to use international classification standards for the diagnosis of a disease. The use of International Statistical Classification of Diseases and Related Health Problems 10th revision (**ICD10**) became obligatory in 2013. According to the Decision of the Ministry of Health, General Directorate of

[20] http://www.epsos.eu/epsos-services/patient-summary.html

Questions	Legal reference	Detailed description
	Decision of the Ministry of Health, General Directorate of design and development of health services, 26.06.2013[21]; and relevant press release National Organization for the Provision of Healthcare Services (Εθνικός Οργανισμός Παροχής Υπηρεσιών Υγείας – ΕΟΠΥΥ) of 21.06.2013[22] Art. 10(2)(d) Law 4213/2013	design and development of health services (26.06.2013), the entry of the disease in the system of **ePrescription** using the International Statistical Classification of Diseases and Related Health Problems 10 (**ICD10**) became obligatory gradually from the 21st of June 2013. The statistical classification in Greek, as well as a manual for its use is available on the website of the Ministry of Health at http://www.moh.gov.gr/articles/health/domes-kai-draseis-gia-thn-ygeia/kwdikopoihseis/86-statistikh-taksinomhsh-noswn-kai-synafwn-problhmatwn-ygeias For the remuneration by the social security authorities of prescriptions that are issued in Greece and are executed in another Member-State, the prescription has to clearly mention (among other things such as the AMKA of the patient and the time of execution) **the ICD10 diagnosis or another recognized International System of Disease Codification**. The ePrescription system introduced the use of DRGs (Diagnosis Related Groups) in order to facilitate and control the reimbursement of health-related expenses. In September 2011 the correlation between DRGs (Κλειστά Ενοποιημένα Νοσήλεια – KEN) and ICD10 was completed. Moreover the ePrescription system already includes a small number of therapeutic protocols, which can be expanded for the needs of the EHR system. There is currently codification for medicines by the National Organization for Medicines (Εθνικός Οργανισμός Φαρμάκων – ΕΟΦ) and codification of medical procedures by the National Organization for the Provision of Healthcare Services (Εθνικός Οργανισμός Παροχής Υπηρεσιών Υγείας – ΕΟΠΥΥ). The Common Ministerial Decision of 29.02.2012 on the full and obligatory use

[21] http://tinyurl.com/ltatjjt (available only in Greek).
[22] http://www.e-syntagografisi.gr/files/20130621-EOP%CE%A5Y-ICD10.pdf

Questions	Legal reference	Detailed description
	Common Ministerial Decision of 29.02.2012 on the full and obligatory use of the therapeutic prescription protocols[23]	of the therapeutic prescription protocols decision made obligatory the full use of the 160 **therapeutic protocols** that have been approved by the Central Council of Health (ΚΕ.Σ.Υ.) and are made public on the website of the National Drug Organization (Εθνικός Οργανισμός Φαρμάκων – ΕΟΦ)[24].
Are EHRs divided into separate categories of health data with different levels of confidentiality (e.g. data related to blood type is less confidential than data related to sexual diseases)?		*Not decided yet*
Are there any specific rules on identification of patients in EHRs?		*Not decided yet*
Is there is a specific identification number for eHealth purposes?	Art. 453 Law 3655/2008	Art. 453 Law 3655/2008[25] introduced the Social Security Number (AMKA) that was established obligatorily as the employment and social security identification number of all citizens in Greece. The use of the Social Security Number (AMKA) in the existing Integrated Information Systems for the Regional Health Directorates facilitates the linking of patient information. This number has already been used for the ePrescription system and, according to the Secretary General of the Ministry of Health will be used as the patient identifier in the EHR system.

[23] Κ.Υ.Α. Υ4α/οικ.Γ.Υ.155/29.02.12, «καθολική και υποχρεωτική εφαρμογή των θεραπευτικών πρωτοκόλλων συνταγογράφησης», GG 545 Β'/01.03.2012, available online at http://tinyurl.com/ndz2pte (only in Greek).

[24] http://www.eof.gr/web/guest/protocols (only in Greek).

[25] Law 3655/2008 "Administrative and organisational reform of the Social Security System and other insurance-related provisions, GG. A' 58/03.04.2008 ("Διοικητική και οργανωτική μεταρρύθμιση τού Συστήματος Κοινωνικής Ασφάλισης και λοιπές ασφαλιστικές διατάξεις), only available in Greek.

2.2. Requirements on the institution hosting EHRs data

2.2.1. Main findings

The Ministry of Health, via its designated services, is assigned as the National Authority for issues relating to Electronic Health and has the full responsibility for the coordination of actions for the realization of the national strategy for Electronic Health, in collaboration with the competent stakeholders. The private law legal person "Social Insurance eGovernance – IDIKA" (Ηλεκτρονική Διακυβέρνηση Κοινωνικής Ασφάλισης – ΗΔΙΚΑ)[26] has been assigned with the development of the system of patient summaries and is planning to develop the system within two years.

[26] www.idika.gr

2.2.2. Table on requirements on the institutions hosting EHRs data

Questions	Legal reference	Detailed description
Are there specific national rules about the hosting and management of data from EHRs?	Art. 13(1) Law 4213/2013	The Ministry of Health, via its designated services, is assigned as the National Authority for issues relating to Electronic Health and has the full responsibility for the coordination of actions for the realization of the national strategy for Electronic Health, in collaboration with the competent stakeholders.
Is there a need for a specific authorisation or licence to host and process data from EHRs?		*Not decided yet*
Are there specific obligations that apply to institutions hosting and managing data from EHRs (e.g. capacity, qualified staff, or technical tools/policies on security confidentiality)?	Article 3(6) of Law 4238/2014	*Not decided yet. However it may be interesting to note the following:* The Greek DPA dealt with the issue of security related obligations in relation to electronic medical records of employees (in accordance with **Law 3850/2010)**. The Greek DPA specified as a minimum the specifications of the online application that is used by the occupational health doctor during the processing of the medical file of the patient. The main points relate to the **encryption of the sensitive** data of the employees, the strict **access** limited only to occupational health doctor and their assistants that are subject to the obligation of professional secrecy or relevant codes of conduct, the secure identification and authentication mechanisms of the users, the security in the systems development and the network that hosts the application, the application of log files, the existence of policy for the creation of security back-ups, the secure destruction of personal data, the physical measures for the security of the computer systems and finally the information of the employees for the processing of their personal data and the way to exercise their right of access[27]. "The Statute (Οργανισμός) of Health Centers will specify […] the content and the **storage process** of the patients' personal file". These Statutes will be issued upon common Ministerial Decisions of the Ministers of Health, Administrative Reform & e-Governance and Finance, following a recommendation of the relevant Regional Health Administration (Δ.Υ.Πε.) and the Central Board of Regional

[27] Permission for processing of the Greek DPA (Protocol number: ΓΝ/ΕΞ/6301/03-10-2012), as cited in the 2012 Annual report, available only in Greek at http://www.dpa.gr/pls/portal/docs/PAGE/APDPX/ANNUALREPORTS/AR2012/ARXH%20PROSTASIAS%20APOLOGISMOS%202012_%20WEBUSE.PDF.

Questions	Legal reference	Detailed description
		Health (ΚΕ.ΣΥ.Πε) (Art. 3(6) of Law 4238/2014).
In particular, is there any obligation to have the information included in EHRs encrypted?		*Not decided yet.* However, in relation to electronic medical records the Greek DPA required that sensitive data are **encrypted** (see cell above)
Are there any specific auditing requirements for institutions hosting and processing EHRs?		*Not decided yet*

2.3. Patient consent

2.3.1. Main findings

As there is no official system of EHRs in Greece, there are no specific requirements about patient consent in EHR. The Greek system of ePrescription does not rely on patients consent and does not offer for the possibility to opt-out[28]. Each doctor in order to get access to the file of a specific patient has to indicate that the consent of the patient has been obtained, but no verification of this action is required. It remains to be seen what choice the Greek legislator will take with regard to the provision of patient consent to the creation of and/or access to data stored in their EHRs.

Consent for the processing of health data has to always be given in writing. Article 7(2)(a) of the Greek Data Protection Law provides that "The data subject has given his/her written consent, unless such consent has been extracted in a manner contrary to the law or bonos mores or if law provides that any consent given may not lift the relevant prohibition". **As in Greece there is currently no infrastructure for electronic signatures, electronic consent cannot be given.** Processing of health data can also be allowed when carried out by a Public Authority and is necessary for the purposes of a) national security, b) criminal or correctional policy and pertains to the detection of offences, criminal convictions or security measures, c) protection of public health or d) the exercise of public control on fiscal or social services (Art. 7(2)(e) Law 2472/1997)[29]. **This provision allows for the processing of health data for the exercise of control on social benefits or for the control of expenses in health**.

According to the Code of Medical Ethics, the doctor is not allowed to the execution of any medical act without the consent of the patient (Art. 12(1)). Valid consent has to be provided after full, clear and understandable information in accordance with Article 11 CME on the obligation to inform and the patient has to have the ability to consent. Article 12(2) CME specified the conditions for acquiring consent when the patient is not able to provide consent, while 12(3) is dedicated to the exceptional cases when consent is not required.

At this moment the entities that can have access to the heath data of patients are specified in the consent forms that patients have provided. For example such consent may allow access to insurance companies in order to examine whether the requirements for insurance are fulfilled. If the patient is not able to provide consent, then the specific provisions of the Code of Medical Ethics will apply.

[28] Law 3892/2010 on "Electronic registration and execution of prescriptions and referral medical examinations", GG A' 189/04.11.2010 (Ηλεκτρονική καταχώριση και εκτέλεση ιατρικών συνταγώνη και παραπεμπτικών ιατρικών εξετάσεων).
[29] Law 2472/1997. Point (e) was replaced as above with par. 2 of article 34 of Law 2915/2001 (Official Gazette 109A/2001). Sub-point (cc) was replaced as above and point (dd) was added with par. 4 of article 26 of Law 3156/2003 (Official Gazette 157A/2003).

2.3.2. Table on patient consent

Questions	Legal reference	Detailed description
Are there specific national rules on consent from the patient to set-up EHRs?		*Not decided yet*
Is a materialised consent needed?		*Not decided yet. However the following may be interesting:* The Greek system of ePrescription does not rely on patients consent and does not even offer for the possibility to opt-out[30]. Each doctor in order to get access to the file of a specific patient has to indicate that the consent of the patient has been obtained, but no verification of this action is required. It remains to be seen what choice the Greek legislator will take with regard to the provision of patient consent to the creation of and/or access to data stored in their EHRs.
Are there requirements to inform the patient about the purpose of EHRs and the consequences of the consent or withholding consent to create EHRs?		*Not decided yet*
Are there specific national rules on consent from the patient to share data?		*Not decided yet*
Are there any opt-in/opt-out rules for patient consent with regard to processing of EHRs?		*Not decided yet*
Are there any opt-in/opt-out rules for patient consent with regard to sharing of EHRs?		*Not decided yet*
Are there requirements to inform the patient about the purpose of EHRs and the consequences of consent or withholding consent on the sharing of EHRs?		*Not decided yet*
Can the patient consent to his/her EHRs being accessed by a health practitioner		*Not decided yet*

[30] Law 3892/2010 on "Electronic registration and execution of prescriptions and referral medical examinations", GG A' 189/04.11.2010 (Ηλεκτρονική καταχώριση και εκτέλεση ιατρικών συνταγών και παραπεμπτικών ιατρικών εξετάσεων).

Questions	Legal reference	Detailed description
or health institution outside of the Member State (cross-border situations)?		
Are there specific rules on patient consent to share data on a cross-border situation?		*Not decided yet*

2.4. Creation, access to and update of EHRs

2.4.1. Main findings

The EHR is created by the family doctor or the medical staff of a health unit, which follows the patient. The family and other doctors are obliged to maintain and to update the EHR of patients with all information that is necessary for the monitoring, therapy and the rehabilitation of patients. A Ministerial Decision of the Minister of Health will specify the details of the application of electronic health records. The EHR data are property of the patient and are safely stored, under the responsibility of the Ministry of Health, in accordance with the Data Protection legislation.

A patient has a right to access their health data, in accordance with Art. 12 of law 2472/1997, on the protection of personal data, as well as in accordance with Art. 14(8) of Law 3418/2005, which states that the patient has the right to access medical records and receive copies of their files. This means that the medical secrecy cannot be raised when the patient wishes to get informed or receive copies. According to Article 14(10) of the Code of Medical Ethics, the patient has a right to access to the national or international files/records where his/her personal data has been added.

2.4.2. Table on creation, access to and update of EHRs

Questions	Legal reference	Detailed description
Are there any specific national rules regarding who can create and where can EHRs be created?	Article 5(3)(e) of Law 4238/2014 Article 51(4)(4) of Law 4238/2014	The family doctors are offering a bunch of health services including "the responsibility for the creation and retention of the personal electronic health record for every citizen that is registered in their catalogues, ensuring the continuity and the coordination of care, as well as its efficiency. A Ministerial Decision of the Minister of Health will specify the details of the application of electronic health records". The EHR is created by the family doctor or the medical staff of a health unit, which follows the patient. The family and other doctors are obliged to maintain and to update the EHR of patients with all information that is necessary for the monitoring, therapy and the rehabilitation of patients. The EHR data are property of the patient and are safely stored, under the responsibility of the Ministry of Health, in accordance with the Data Protection legislation.
Are there specific national rules on access and update to EHRs?	Art. 7(2)(e) Law 2472/1997	Ministerial Decision of the Minister of Health will specify the access to EHR Processing of health data can also be allowed when carried out by a Public Authority and is necessary for the purposes of a) national security, b) criminal or correctional policy and pertains to the detection of offences, criminal convictions or security measures, c) protection of public health or d) the exercise of public control on fiscal or social services. This provision allows for the processing of health data for the exercise of **control on social benefits** or for the **control of expenses in health**.
Are there different categories of access for different health professionals?		*Not decided yet. However the following may be useful:* Law 3235/2004[31] on the primary health care specified who would have **access** to the information of the electronic medical record and the electronic health card. Although the Ministerial Decision that would specify the necessary information for the creation of the electronic medical records and the issuing of the electronic health cards was never adopted, it may be interesting to note

[31] Law 3235/2004 on Primary Health Care, G.G. A'53/18.02.2004 (Πρωτοβάθμια Φροντίδα Υγείας).

Questions	Legal reference	Detailed description
		on how the Greek legislator had decide to regulate the issue of access to the data in that context. According to Art. 10 Law 3235/2004, access to the information of the electronic medical records and the electronic health cards would be allowed to (a) the patient to full information, (b) the family and personal doctor to the full information, with the exception of the information that the patients refuses to provide access to, (c) the substantive competent healthcare providers of the healthcare unit to the full information about the citizen to whom they provide this service. The access to the information of the electronic medical records and the electronic health cards of minors (below 18) and people under judicial support I offered by authorisation of the legal guardians, as specified in the Civil Code.
Are patients entitled to access their EHRs?		*Not decided yet. However it may be interesting to note that:* In principle the patient should be able to have access to all their data. However, an issue that still needs to be discussed with the associations of medical professionals in Greece is the possibility of graduated access to health data by patients, for instance for cases when the patient is in a terminal stage.
Can patient have access to all of EHR content?	Art. 12 of law 2472/1997 Art. 14(8) of Law 3418/2005 Article 14(10) of the Code of Medical Ethics	*Not decided yet.* However, generally, a patient has a right to access their health data. This means that the medical secrecy cannot be raised when the patient wishes to get informed or receive copies. The patient has the right to access medical records and receive copies of their files. This means that the medical secrecy cannot be raised when the patient wishes to get informed or receive copies. The patient has a right to access to the national or international files/records where his/her personal data has been added
Can patient download all or some of EHR content?		*Not decided yet.*
Can patient update their record, modify and erase EHR content?		*Not decided yet.*
Do different types of health		*Not decided yet. maybe interesting to note:*

Questions	Legal reference	Detailed description
professionals have the same rights to update EHRs?		The authentication of health professionals to the EHR system will be done based on the system that already exists in the ePrescription system. Doctors have to be certified to the ePrescription system and are given access to the system via a username and password.
Are there explicit occupational prohibitions? (e.g. insurance companies/occupational physicians…)		*Not decided yet.*
Are there exceptions to the access requirements (e.g. in case of emergency)?		*Not decided yet.*
Are there any specific rules on identification and authentication for health professionals? *Or are they aggregated?*		*Not decided yet.*
Does the patient have the right to know who has accessed to his/her EHRs?		*Not decided yet.*
Is there an obligation on health professionals to update EHRs?		*Not decided yet.*
Are there any provisions for accessing data on 'behalf of' and for request for second opinion?		*Not decided yet.*
Is there in place an identification code system for cross-border healthcare purpose?		*Not decided yet.*
Are there any measures that consider access to EHRs from health professionals in another Member State?		*Not decided yet.*

2.5. Liability

2.5.1. Main findings

There is currently no legal obligation for physicians to maintain a full medical record of patients.

Law 3235/2004[32] on the primary health care specified who would have access to the information of the electronic medical record and the electronic health card. Although the Ministerial Decision that would specify the necessary information for the creation of the electronic medical records and the issuing of the electronic health cards was never adopted, it is interesting to note on how the Greek legislator had decide to regulate the issue of liabilities with regard to electronic medical records. Art. 11 established **criminal sanctions** specifying that anybody that in any way and without having any right to gain access to the content of an electronic medical record or alters or destroys data or information that are entered in the record or announces to third parties elements or part of their content, is punished with imprisonment of at least 2 years, unless this act is punished more heavily upon another provision.

Currently there is a legal gap in relation to medical liability for advice provided in distance. In Greece medical advice from a distance (i.e. telecare, eHealth, etc) is not reimbursable. This means that such services are not recognized as standard health services.

Moreover if a doctor does not register information in the patient file (e.g. about an allergy), they do not have any liability is something goes wrong (neither civil, nor criminal). There is no legal obligation for the doctor to consult the medical information that is in the ePrescription system.

[32] Law 3235/2004 on Primary Health Care, G.G. A'53/18.02.2004 (Πρωτοβάθμια Φροντίδα Υγείας).

2.5.2. Table on liability

Questions	Legal reference	Detailed description
Does the national legislation set specific medical liability requirements related to the use of EHRs?		*Since the system of EHRs has not been fully implemented yet, there are no specific provisions on liabilities. However it may be interesting to note the following:* Law 3235/2004[33] on the primary health care specified who would have access to the information of the electronic medical record and the electronic health card. Although the Ministerial Decision that would specify the necessary information for the creation of the electronic medical records and the issuing of the electronic health cards was never adopted, it may be interesting on how the Greek legislator had decide to regulate the issue of liabilities with regard to electronic medical records. Art. 11 established **criminal sanctions** specifying that anybody that in any way and without having any right to gain access to the content of an electronic medical record or alters or destroys data or information that are entered in the record or announces to third parties elements or part of their content, is punished with imprisonment of at least 2 years, unless this act is punished more heavily upon another provision.
Can patients be held liable for erasing key medical information in EHRs?	Art. 21 Law 2472/1997	Erasure of key medical information can raise liability issues according to the data protection legislation. Administrative sanctions: According to Art. 21(1) the Greek DPA may impose the following administrative sanctions for breach of the data protection legislation: a) a warning with an order for the violation to cease within a specified time limit. b) a fine amounting between three hundred thousand Drachmas (GRD 300,000) and fifty million Drachmas (GRD 50,000,000). c) a temporary revocation of the permit. d) a definitive revocation of the permit. e) the destruction of the file or a ban of the processing and the destruction, return or locking of the relevant data

[33] Law 3235/2004 on Primary Health Care, G.G. A'53/18.02.2004 (Πρωτοβάθμια Φροντίδα Υγείας).

Questions	Legal reference	Detailed description
		Art. 21(2) clarifies that such sanctions shall be commensurate to the gravity of the violation impeached. The administrative sanctions under c, d, and e shall be imposed in case of a particularly serious or repeated violation. A fine may be imposed in conjunction with the sanctions provided for under c, d and e.
	Art. 22 of Law 2472/1997 on penal sanctions	According to Art. 22(4) of Law 2472/1997 Anyone who unlawfully interferes in any way whatsoever with a personal data file or takes notice of such data or extracts, alters, affects in a harmful manner, destroys, processes, transfers, discloses, makes accessible to unauthorised persons or permits such persons to take notice of such data or anyone who exploits such data in any way whatsoever, will be punished by imprisonment and a fine and, regarding sensitive data, by imprisonment for a period of at least one (1) year and a fine amounting between one million Drachmas (GRD 1,000,000) and ten million Drachmas (GRD 10,000,000), unless otherwise subject to more serious sanctions. According to Article 22(6) the person that erases key medical information (health data) purporting to gain unlawful benefit on his/her behalf or on behalf of another person or to cause harm to a third party, then s/he shall be punished with confinement in a penitentiary for a period of up to ten (10) years and a fine amounting between two million Drachmas (GRD 2,000,000) and ten million Drachmas (GRD 10,000,000).
	Art. 23 of Law 2472/1997 on civil liability	If the erasure causes material damage, then whoever erased the data shall be liable for damages in full. If the same causes non pecuniary damage, s/he shall be liable for compensation. Liability subsists even when said person or entity should have known that such damage could be brought about (Art. 23(1) Law 2472/1997). Art. 23(2) specifies that the compensation payable according to article 932 of the Civil Code for non pecuniary damage caused in breach of Law 2472/1997 is set at the amount of at least two million Drachmas (GRD 2,000,000), unless the plaintiff claims a lesser amount or the said breach was due to negligence. Such compensation shall be awarded irrespective of the claim for damages.
Can physicians be held liable because of input errors?		If this can be considered as alteration of a file of personal data, then the sanctions mentioned above can also apply.
Can physicians be held liable because they have erased data from the EHRs?		To the extent that the erased data were personal data, then the sanctions mentioned above can apply.

Questions	Legal reference	Detailed description
Are hosting institutions liable in case of defect of their security/software systems?	Art.10 2472/1997 on security	Article 10(3) law 2472/1997 stipulates that "the Controller must implement appropriate organisational and technical measures to secure data and protect them against accidental or unlawful destruction, accidental loss, alteration, unauthorised disclosure or access as well as any other form of unlawful processing. Such measures must ensure a level of security appropriate to the risks presented by processing and the nature of the data subject to processing". In case of breach of security the aforementioned sanction can also be applied, depending on the circumstances.
Are there measures in place to limit the liability risks for health professionals (e.g guidelines, awareness-raising)?		NA
Are there liability rules related to breach of access to EHRs (e.g. privacy breach)?		NA
Is there an obligation on health professionals to access EHRs prior to take a decision involving the patient?		NA
Are there liability rules related to the misuse of secondary use of health data?	See Art. 21, 22 and 23 Law 2472/1997	See above.

2.6. Secondary uses and archiving durations

2.6.1. Main findings

The processing of sensitive data is allowed **after a permit** of the Greek DPA only for the **grounds that are mentioned in Article 7(2) of Law 2472/1997** (e.g. for research and scientific purposes, protection of public health etc).

In addition, the Greek DPA found, in the context of a decision on the 2011 population census, that the processing of sensitive personal data for **statistical purposes** is not prohibited when it is foreseen in a law that provides for the necessary safeguards (reasoning deriving according to the Greek DPA from art. 8(4) of Directive 1995/46/EC in combination with recital 34).[34] For such cases, no permit is required.

The obligation for storage of medical records is specified in Article 14(4) of the Code of Medical Ethics as follows: private practices and other primary care units of the private sector, for 10 (ten) years from the last visit of the patient; in any other case for 20 (twenty) years from the last visit of the patient.

[34] 2011 Annual Report of the Greek DPA, p. 48, available only in Greek at http://www.dpa.gr/pls/portal/docs/PAGE/APDPX/ANNUALREPORTS/AR2011/ARXH_PROSTASIAS_2011.PDF.

2.6.2. Table on secondary uses and archiving durations

Questions	Legal reference	Detailed description
Are there specific national rules on the archiving durations of EHRs?		*No specific legislation of EHR exists. However,* The obligation for storage of medical records is specified in Article 14(4) of the Code of Medical Ethics as follows: private practices and other primary care units of the private sector, for 10 (ten) years from the last visit of the patient; in any other case for 20 (twenty) years from the last visit of the patient.
Are there different archiving rules for different providers and institutions?		NA
Is there an obligation to destroy data at the end of the archiving duration or in case of closure of the EHR?		NA
Are there any other rules about the use of data at the end of the archiving duration or in case of closure of the EHR?		NA
Can health data be used for secondary purpose (e.g. epidemiological studies, national statistics...)?	*Article 7(2) Law 2472/1997 & 2011 Annual Report Greek DPA*	The processing of sensitive data is allowed **after a permit** of the Greek DPA only for the **grounds that are mentioned in Article 7(2) of Law 2472/1997** (e.g. for research and scientific purposes, protection of public health etc). In addition, the Greek DPA found, in the context of a decision on the 2011 population census, that the processing of sensitive personal data for **statistical purposes** is not prohibited when it is foreseen in a law that provides for the necessary safeguards (reasoning deriving according to the Greek DPA from art. 8(4) of Directive 1995/46/EC in combination with recital 34).[35] For such cases, no permit is required. *The following may be useful:* Law 3235/2004 on the primary health care specified who would have access to the information of the electronic medical record and the electronic health card. Although the Ministerial Decision that would specify the necessary information for the creation of the electronic medical records and the issuing of the electronic

[35] 2011 Annual Report of the Greek DPA, p. 48, available only in Greek at http://www.dpa.gr/pls/portal/docs/PAGE/APDPX/ANNUALREPORTS/AR2011/ARXH_PROSTASIAS_2011.PDF.

Questions	Legal reference	Detailed description
		health cards was never adopted, it may be interesting to note on how the Greek legislator had decide to regulate the issue of **secondary use** of the data. According to Art. 10(3) for the carrying out of epidemiological, medical, financial, statistical and other relevant analyses and for the evaluation of services offered to citizens, the use of data from the electronic medical records is allowed after the consent of the citizen or without it, as long as their identity is not made public.
Are there health data that cannot be used for secondary use?		No. However, their processing has to take place under specific conditions (see next cell).
Are there specific rules for the secondary use of health data (e.g. no name mentioned, certain health data that cannot be used)?		The Greek DPA has consistently published opinions on the use of health data for secondary purposes. The Greek DPA has ruled in a case relating to health data that, after the period for which data are processed for specific purposes, data can be stored for **statistical purposes** only when anonymous or collective statistics.[36] The Greek DPA permitted third parties to access hospital patient records for scientific research purposes (in the context of carrying out scientific research, master or doctoral theses) under the following conditions: a) the access has to take place in the premises of the hospital, b) the researcher will extract only the data that are according to his scientific judgment necessary for the completion of the specific scientific goal and c) the anonymisation of the patient data will be done by the scientist him/herself and at the time of accessing the data, in the sense that it is not allowed to write down and link information that identifies the researched patients (e.g. name/last name) with the sensitive data that are collected and relate to him/her.[37]
Does the law say who will be entitled to use and access this data?		This is decided on a case by case basis by the Greek DPA or is specified in the relevant law (see cell above).
Is there an opt-in/opt-out system for the		NA

[36] Protocol number ΓΝ/ΕΞ/505-2/14-06-2012, as sited in the 2012 Annual Report of the Greek DPA, p. 94, available only in Greek at http://www.dpa.gr/pls/portal/docs/PAGE/APDPX/ANNUALREPORTS/AR2012/ARXH%20PROSTASIAS%20APOLOGISMOS%202012_%20WEBUSE.PDF.

[37] See for example Greek DPA decision 157/2011 and a number of 2012 decisions: 49/2012, 50/2012, 53/2012, 64/2012, 65/2012, 86/2012, 87/2012, 159/2012, 164/2012 and 178/2012, available in Greek at www.dpa.gr.

Questions	Legal reference	Detailed description
secondary uses of eHealth data included in EHRs?		

2.7. Requirements on interoperability of EHRs

2.7.1. Main findings

Currently there is no law that provides for compliance to specific standards in relation to healthcare systems. However, in practice compliance with the HL7 standard (Health Level Seven) for exchanging information between health applications is required. This was already a prerequisite in the development of the Integrated Information Systems of the Greek Regional Health Directorates and has been included in a Circular of the Committee for Health Public Procurement for the procurement of health systems. The issue of **interoperability** is a main barrier, as there is no commonly accepted standard at international level; however as a best practice the HL7 standard is used, which allows interoperability between foreign systems as well. Interoperability between the existing Integrated Information Systems of the Greek Regional Health Directorates could be achieved through the use of middleware. However this requires investment and it is difficult to see how the relevant costs could be covered at this moment. HL7 Hellas is promoting a Memorandum of Understanding for the compliance to the HL7 standard.

No public interfaces exist for ePrescription. The Integrated Information Health Systems of National Health System hospitals must be linked to the ePresciption system and have mechanisms for the exchange of data in place. Standardisation of content is necessary for the creation of an EHR system and agreement for a common model at national level to facilitate EHR information exchange at a national level and to support personalised delivery of healthcare.

2.7.2. Table on interoperability of data requirements

Questions	Legal reference	Detailed description
Are there obligations in the law to develop interoperability of EHRs?		NA
Are there any specific rules/standards on the interoperability of EHR?		NA
Does the law consider or refer to interoperability issues with other Member States systems?		NA

2.8. Links between EHRs and ePrescriptions

2.8.1. Main findings

The system of ePrescriptions in Greece is built in such as way to allow for the inclusion of relevant information in the EHR. 98% of the Greek doctors are certified with the ePrescription system. Currently the national ePrescription system has included some medical protocols, i.e. medical guidelines for medical treatments.

All medicines, blood tests, radiology and medical examinations for uninsured patients as well as unemployed that are not any more insured are not visible in the ePrescription system. The same with preventive medical examinations that are carried out by non-governmental organizations. These are limitations of the current ePrescription system that need to be taken into account when the ePrescription system is linked with the EHR system.

2.8.2. Table on the links between EHRs and ePrescriptions

- ***Infrastructure***

Questions	Legal reference	Detailed description
Is the existence of EHR a precondition for the ePrescription system?	Law 3892/2010	No. The ePrescription system was put in place via Law 3892/2010 and has been a reality in Greece before the realisation of the EHR system.
Can an ePrescription be prescribed to a patient who does not have an EHR?	Law 3892/2010	As there is no EHR system in Greece, any patient with Social Security Number (AMKA), who is insured with EOPYY can get an ePrescription.

- ***Access***

Questions	Legal reference	Detailed description
Do the doctors, hospital doctors, dentists and pharmacists writing the ePrescription have access to the EHR of the patient?		NA
Can those health professionals write ePrescriptions without having access to EHRs?		NA

2.9. International cooperation

Greece is participating in the European Innovation Partnership on Active and Healthy Ageing[38], which uses as a basis a basic Electronic Health Record.

FORTH is currently participating in the e-SENS project (Electronic Simple European Networked Services). e-SENS is a new large-scale project that embodies the idea of European Digital Market development through innovative ICT solutions. The project will consolidate, improve, and extend technical solutions to foster electronic interaction with public administrations across the EU.[39] One of the areas that the e-SENS project is focusing on is eHealth and is based on the released products from the epSOS project (as well as the projects PEPPOL, SPOCS, STORK and e-CODEX).

FORTH has participated in the EHR-IMPLEMENT project (National policies for EHR Implementation in the European area: social and organisational issues)[40]. Aim of the EHR-IMPLEMENT is to collect, analyze and compare broad scale electronic health record (EHR) implementations among European countries and provide best practice, policy and strategic recommendations to facilitate EHR implementation initiatives throughout Europe.[41]

FORTH has also participated in the EHR-QTN project.[42] The EHR-QTN project is a Thematic Network project that prepares the health community across Europe for systematic and comparable quality assurance and certification of e-Health products, more specifically of the Electronic Healthcare Record systems.

The EuroRec has developed two EuroRec EHR Quality Seals, Level 1 and Level 2. The Level 2 EuroRec EHR Quality Seal encompasses 50 functional quality criteria, addressing various essential functions of the EHR: access and security management of the systems, basic functional requirements on medication, clinical data management and the generic statements focusing on trustworthiness of the clinical data already included in the Level 1 Seal.[43] The Center for eHealth Applications and Services (ICS-FORTH) has been certified and awarded the EuroRec EHR Quality Seal for its software product line ICS-M (Nursing and Medical Applications) which was tested and proved to be compliant with all 50 Seal-2 criteria. ICS-M has been installed and is operating in more than 20 hospitals in Greece.

[38] http://ec.europa.eu/research/innovation-union/index_en.cfm?section=active-healthy-ageing
[39] http://www.esens.eu/home/
[40] http://www.eurorec.org/RD/ehr_implement.cfm
[41] http://www.eurorec.org/RD/ehr_implement.cfm
[42] http://www.eurorec.org/RD/EHR-Q-TN.cfm
[43] http://www.eurorec.org/services/seal/

3. Legal barriers and good practices for the deployment of EHRs in Greece and for their cross-border transfer in the EU.

Legal Barriers

Law 3235/2004 on the primary health care already established the legal framework of the development of EHR system in Greece. However, its application depended on Ministerial decisions that were never adopted. The application of Law 4238/2014 also depends on several Ministerial Decisions, which leads to uncertainty.

The patient summary that has been developed by the epSOS project will be used in the first pilot phase of the EHR, while in the full EHR more information will be added, including lab tests and medication summary. However, as there is currently no legal obligation for physicians and hospitals to have an electronic record of their patients, parts of the patients' records are kept at this moment in legacy systems and in non-digital form (paper or film) which is often scanned and indexed.

For the creation of the EHR system, consultation with all interested stakeholders will take place, which will require time. Crucial will be the issue of what data are going to be included in EHRs, as consensus seems to be difficult with the medical community.

The Greek system of ePrescription does not rely on patients consent and does not offer for the possibility to opt-out. Each doctor in order to get access to the file of a specific patient has to indicate that the consent of the patient has been obtained, but no verification of this action is required. Such a choice also for EHR system may not be in line with the respect of fundamental rights of patients, especially their right to privacy and data protection. As in Greece there is currently no infrastructure for electronic signatures, electronic consent cannot be given.

The system of accessing patient information has to be optimised in the development of the EHR system. Currently any physician that is certified with the ePrescription system and knows the Social Security Number (AMKA) of a person can get access to the medical prescriptions and examinations of the patient by ticking a check box saying that the consent of the patient has been acquired. However, no actual consent verification mechanism exists.

Doctors should follow the national medical protocols of the National Drug Organization (Εθνικός Οργανισμός Φαρμάκων – ΕΟΦ) in a number of medical diseases. However, private doctors that are not paid by EOPYY, although they are registered with the ePrescription system, they cannot prescribe medicines recommended by national medical protocols that are offered by the Institute of Pharmaceutical Research and Technology (Ινστιτούτο Φαρμακευτικής Έρευνας & Τεχνολογίας – ΙΦΕΤ), which is a publicly owned company, subsidiary of the National Drug Organization (NDO). In short, the ePrescription system covers only medicines that can be prescribed and reimbursed and are imported by pharmaceutical companies. It leaves out medicines that are offered by the Institute of Pharmaceutical Research and Technology, medicines that belong to the negative list (medicine provided with medical prescription but not reimbursed by EOPYY), orthopedic devices, etc. Moreover a number of medical treatments are not prescribed in ePrescription, leaving out for example logotherapy. As the ePrescrption system is going to be used as the basis for the creation of the EHR system, these limitations need to be taken into account and addressed from the beginning.

The authentication of health professionals to the EHR system will be done based on the system that already exists in the ePrescription system. Doctors have to be certified to the ePrescription system and are given access to the system via a username and password. Additional safeguards may be

required given the sensitivity of data included in EHRs.

The Greek ePrescription system is using the ICD10 codification for diseases in primary care. ICPC-2[44] classifies patient data and clinical activity in the domains of General/Family Practice and primary care and should be used together with ICD10, taking into account the frequency distribution of problems seen in these domains. There is currently no codification for medical devices, but there are committees that are trying to resolve this issue.

Currently there is a legal gap in relation to medical liability for advice provided in distance. In Greece medical advice from a distance (i.e. telecare, eHealth, etc) is not reimbursable. This means that such services are not recognized as standard health services. There is no legal obligation for the doctor to consult the medical information that is in the ePrescription system, which can be justified due to the scope of the ePrescription system. However this needs to be revisited if the ePrescirption system will be linked to EHRs. Moreover, the national ePrescription system has included some medical protocols, i.e. medical guidelines for medical treatments. However a broader problem (not only relevant for Greece) is that there are not many standardised medical protocols and guidelines.

Interoperability between the existing Integrated Information Systems of the Greek Regional Health Directorates could be achieved through the use of middleware. However it is difficult to see how the relevant costs could be covered at this moment.

The legal framework for public procurement needs to be simplified. Currently even for the maintenance of systems (i.e. EHR systems) there is a need for public procurement.

The creation of EHR system is expensive and financial issues are a main barrier in Greece at this moment.

Good practices

The Social Security Number (AMKA) has been established as the employment and social security identification number of all citizens in Greece.It has been used in the ePrescription System and will be used in the EHRs. The use of the Social Security Number (AMKA) in the existing Integrated Information Systems for the Regional Health Directorates facilitates the linking of patient information.

The Greek DPA dealt with the issue of security related obligations in relation to electronic medical records of employees and specified as a minimum the specifications of the online application that is used by the occupational health doctor during the processing of the medical file of the patient. The main points relate to the encryption of the sensitive data of the employees, the strict access limited only to occupational health doctor and their assistants that are subject to the obligation of professional secrecy or relevant codes of conduct, the secure identification and authentication mechanisms of the users, the security in the systems development and the network that hosts the application, the application of log files, the existence of policy for the creation of security back-ups, the secure destruction of personal data, the physical measures for the security of the computer systems and finally the information of the employees for the processing of their personal data and the way to exercise their right of access[45]. These specifications can be used as a good practice for the legislator in relation to EHRs.

[44] http://www.who.int/classifications/icd/adaptations/icpc2/en/

[45] Permission for processing of the Greek DPA (Protocol number: ΓΝ/ΕΞ/6301/03-10-2012), as cited in the 2012 Annual report, available only in Greek at http://www.dpa.gr/pls/portal/docs/PAGE/APDPX/ANNUALREPORTS/AR2012/ARXH%20PROSTASIAS%20APOLOGISMOS%202012_%20WEBUSE.PDF.

The use of ICD10 codification and DRGs, already used in the ePrescription system, is very important for the development of the EHR system.

Currently there is no law that provides for compliance to specific standards in relation to healthcare systems. However, in practice compliance with the HL7 standard (Health Level Seven) for exchanging information between health applications is required. HL7 Hellas is promoting a Memorandum of Understanding for the compliance to the HL7 standard.