

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

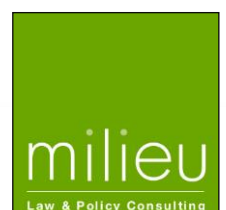
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Overview of the national laws on electronic health records in the EU Member States

National Report for ROMANIA



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Executive Summary

1. Stage of development of EHRs in Romania

Health Electronic Record (*Dosarul Electronic de Sanatate*) (EHR) is the Romanian national electronic health record which is currently being developed in order to be implemented in Romania the second half of 2014.

EHR is developed and will be implemented in Romania by the National Health Insurance House – CNAS¹.

Although the EHR project was subject of discussions a few years ago, after two rounds of tenders carried out in 2011 and 2012, CNAS started developing the EHR system only in 2013. The EHRs will be implemented initially as a pilot program, and afterwards it will be implemented throughout the country.

2. Summary of legal requirements applying to EHRs

There is no specific legislation with regard to the EHRs in Romania. There are references to EHRs in the Health Law. However the Health Law does not cover health data to be included in the EHRs, requirements on the institution hosting EHRs data, patient consent, creation, access to and update of the EHRs, liability, secondary uses and archiving durations, requirements on interoperability of the EHRs.

The recent amendment of the Health Law of February 21, 2014, introduced the obligation for certain entities to provide conditions for medical information mobility in electronic format, by using the patient's electronic health record. Thus, the Health Law provides that offices of family doctors and other specialized doctors, diagnosis and treatment centres, medical centres, labs, as well as other public and private medical units, and public and private medical units with beds must use EHRs.

CNAS advised that prior to the initiation of the pilot phase of EHRs, CNAS and the Health Ministry will issue a joint order with regard to EHR on issues such as data to be included in the EHRs, requirements regarding the institution hosting EHRs data, patient consent, creation, access to and update of the EHRs, liability, secondary uses and archiving durations, requirements on interoperability of the EHRs.

Pursuant to available information the future legal text regulating EHRs will provide limited rights to the patient regarding the management of his/her EHR, and restricted rights regarding the possibility to amend or to delete information. CNAS advised that the EHRs will be set up without the prior consent of the patients².

CNAS intends to implement an opt-out procedure for patients who do not want to have an EHR. However such procedure is cumbersome to the patient, as he/she must go before the notary to issue an authentic Opt-Out Declaration. However, even if such Declaration is issued by the patient, the doctor will still include in the EHR a minimum amount of information entitled Relevant Health Data (*Date Medicale Relevante*).

The doctors will be able to access the EHRs based on their extended electronic signature, and on the health insurance card of the patient. Patients will have the right to access their EHR based on a

¹ According to the recently amended Health Law, CNAS organizes and manages the Health Insurance Information Platform which consists of: the integrated health information system, the national system of the social health insurance card, the national system of electronic prescription and the system of the patient's electronic health record.

² Interview with the Vice-President of CNAS of February 24, 2014

matrices provided by the physician, which will be used to register and obtain a user name and a password to access the EHR. Hard copy records will be used in parallel with EHRs, for several years.

3. Good practices

ePrescriptions have been implemented in Romania since the second half of 2012. ePrescriptions have been functioning across Romania, being one of the eHealth components which were successfully implemented.

In addition to the ePrescription program, CNAS intends to issue during the year of 2014, and distribute the Health Insurance Cards. Once the EHRs will be implemented and the Health Insurance Cards will be distributed to Romanian citizens, the doctors will be able to access the EHRs based on the Health Insurance Card provided by the patient.

The current data protection legislation, which reflects the EU directive, regulates the collection and processing of health-related data, and the transfer of such data to a foreign country. The procedure provided by Data Protection Law for the filing by the data controller of the Notification regarding the collection and processing of health-related data is not complex. A standard template of the Notification must be filled in with the relevant data and filed with the DPA.

The recent amendment of the Health Law, of February 21, 2014 introduced the obligation of certain entities to provide conditions for medical information mobility in electronic format, by using the patient's electronic health record. Thus, the Health Law provides the obligation of hospitals and family doctors to use the EHRs - this will help the development of EHRs in Romania.

4. Legal barriers

At present, the most important barrier in the development of EHRs in Romania is the lack of specific legislation in respect thereof.

As mentioned throughout this Report, CNAS, which is the authority in charge with the development and implementation of the EHRs, confirmed that the EHR system is currently in technical tests. The development of the EHRs was carried out by CNAS without a pre-existing specific legal framework. As advised by the representative of CNAS, prior to the implementation of the pilot of the EHRs system, CNAS and the Health Ministry will issue jointly an Order which will provide the specific rules for the EHRs. Thus it appears that the specific rules on EHRs will be tailored after the finalization of the actual system.

Note that some of the stakeholders³ are opposing the CNAS initiative, while others⁴ expressed their concerns regarding the rules planned on consent for the creation and access to EHRs that would limit patient rights to control the use of their health data.

³ The President of the Romanian College of Physicians mentioned in the interview of February 21, 2014 that the Romanian College of Physicians opposes to the implementation of EHRs as long as it will not have the confirmation that safety measures were taken in order to make sure that the personal and medical data of the patients are secured, and cannot be disclosed for purposes other than medical ones.

⁴ Romanian National Society of Family Medicine during the interview of February 18, 2014, National Supervisory Authority for Personal Data Processing - DPA during the interview of February 24, 2014

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List of abbreviations

CNAS	National Health Insurance House (<i>Casa Nationala de Asigurari de Sanatate</i>)
Data Protection Law	Law No. 677/2001 on the Protection of Individuals with Regard to the Processing of Personal Data and the Free Movement of Such Data, (<i>Legea pentru protectia persoanelor cu privire la prelucrarea datelor cu caracter personal si libera circulatie a acestor date</i>)
DPA	The National Supervisory Authority For Personal Data Processing (<i>Autoritatea Nationala de Supraveghere a Prelucrarii Datelor cu Caracter Personal</i>)
EHRs	Electronic Health Records, Patient's Electronic File or Medical Electronic File (<i>Dosarul Electronic al Pacientului sau Dosar electronic Medical</i>)
Health Law	Law no. 95 of 2006 of Health Reform (<i>Legea nr. 95 din 2006 privind Reforma in Domeniul Sanatatii</i>)
SIUI	Integrated Health Information System (<i>Sistemul Informatic Unic Integrat</i>)

1. General context

1.1. EHR systems in place

Health Electronic Record (*Dosarul Electronic de Sanatate*) (EHR) is the Romanian national electronic health record which is currently being developed in order to be implemented in Romania the second half of 2014.

References to the existence and use of the EHRs are included in the Health Law. Although the Health Law imposes the obligation of offices of the family doctors and of other specialized doctors, diagnosis and treatment centres, medical centres, labs, as well as other public and private medical units, and public and private medical units with beds to use EHRs, it does not include specific rules regarding the implementation of the EHRs.

In Romania there are currently EHRs developed by private entities which are used by private hospitals, and private practices. However, there is no identical system used by all the entities, i.e. the EHRs are different depending on the provider of the system.

In addition to the lack of specific legislation of EHRs, there are also few documents issued by Romanian authorities with regard to EHRs. The authority in charge with the implementation in Romania of the EHRs, i.e. CNAS, published on its website some General Information regarding the EHRs.

The General Information⁵ regarding the Electronic File Program to be implemented by CNAS is posted on the website of CNAS (“**CNAS General Information**”). According to CNAS General Information, EHR will consist of a collection of electronic recordings cumulated from various sources and locations, and the data to be stored will be of the following type: medical history, allergies, immunizations, results of lab tests, documents produced during medical procedures, which will prove to be relevant for the medical decision.

In addition to CNAS General Information, the representatives of CNAS created a group of discussions (“**CNAS Discussions Group**”) where additional information regarding EHR was posted.⁶

Also, CNAS provided written responses and clarifications to the questions and queries included in this Report (“**CNAS’s Responses**”), which were reflected accordingly.

According to the representatives of CNAS, the EHR system is currently being tested. Once the technical testing will be finalized, by joint order of the Health Ministry and of CNAS the implementation of EHRs will be approved. The said joint order will also provide specific provisions with regard to EHRs.

At the CNAS Discussions Group the EHR was presented as being designed to provide limited rights to the patients in the management of their EHRs, and restricted rights regarding the possibility to amend or to delete information. Moreover, CNAS advised that initially the EHRs will be set up without the prior consent of the patients⁷.

CNAS intends to implement an opt-out procedure for patients who do not want to have an EHR. However such procedure is cumbersome to the patient, as he/she must go before the notary to issue an authentic Opt-Out Declaration. However, even if such Declaration is issued by the patient, the doctor

⁵ <http://www.cnas.ro/despre-noi/proiect-sistem-informativ-dosarul-electronic-al-pacientului>, available only in Romanian

⁶ Such information is available only to group members. We became members of the CNAS Discussions Group, and reviewed the documentation posted for the members.

⁷ Interview with the Vice-President of CNAS of February 24, 2014

will still include in the EHR a minimum amount of information entitled Relevant Health Data (*Date Medicale Relevante*).

The doctors will be able to access the EHRs based on their extended electronic signature, and on the health insurance card of the patient. Patients will have the right to access their EHR based on a matrix provided by the physician, which will be used to register and obtain an user name and password to access the EHR. Hard copy records will be used in parallel with EHRs, for several years.

CNAS further advised that hard copy records will continue to be used, and most likely will be used in parallel with EHRs, for several years.

1.2. Institutional setting

The main institutions involved in the development and deployment of the EHRs scheme in Romania are:

(i) *The Health Ministry (Ministerul Sanatatii)*

The Health Ministry is responsible for public health and the organisation of the healthcare system. It is responsible for overseeing the implementation of the EHRs scheme in Romania.

(ii) *The National Health Insurance House - CNAS (Casa Nationala de Asigurari de Sanatate)*

CNAS is an autonomous institution of national public interest, having as main object of activity the assurance of the unitary and coordinated functioning of the health insurance system in Romania. According to the provisions of the Health Law⁸, CNAS organizes and manages the Health Insurance Information Platform which consists of: the integrated health information system, the national system of the social health insurance card, the national system of electronic prescription and the system of the patient's electronic health record, providing the interoperability thereof with the e-Health solutions at the national level, for an efficient use of the information upon the preparation of the health policies and for the management of the health system.

(iii) *The National Supervisory Authority for Personal Data Processing – DPA (Autoritatea Nationala de Supraveghere a Prelucrarii Datelor cu Caracter Personal)*

The National Supervisory Authority for Personal Data Processing is a public autonomous and independent authority. Its main goal is protecting the fundamental rights and freedoms of the natural persons, especially the right to intimate, family and private life, in connection with the processing of personal data and the free circulation of these data. The DPA carries out its' activity in terms of complete independence and impartiality. The authority supervises and controls the legality of the personal data processing which falls under the Data Protection Law.

1.3. Legal setting and future legal development

As mentioned above, there is no specific legislation with regard to the EHRs. There are references to EHRs in the Health Law; however these references do not cover the health data to be included in the EHRs, requirements on the institution hosting EHRs data, patient consent, creation, access to and update of the EHRs, liability, secondary uses and archiving durations, requirements on interoperability of the EHRs.

The recent amendment of the Health Law, of February 21, 2014 introduced the obligation of certain entities to provide conditions for medical information mobility in electronic format, by using the patient's electronic health record. Thus, the Health Law provides the obligation of offices of the

⁸ Art. 270 of the Health Law, last updated on February 21, 2014

family doctors and of other specialized doctors, diagnosis and treatment centres, medical centres, labs, as well as other public and private medical units, and public and private medical units with beds to use the EHRs.

CNAS⁹ advised they are currently carrying out technical tests of the EHR system. Once the technical tests are finalized (within several months), the pilot phase of EHR will be initiated.

Prior to the initiation of the pilot phase of EHRs, CNAS and the Health Ministry will issue a joint order with regard to EHR on issues such as data to be included in the EHRs, requirements on the institution hosting EHRs data, patient consent, creation, access to and update of the EHRs, liability, secondary uses and archiving durations, and requirements on interoperability of the EHRs. No draft legal initiative is available at the time of writing this report.

List of relevant national legislation:

Romania does not have a special legislation with regard to EHRs.

There are few official documents which refer to EHR, i.e.:

- (i) CNAS General Information regarding the EHRs to be implemented by CNAS, posted on the website of CNAS.
- (ii) Health Law (*Legea privind reforma in domeniul sanatatii*)

Since its entry into effect in 2006, the Health Law was amended several times. The most recent amendment of the Health Law was carried out through the Government Emergency Ordinance no. 2 of February 21, 2014.

The Health Law includes references to EHRs, as well as the obligation of offices of the family doctors and of other specialized doctors, diagnosis and treatment centers, medical centers, labs, other public and private medical units, and public and private medical units with beds to provide conditions for medical information mobility in electronic format by using the patient's EHR.

- (iii) Order no. 1571 of 2010 of the Ministry of Health regarding the Approval of the Measures for the Application of the Strategy e-Romania and e-Health and the Implementation of the Projects SIUI, National Social Insurance Card, e-Prescription, and Medical Electronic File.

However, none of the above-mentioned documents provides a specific legal framework with regard to the health data to be included in EHR, requirements regarding the institution hosting EHRs data, patient consent, creation, access to and updated of EHRs, liability regarding use of the EHRs, secondary uses and archiving durations of the EHRs, links between EHRs and ePrescriptions. Such specific framework will be issued, according to CNAS¹⁰, prior to the pilot implementation of the EHRs.

Additional laws which are applicable to the EHRs:

- (a) Data Protection Law (*Legea privind protecția persoanelor cu privire la prelucrarea datelor cu caracter personal și libera circulație a acestor date*)

The Data Protection Law regulates the collection and processing of health personal data.

- (b) Medical Deontology Code of the Romanian College of Physicians (*Codul de deontologie*)

⁹ Interview with the Vice-President of CNAS of February 24, 2014

¹⁰ Interview with the Vice-President of CNAS of February 24, 2014

medicală al Colegiului Medicilor din România)

It includes provisions regarding the confidentiality obligations of the physicians

(c) **Romanian Criminal Code (*Codul Penal al României*)**

The Romanian Criminal Code includes provisions relating to the liability of individuals and companies.

2. Legal requirements applying to EHRs in Romania

2.1. Health data to be included in EHRs

2.1.1. Main findings

Romania does not have specific legislation with regard to EHRs. There are few official documents which expressly refer to EHRs, such as the CNAS General Information or the Health Law.

In addition to CNAS General Information, the representatives of CNAS created a group of discussions (“**CNAS Discussions Group**”) where additional information regarding EHR was posted.¹¹

However, none of the above-mentioned documents expressly states the health data to be included in EHR. At the moment, details of the elements that will be included in EHRs can be extrapolated from the CNAS General Information, and the documents posted on CNAS Discussions Group.

According to CNAS General Information, EHR will consist of a collection of electronic records cumulated from various sources and locations, and the data to be stored will be of the following type: medical history, allergies, immunizations, results of lab tests, documents produced during medical procedures, which will prove to be relevant for the medical decision.

According to the representatives of CNAS, the EHR system is currently in technical testing. Once the technical testing will be finalized, by joint order of the Health Ministry and of CNAS the implementation of EHRs will be approved. The said joint order will also provide specific provisions with regard to EHRs, including the data to be included in EHRs.

CNAS, as the authority developing and implementing the EHRs, has all the details regarding data to be included in the EHRs, requirements on the institution hosting EHRs data, patient consent, creation, access to and update of EHRs, liability regarding the use of the EHRs, secondary uses and archiving durations of the EHRs, requirements on interoperability of EHRs, and links between the EHRs and ePrescriptions. The Vice-President of CNAS was however reluctant in providing any information, and advised that they will provide answers to the issues raises in this Report in writing. So far we did not receive such answers.

¹¹ Such information is available only to group members. We became members of the CNAS Discussions Group, and reviewed the documentation posted for the members.

2.1.2. Table on health data

Questions	Legal reference	Detailed description
<p><i>Are there specific rules on the content of EHRs? (or regional provisions, agreements, plans?)</i></p>		<p>CNAS General Information provides that the data to be stored will be of the following type: medical history, allergies, immunizations, results of lab tests, documents produced during medical procedures, which will prove to be relevant for the medical decision.</p> <p>According to the information posted on CNAS Group of Discussions, there will be several types of data to be collected such like:</p> <ul style="list-style-type: none"> (i) personal data: name, surname, personal numeric code, sex, age, blood type, religion; (ii) medical history: diagnostics, interventions/procedures carried out, immunizations, investigations carried out, intolerance towards medicine/food; (iii) emergency data: chronic diseases, warnings (allergies, internal prosthesis, transplants), patient's options; (iv) clinical records: physiologic, pathological, occupation, life style/behaviours, family history; (v) medical documents: consultations of the family doctors, specialized consultations, history of the referrals, history of prescriptions, hospitalizations.
<p><i>Are these data restricted to purely medical information (e.g. physical or mental health, well-being)?</i></p>		<p>Pursuant to the information posted on CNAS Group of Discussions, the data to be included in EHR is not limited to purely medical information. Thus, it appears that information on religion, sex, age, occupation, lifestyle/behaviour, family history will also be included in EHR.</p> <p>As the EHR is currently being tested, and there is no specific legislation regarding the data to be included in EHR, the above-mentioned categories of data are still subject to discussions.</p> <p>However, pursuant to CNAS's Responses, the minimum health data included in</p>

Questions	Legal reference	Detailed description
		the EHR are limited to purely medical information. The EHRs also contains other non-related health personal data, such as address, place of work. However, such data are not mandatorily included in the EHRs.
<i>Is there a definition of EHR or patient's summary provided in the national legislation?</i>		<p>There is no definition of EHRs in the national legislation, as per the CNAS's Responses. There are paper medical records of the patient for each area of medical care.</p> <p>CNAS General Information refers to EHR as a collection of electronic records cumulated from various sources and locations, and the data to be stored will be of the following type: medical history, allergies, immunizations, results of lab tests, documents produced during medical procedures, etc., which will prove to be relevant for the medical decision.</p>
<i>Are there any requirements on the content of EHRs (e.g. detailed requirements on specific health data or general reference to health data)?</i>		<p>As mentioned above, pursuant to the documents available for discussions within the CNAS Group of Discussions, there will be several types of data to be collected, such as personal data, medical history; emergency data; clinical records; medical documents.</p> <p>CNAS's Responses provide that EHR includes both general information regarding health as well as specific detailed information. Some of this information must be mandatorily filled in, other are left for the doctor to decide whether to include them or not.</p>
<i>Are there any specific rules on the use of a common terminology or coding system to identify diseases, disorders, symptoms and others?</i>		<p>According to the information posted on the CNAS Group of Discussions, EHRs will connect the local medical systems through standards opened in HL7 v3 CDA release 2.</p> <p>One of the interviewed stakeholders¹² mentioned that currently the terminology used for identifying diseases is ICD 10 (CIM 999).</p>
<i>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)?</i>		<p>Given the lack of specific legislation on EHRs, there is no legal division between separate categories of data with different levels of confidentiality.</p> <p>However, the Vice-President of CNAS mentioned during the interview of February 24, 2014 that the patient will have a set of data which will have to be</p>

¹² Interview with the Vice President of the Romanian National Society of Family Medicine of February 18, 2014.

Questions	Legal reference	Detailed description
		<p>included in EHRs, entitled Medical Relevant Data. The patient has the right to decide that any data exceeding the Medical Relevant Data should not be included in his/her EHR.</p> <p>Pursuant to CNAS's Responses, the EHR system includes a category of data entitled "Emergency Summary", and another category of data with different levels of confidentiality which will be determined by the patient.</p>
<p><i>Are there any specific rules on identification of patients in EHRs?</i></p>		<p>As there is no specific legislation regarding EHRs, there are no provisions regarding the identification of patients in EHRs.</p> <p>However, currently, patients are identified through their personal numeric code ("CNP"). An identification code, i.e. CID, of the insured patients is also used in order to access SIUI. CID is an identification code which is automatically generated based upon the CNP of each person.</p> <p>Most likely, the CNP and CID will be the numbers used for the identification of the patients in EHRs.</p> <p>In addition to the above-mentioned identification numbers, CNAS currently is in process of issuing the National Health Insurance Card, which according to the information posted on the CNAS Group of Discussions will be used for accessing the EHRs.</p> <p>Pursuant to the CNAS's Responses, the patients' identification will be carried out based on their National Health Insurance Card. If the National Health Insurance Card is not available, the identification of the patient will be carried out based on his/her username, password and security matrix.</p> <p>In case of emergency, the patient will be identified based on his/her ID.</p>
<p><i>Is there is a specific identification number for eHealth purposes?</i></p>		<p>As mentioned above, currently, patients are identified through their CNP and through CID, which is an identification code which is automatically generated based upon the CNP.</p> <p>Both the CNP and CID are numbers uniquely assigned to an individual across</p>

Questions	Legal reference	Detailed description
		Romania. CNAS's Reponses confirmed that CID will be used as identification number for EHR purposes.

2.2. Requirements on the institution hosting EHRs data

2.2.1. Main findings

There are no specific provisions with regard to the requirements on the institution hosting and managing EHRs data.

The Data Protection Law provides certain requirements which must be met by data controllers which are collecting and processing personal health data, or health related data.

Entities which collect and process health personal data, must register with the DPA as data controllers, and in certain cases must obtain an authorization prior to the start of the collection and processing of health data.

2.2.2. Table on requirements on the institutions hosting EHRs data

Questions	Legal reference	Detailed description
<p><i>Are there specific national rules about the hosting and management of data from EHRs?</i></p>	<p>Data Protection Law, Art. 22 (last amended in 2012)</p>	<p>There are no specific rules about the hosting and management of data from EHRs.</p> <p>Art. 270 (1¹) of the Health Law provides that CNAS organizes and manages the EHR system for an efficient use of the information upon the preparation of the health policies and for the management of the health system.</p> <p>The Data Protection Law provides a specific procedure for the registration of entities which are collecting and processing personal data as data controllers.</p> <p>The procedure to register as a data controller with the DPA is not complex. Thus, entities which are collecting and processing personal data must file a Notification with the DPA by filling in a standard form available on the website of the DPA. Further to the filling in of the standard form, such is uploaded on the website of the DPA.</p> <p>CNAS, the authority which is implementing the EHRs, is registered as data controller with the DPA.</p> <p>The representative of the DPA mentioned that with regard to the processing of personal data, the institution that hosts the data from EHR must:</p> <ul style="list-style-type: none"> (i) be registered as a data controller with the DPA; (ii) make sure that the patient is informed about his or her rights under the Data Protection Law; (iii) the consent of the patient must exist except that such consent is not required in the cases mentioned in Art. 7 of the Data Protection Law as follows: <ul style="list-style-type: none"> a. when the processing is required in order to protect the data subject's life, physical integrity or health or that of another person which is legally or physically unable to express his/her consent;

Questions	Legal reference	Detailed description
		<p>b. when the processing is required for preventive medical care, to establish a medical diagnosis, to provide medical care or treatment in the interest of the data subject, or to manage health services that are in the best interest of the data subject, on the condition that the processing of that data is performed by, or under the supervision of medical staff bound by professional secrecy or by or under the supervision of another person subject to a similar obligation regarding the secrecy;</p> <p>c. if the processing is necessary for the protection of public health;</p> <p>(iv) must ensure the confidentiality and security of the database.</p>
<p><i>Is there a need for a specific authorisation or licence to host and process data from EHRs?</i></p>	<p>Data Protection Law, Art. 9 (last amended in 2012)</p>	<p>There are no specific rules about the need to obtain an authorization or license to host and process data from EHRs.</p> <p>However, pursuant to the provisions of Art. 9 of the Data Protection Law, a prior authorization must be obtained from the DPA for processing health related data, except for the cases in which the data processing is required in order to protect the data subject's life, physical integrity or health.</p> <p>The Data Protection Law further provides that when the purposes of the processing refer to other people or to the general public, and the data subject has not given his/her written and unequivocal consent, the preliminary authorization of the DPA must first be demanded and obtained. The processing of personal data beyond the limits of the authorization is prohibited.</p> <p>Except for emergency reasons, the authorization mentioned above may be given only after consulting the Romanian College of Physicians.</p> <p>Pursuant to the CNAS's Responses, the medical services suppliers, which will also be data controllers, have the obligation to comply with the provisions of the Data Protection Law.</p>
<p><i>Are there specific obligations that apply to institutions hosting and managing data from EHRs (e.g. capacity, qualified staff,</i></p>	<p>Data Protection Law, Art. 9 (last amended in 2012)</p>	<p>There are no specific rules about obligations that apply to institutions hosting and managing data from EHRs.</p>

Questions	Legal reference	Detailed description
<p><i>or technical tools/policies on security confidentiality)?</i></p>		<p>However, the Data Protection Law provides that the processing of health data may be carried out only by, or under the supervision of, medical staff who is bound by a pledge of professional confidentiality.</p> <p>The processing may be carried out by non-medical staff when the data subject has given, in writing, his/her unequivocal consent and as long as the consent has not been withdrawn. Also the processing may be carried out by non-medical staff in the cases when the data processing is necessary for the prevention of an imminent danger, the prevention of a criminal offence, or of the consequences, of such offence.</p> <p>The medical staff, health institutions and their staff may process personal health data without the authorization of the DPA only when the data processing is required in order to protect the data subject's life, physical integrity, or health.</p> <p>As a general rule of the Data Protection Law, personal health data may only be collected from the data subjects themselves. Exceptionally, these data can be collected from other sources only when it is required in order not to compromise the processing's purpose, and when the data subject cannot or does not want to provide them.</p> <p>According to CNAS's Responses, the employees of CNAS observe the rules of the public officers regarding capacity, qualifications and confidentiality.</p>
<p><i>In particular, is there any obligation to have the information included in EHRs encrypted?</i></p>		<p>There are no specific obligations to have the information included in EHRs encrypted.</p> <p>Pursuant to CNAS's Responses, the data are included in EHR by the physicians based on their extended electronic signature. The diseases, the diagnosis, the drugs, and the medical procedures are pre-established and coded according to the international common name.</p>
<p><i>Are there any specific auditing requirements for institutions hosting and processing EHRs?</i></p>		<p>There are no specific auditing requirements for institutions hosting and processing EHRs.</p> <p>CNAS's Responses provide that CNAS is audited by the DPA on a regular basis.</p>

2.3. Patient consent

2.3.1. Main findings

As there is no specific legislation with regard to EHRs, there are no provisions regarding the consent of the patient in relation to EHRs.

According to some of the stakeholders¹³, the consent of the patient is a major issue for the development of EHRs.

The CNAS's approach is to implement the EHRs based on the data CNAS currently receives based on the reporting obligations of the hospitals and doctors, without prior consent of the patient. CNAS intends to implement an opt-out procedure for patients who do not want to have an EHR. However such procedure is cumbersome for the patient. Thus, the patient must issue a Declaration before the notary that he/she does not want to have an EHR – the patient will lose some time, and will have to pay notary fees.

Moreover, even if the patient intends to opt-out, the EHR will not be entirely deleted, the information included in the EHR will be limited to a set of minimum data, i.e. the Medical Relevant Data.

It is debatable whether the above-described mechanism complies with the Data Protection Legislation, which requests the express consent of the patient, and in case of transfer of health data to foreign countries, it requests a written consent.

The mechanism proposed by CNAS was not included in any legislative initiative; consequently it was not made available for public debate, and was not discussed so far with the DPA.

¹³ The Vice-President of Romanian National Society of Family Medicine, the President of the Romanian Hospital Association, the President of the Romanian College of Physicians, the Legal Manager of the DPA.

2.3.2. Table on patient consent

Questions	Legal reference	Detailed description
<p><i>Are there specific national rules on consent from the patient to set-up EHRs?</i></p>	<p>Data Protection Law, Arts. 7, 9 (last amended in 2012)</p>	<p>There are no express legal provisions with regard to the consent of the patient for EHR.</p> <p>However, the Data Protection Law includes specific provisions regarding the collection and processing of health related data.</p> <p>Thus, as a general rule, Art. 7 (1) of the Data Protection prohibits the processing of personal data regarding ethnic or racial origin, political, religious or philosophical beliefs or those of similar nature, trade-union allegiance, as well as personal data regarding the state of health, or sex life.</p> <p>However, Art. 7 (2) provides certain cases when the above-mentioned prohibition does not apply, the relevant cases in relation to EHRs being:</p> <ul style="list-style-type: none"> a) when the data subject has expressly given his/her consent for such data processing; b) when the processing is required in order to protect the data subject's life, physical integrity or health or that of another person which is legally or physically unable to express his/her consent; c) when the processing is required for preventive medical care, to establish a medical diagnosis, to provide medical care or treatment in the interest of the data subject, or to manage health services that are in the best interest of the data subject, on the condition that the processing of that data is performed by, or under the supervision of medical staff bound by professional secrecy or by or under the supervision of another person subject to a similar obligation regarding the secrecy; d) if the processing is necessary for the protection of public health; <p>The processing of health data may be carried out only by, or under the</p>

Questions	Legal reference	Detailed description
		<p>supervision of medical staff who is bound by professional confidentiality, except for the cases when the data subject has given, in writing, his/her unequivocal consent and as long as the consent has not been withdrawn, as well as except for the cases when the data processing is necessary for the prevention of an imminent danger, the prevention of a criminal offence or of the consequences, of such offence.</p> <p>Four of the stakeholders¹⁴ with whom we discussed mentioned that the consent of the patient is a major issue with regard to the implementation of EHRs. The patient should give his/her informed consent, which should be materialized.</p> <p>However, the Vice-President of CNAS mentioned that the EHRs will be created initially from the electronic information that CNAS already collects through the reporting obligations the hospitals and doctors have. Thus, the consent of the patient will not be required for the setting up of the EHRs.</p> <p>Further on, pursuant to CNAS's Responses, the concept of consent has not been defined yet. As the EHR is currently being developed, it can be properly improved.</p>
<p><i>Is a materialised consent needed?</i></p>		<p>There are no specific provisions regarding the consent of the patient with regard to EHRs.</p> <p>However, as mentioned above, according to the statement of the Vice-President of CNAS it appears that the EHRs will be set up without the prior consent of the patient.</p> <p>It is debatable whether the setting up of the EHRs without the prior consent of the patient will not breach the current provisions of the Data Protection Law.</p> <p>Further to the interviews that we had with both the representatives of CNAS and of the DPA, it appears that the implementation of EHRs without the initial</p>

¹⁴ The Vice-President of Romanian National Society of Family Medicine, the President of the Romanian Hospital Association, the President of the Romanian College of Physicians, the Legal Manager of the DPA.

Questions	Legal reference	Detailed description
		<p>consent of the patient proposed by CNAS was not discussed with the DPA. Given that the implementation of the EHRs is not materialized yet in any legislative document, the DPA did not have the chance to object to such approach so far.</p> <p>CNAS¹⁵ only refers to the consent of the patient to access his/her EHR, it does not refer to the consent of the patient to set up the EHRs.</p>
<p><i>Are there requirements to inform the patient about the purpose of EHRs and the consequences of the consent or withholding consent to create EHRs?</i></p>	<p>Data Protection Law, Art. 12 (last amended in 2012)</p>	<p>There are no specific provisions regarding the requirements to inform the patient about the purpose of EHRs and the consequences of the consent or withholding consent to create EHRs.</p> <p>As a general rule, the Data Protection Law provides the obligation of the data controller to inform the data subject, i.e. the patient, about the purposes of the processing of personal data, and about the consequences of the consent, or of withholding consent.</p> <p>Pursuant to CNAS¹⁶, the physician will have the obligation to inform the patient with regard to the data included in the EHR.</p>
<p><i>Are there specific national rules on consent from the patient to share data?</i></p>	<p>Data Protection Law, Art. 7 (last amended in 2012)</p>	<p>There are no specific national rules on consent from the patient to share data in relation to EHRs.</p> <p>However, pursuant to the provisions of the Data Protection Law, the disclosure of health related data can be carried out only with the consent of the patient, or in the exceptional cases provided by Art. 7 of the Data Protection Law.</p> <p>The EHR will include a patient portal pursuant to which the patient will be able to determine the health data access policy for the physicians.</p>
<p><i>Are there any opt-in/opt-out rules for patient consent with regard to processing of EHRs?</i></p>	<p>Data Protection Law, Art. 15 (last amended in 2012)</p>	<p>There are no specific opt-in/opt-out rules for patient consent with regard to processing of EHRs.</p> <p>However, during the interview with CNAS, the Vice-President advised that further to the implementation of EHRs, the patient will have an opt-out right with</p>

¹⁵ According to the information included in the CNAS's Responses.

¹⁶ According to the information included in the CNAS's Responses.

Questions	Legal reference	Detailed description
		<p>regard to EHRs. This opt-out right will regard however only the health data exceeding the set of Medical Relevant Data, which will be mandatory for all patients. According to the Vice-President of CNAS, the opt-out right will be exercised by the patient by issuing a declaration before the notary stating that he/she does not want to have an EHR. This procedure is cumbersome for the patient who has to spend time and money for issuing the declaration before the notary.</p> <p>In addition to the above, pursuant to Art. 15 of the Data Protection Law, the patient has the right to oppose to the processing of his/her personal data, including health data.</p> <p>CNAS¹⁷ confirmed that the EHR system will have opt-out rules.</p>
<p><i>Are there any opt-in/opt-out rules for patient consent with regard to sharing of EHRs?</i></p>	<p>Data Protection Law, Art. 7 (last amended in 2012)</p>	<p>There are no specific opt-in/opt-out rules for patient consent with regard to sharing of EHRs.</p> <p>However, as mentioned above according to the Data Protection Law, the disclosure of health related data can be carried out only with the consent of the patient, or in the exceptional cases provided by Art. 7 of the Data Protection Law.</p> <p>Pursuant to the CNAS's Responses, the EHR will include a patient portal according to which the patient will be able to determine different health data access policy for the physicians.</p>
<p><i>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?</i></p>	<p>Data Protection Law, Art. 12 (last amended in 2012)</p>	<p>There are no specific requirements to inform the patient about the purpose of EHRs and the consequences of consent or withholding consent on the sharing of EHRs.</p> <p>As mentioned above, the Data Protection Law provides the obligation of the data controller to inform the data subject, i.e. the patient, about the purposes of the processing of personal data, about the consequences of the consent or of the withholding consent, and about his/her rights under the Data Protection Law.</p>

¹⁷ According to the information included in the CNAS's Responses.

Questions	Legal reference	Detailed description
		As per CNAS's Responses, the physicians will have the obligation to inform the patient with regard to the EHRs.
<i>Can the patient consent to his/her EHRs being accessed by a health practitioner or health institution outside of the Member State (cross-border situations)?</i>		There are no specific provisions allowing a patient to consent to his/her EHRs being accessed by a health practitioner or a health institution outside of the Member State. CNAS ¹⁸ advised that the EHR system is still being developed. No facilities for the interconnection with foreign EHRs have been developed so far.
<i>Are there specific rules on patient consent to share data on a cross-border situation?</i>		No

¹⁸ According to the information included in the CNAS's Responses.

2.4. Creation, access to and update of EHRs

2.4.1. Main findings

The Health Law obliges the following entities to provide conditions for medical information mobility in electronic format by using the patient's EHR:

- (a) offices of the family doctors and of other specialized doctors, diagnosis and treatment centres, medical centres, labs, as well as other public and private medical units;
- (b) public and private medical units with beds.

The representatives of CNAS advised that the EHRs are created by the health professionals. Upon the first visit of the patient at the doctor's office or hospital, the doctor uses the EHR system in order to include the medical data of the patient, thus creating the EHR. Once the EHR is created for a patient, the EHRs system will automatically import the already available data from the SIUI.

According to the information posted on CNAS Discussions Group, initially, family doctors and hospitals will have the obligation to use and update the EHRs.

Pursuant to the information posted on CNAS Discussions Group, it appears that the health professionals or health institutions will have access to the EHRs based on their extended electronic signature and on the Health Insurance Card of the patient, or a security matrix.

Currently, the Health Insurance Card was not issued and distributed to Romanian citizens. The process of the distribution of the Health Insurance Card is estimated to take one year to be finalized.

Patients will have access to their EHRs based on a security matrix provided by their doctor. The matrix will be used to create a user name and password to access the EHR.

As the EHRs are currently in technical testing, some of the aspects regarding the access to the EHRs, amendment, upload, deletion, and update thereof are not clarified yet. At the moment such information is available only to CNAS, which is implementing the EHRs.

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

Questions	Legal reference	Detailed description
<p><i>Are there any specific national rules regarding who can create and where can EHRs be created?</i></p>	<p>Health Law, Art. 29, 270 (last amended February 21, 2014)</p>	<p>Art. 29 of the Health Law stipulates the obligation of the following entities to provide conditions for medical information mobility in electronic format, by using the patient's electronic health record:</p> <ul style="list-style-type: none"> (a) offices of the family doctors and of other specialized doctors, diagnosis and treatment centres, medical centres, labs, as well as other public and private medical units; (b) public and private medical units with beds. <p>The representatives of CNAS advised that the EHRs are created by the health professionals. Upon the first visit of the patient at the doctor's office or hospital, the doctor uses the EHR system in order to include the medical data of the patient, thus creating the EHR. Once the EHR is created for a patient, the EHRs system will automatically import the already available data from the SIUI.</p> <p>According to the information posted on CNAS Discussions Group, family doctors and hospitals will have initially the obligation to use and update the EHRs.</p> <p>Art. 270 of the Health Law provides that CNAS organizes and manages the Health Insurance Information Platform which consists of: the integrated sole information database, the national database of the social health insurance card, the national database of electronic prescription, and the database of the electronic health records of the patients, ensuring the interoperability thereof with the e-Health solutions at the national level for an efficient use of the information for the purpose of the formulation of the health policies, and the management of the health system.</p>
<p><i>Are there specific national rules on access and update to EHRs?</i></p>		<p>There are no specific rules on the access and update of the EHRs.</p> <p>Pursuant to the information posted on CNAS Discussions Group, it appears</p>

Questions	Legal reference	Detailed description
		<p>that the health professionals or health institutions will have access to the EHRs based on their extended electronic signature and on the Health Insurance Card of the patient, or a security matrix.</p> <p>Currently, the Health Insurance Card was not issued and distributed to Romanian citizens. The process of the distribution of the Health Insurance Card is estimated to take up to one year to be finalized.</p> <p>CNAS considers that the mere provision of the Health Insurance Card to the doctor represents the consent of the patient to access the EHR of the patient. However, from a data protection point of view, the mere provision of the Health Insurance Card is not sufficient to value as consent.</p> <p>CNAS¹⁹ further advised that the patient has access to his/her own EHR using the national Health Insurance Card, or by username, password, and security matrix. The physicians have access to the patient's EHRs in the presence of the patient using their extended electronic signature.</p>
<p><i>Are there different categories of access for different health professionals?</i></p>		<p>There are no provisions regarding the different categories of access for different health professionals.</p> <p>As a general rule, the access of the doctor to EHRs is possible when the patient is present and provides his/her Health Insurance Card.</p> <p>Pursuant to CNAS's Responses, the patient decides who can have access to his/her EHR, by determining the rules for accessing the EHR. The physicians in the surgery emergency system represent an exception. Thus, if the life of the patient is in danger, the physicians in the surgery emergency system can access the Emergency Summary, a section of the EHR containing certain minimum medical data.</p>
<p><i>Are patients entitled to access their EHRs?</i></p>	<p>Data Protection Law, Art. 13 (last amended in 2012)</p>	<p>Although there are no specific provisions with regard to access to the EHRs, pursuant to the Data Protection Law, the patient as data subject has the right to have access to his/her data.</p>

¹⁹ According to the information included in the CNAS's Responses.

Questions	Legal reference	Detailed description
		<p>According to the information posted on CNAS Discussions Group, and also further to the interview with CNAS, the patient will have the right to access his or her EHR based on a security matrix provided by his or her doctor. The matrix will be used to create a user name and password to access the EHR.</p> <p>CNAS²⁰ confirmed that the patient has access to his/her own EHR using the national Health Insurance Card, or by username, password, and security matrix.</p>
<i>Can patient have access to all of EHR content?</i>		<p>Although there are no specific provisions with regard to access to EHRs, it appears that the patient will have access to the entire content of the EHR.</p> <p>CNAS²¹ confirmed that the patient will have access to all of the EHR content.</p>
<i>Can patient download all or some of EHR content?</i>		<p>There are no provisions or information available with regard to the right of the patient to download all or some of EHR's content.</p> <p>However, pursuant to the CNAS's Responses, the patients will be able to download the medical data included in the EHRs.</p>
<i>Can patient update their record, modify and erase EHR content?</i>	Data Protection Law, Art. 14 (last amended in 2012)	<p>Although there are no specific provisions regarding the right to update, modify, or erase the content of the EHRs, as resulted from the interview with CNAS, the patient will have the right to make amendments in the EHRs.</p> <p>However, the right of the patient to amend the EHR is limited to information such as, for example, whether he/she is a smoker or not. Also, the doctor when accessing the EHR will view which information was amended by the patient. CNAS mentioned that in this way the doctor can confirm with the patient whether the amended information is correct or not.</p> <p>Moreover, according to the Data Protection Law, the patient, as data subject, has the right to obtain from the data controller, upon request, and free of any charge the rectification, updating, blocking or deletion of data whose</p>

²⁰ According to the information included in the CNAS's Responses.

²¹ According to the information included in the CNAS's Responses.

Questions	Legal reference	Detailed description
		<p>processing does not comply with the provisions of the Data Protection Law, notably of incomplete or inaccurate data. In such case, the patient cannot amend or delete the data himself/herself, but he or she will have to request such amendment or deletion from the data controller, i.e. CNAS.</p> <p>In addition to the above, CNAS²² advised that the data inserted by a physician in the EHRs can be amended only by the physician who initially inserted the said data. The patient can only access such data.</p>
<i>Do different types of health professionals have the same rights to update EHRs?</i>		<p>There are no provisions or information available with regard to the right of different types of health professionals to update EHRs.</p> <p>However, pursuant to the CNAS's Responses, only the physicians based on their extended electronic signature can access the medical records of a patient, included in the EHR.</p>
<i>Are there explicit occupational prohibitions? (e.g. insurance companies/occupational physicians...)</i>	Health Law, Art. 29 (last amended on February 21, 2014)	<p>There are no provisions or information with regard to explicit occupational prohibitions.</p> <p>However, the Health Law refers only to offices of the family doctors and of other specialized doctors, diagnosis and treatment centres, medical centres, labs, other public and private medical units, and public and private medical units with beds as having the obligation to use the EHRs.</p> <p>Also, as mentioned above, CNAS advised that only the physicians, based on their extended electronic signature, can access the medical records of a patient included in the EHR.</p>
<i>Are there exceptions to the access requirements (e.g. in case of emergency)?</i>		<p>Although there are no specific provisions regarding the exceptions to the access requirements, the Vice-President of CNAS advised that in case of emergency the doctors will have access to the minimum set of data, i.e. the Medical Relevant Data.</p>
<i>Are there any specific rules on identification and authentication for health professionals?</i>		<p>There are no specific rules on the identification and authentication for health professionals.</p>

²² According to the information included in the CNAS's Responses.

Questions	Legal reference	Detailed description
<i>Or are they aggregated?</i>		However, according to the information available on the CNAS Discussions Group, the doctors will be able to access the EHRs based on an extended electronic signature, together with the Health Insurance Card of the Patient, or with the security matrix.
<i>Does the patient have the right to know who has accessed to his/her EHRs?</i>		There are no specific rules on whether the patient has the right to know who has accessed to his/her EHRs or not. However, according to the CNAS's Responses, the patient can review who accessed his/her EHR.
<i>Is there an obligation on health professionals to update EHRs?</i>	Health Law, Art. 29 (last amended on February 21, 2014)	Art. 29 of the Health Law provides the obligation of the following entities to provide conditions for medical information mobility in electronic format, by using the patient's electronic health record: (a) offices of the family doctors and of other specialized doctors, diagnosis and treatment centres, medical centres, labs, and other public and private medical units; (b) public and private medical units with beds.
<i>Are there any provisions for accessing data on 'behalf of' and for request for second opinion?</i>		There are no provisions regarding the accessing data on 'behalf of' and for request for second opinion with regard to EHRs. CNAS also confirmed that there are no such provisions.
<i>Is there in place an identification code system for cross-border healthcare purpose?</i>		There is no identification code system for cross-border healthcare purpose. Upon implementation, only the Romanian health professionals can create and update the EHRs. Pursuant to CNAS's Responses, the EHR system is currently being developed. So far, no interconnection facilities with foreign systems have been developed.
<i>Are there any measures that consider access to EHRs from health professionals in another Member State?</i>	Health Law, Art. 872 (last amended on February 21, 2014)	There are no measures that consider access to EHRs from health professionals in another Member State. However, the Health Law provides that the Romanian patients who wish to benefit or who benefit from cross-border medical assistance have the right to

Questions	Legal reference	Detailed description
		<p>access their medical records from distance, or have the right to receive at least a copy thereof.</p> <p>CNAS also confirmed that there are no measures that consider access to EHRs from health professionals in another Member State.</p>

2.5. Liability

2.5.1. Main findings

The national legislation does not include specific liability provisions with regard to the access and use of the EHRs. Consequently, the general rules on medical liability are applicable.

Health professionals can be held liable for breach of their professional secrecy under the provisions of the Romanian Criminal Code. The criminal liability is engaged if by disclosure of data the health professional caused harm to the patient.

2.5.2. Table on liability

Questions	Legal reference	Detailed description
<p><i>Does the national legislation set specific medical liability requirements related to the use of EHRs?</i></p>	<p>Romanian Criminal Code, Art. 227 (last amended on February 1, 2014)</p> <p>Health Law, Art. 642 (last amended on February 21, 2014)</p>	<p>The national legislation does not provide specific medical liability requirements related to EHRs.</p> <p>Consequently, the general rules on medical liability would be applicable.</p> <p>First of all, medical personnel can be held liable for breach of their professional secrecy obligation as provided by the Romanian Criminal Code. Thus, the disclosure, of data or information regarding the private life of a person, likely to cause damages to that person, by the person who has become aware of such data or information by virtue of his/her profession or position and who must keep confidential these data or information, is sanctioned with prison from 3 months up to 3 years or by fine.</p> <p>Also the Health Law includes a set of provisions regarding the liability of health professionals. Thus, the medical personnel is liable for damages resulting from the failure to comply with the regulations regarding confidentiality, informed consent, and the obligation to grant medical assistance.</p> <p>The medical personnel is further liable with regard to the damages caused while exercising their profession, and if they exceed the limits of their competence, except for the emergency cases when medical personnel with the necessary competence is NOT available.</p> <p>The civil liability regulated by the Health Law does not exclude the criminal liability if the action/inaction that caused the damages represents a crime according to the law.</p> <p>The norms for the application of the Health Law further provide that the professional error committed while exercising the medical act, or the medical and pharmaceutical act which caused damages to the patient triggers the civil liability of the medical personnel and/or the supplier of medical, sanitary and pharmaceutical products and services.</p>

Questions	Legal reference	Detailed description
<i>Can patients be held liable for erasing key medical information in EHRs?</i>		As advised by CNAS, the patients will not have the right to delete key medical information in the EHRs. Consequently, the patients will not be held liable for erasing key medical information in EHRs.
<i>Can physicians be held liable because of input errors?</i>	Romanian Criminal Code, Art. 362 (last amended on February 1, 2014)	<p>There are no specific provisions regarding the possibility to hold liable the physicians for input errors in the EHRs.</p> <p>However, inputting erroneous information in the EHRs could be considered a professional fault which triggers the medical liability as mentioned above.</p> <p>Also, under the provisions of the Romanian Criminal Code, amending, deleting or altering electronic data, or restricting the access to such data, without having such right, is sanctioned with imprisonment from 1 up to 5 years.</p> <p>CNAS confirmed that the physicians may be held liable for input errors is such errors cannot be corrected, or if such errors lead to malpraxis.</p>
<i>Can physicians be held liable because they have erased data from the EHRs?</i>		<p>There are no specific provisions regarding the possibility to hold liable the physicians for erasing data from the EHRs.</p> <p>However, deleting information including in the EHRs could be considered a professional fault which triggers medical liability as mentioned above.</p> <p>Pursuant to CNAS's Responses, the physicians cannot erase data. They can add data pursuant to a medical act, being responsible for the accuracy and consistency of such data.</p>
<i>Are hosting institutions liable in case of defect of their security/software systems?</i>	Data Protection Law, Art. 33 (last amended 2012)	<p>There are no specific provisions regarding the liability of the hosting institutions in case of defect of their security /software systems regarding the EHRs.</p> <p>However, the Data Protection Law provides that the failure of the data controller to fulfil the obligations regarding the enforcement of the security measures, and the confidentiality is a contravention and is sanctioned with a fine ranging from Lei 1,500 to Lei 50,000, i.e. about EUR 333 to EUR 1,000.</p> <p>CNAS confirmed that the hosting institutions will be liable in case of defect of their security /software systems regarding the EHRs.</p>
<i>Are there measures in place to limit the</i>		The national legislation does not set specific medical liability requirement related

Questions	Legal reference	Detailed description
<i>liability risks for health professionals (e.g. guidelines, awareness-raising)?</i>		<p>to EHRs, and therefore no measures are in place to limit the liability risk of health professionals in relation to the EHRs.</p> <p>CNAS advised that the physicians using the system will be trained regarding the use of the EHRs.</p>
<i>Are there liability rules related to breach of access to EHRs (e.g. privacy breach)?</i>	Romanian Criminal Code, Art. 360 (last amended on February 1, 2014)	<p>The national legislation does not provide liability rules related to the breach of access to EHRs.</p> <p>However, the Romanian Criminal Code provides that the access to an electronic database without right is sanctioned with imprisonment from 3 months up to 3 years, or fine. If the electronic database was accessed in order to obtain data, such action is sanctioned with imprisonment from 6 months up to 5 years. If the access regards a restricted system for certain categories of users, the sanction is imprisonment from 2 up to 7 years.</p>
<i>Is there an obligation on health professionals to access EHRs prior to take a decision involving the patient?</i>		<p>There are no legal provisions regarding the obligation of health professionals to access EHRs prior to taking a decision involving the patient.</p> <p>Pursuant to CNAS's Responses, the medical service providers will have the obligation to use the EHRs.</p>
<i>Are there liability rules related to the misuse of secondary use of health data?</i>	Data Protection Law, Art. 32 (last amended 2012)	<p>There are no specific provisions regarding the liability rules related to the misuse of secondary use of health data.</p> <p>However, as a general rule, the Data Protection Law provides that the processing of personal data by a controller or by a representative of the data controller in breach of the provisions of the data protection law is considered a contravention and it is sanctioned with a fine ranging from Lei 1,000 to Lei 25,000, i.e. about EUR 221 to EUR 5,540.</p> <p>CNAS mentioned that the legislation regarding the EHRs will include provisions regarding the liability rules related to the misuse of secondary use of health data.</p>

2.6. Secondary uses and archiving durations

2.6.1. Main findings

The Romanian legislation does not include any specific provisions with regard to the archiving durations of EHRs.

Under the Data Protection Law, there is no maximum period of time during which the personal data may be processed. However, the personal data must be archived for a period of time proportional with the purpose of the data processing. The proportionality will be reviewed upon the registration of the processing with the DPA.

There are no specific rules on the secondary use of EHRs health data (e.g. statistics, research).

According to the Data Protection Law, at the end of the data processing, the data can be either deleted, processed for a different purpose, transferred to a different data controller, or transformed to anonymous data for statistics, historical or technical research purposes.

Moreover, the Data Protection Law provides that the processing of personal data for statistics, historical or scientific research will not be considered incompatible with the purpose they were initially collected for. In such case, the personal data must be anonymous.

2.6.2. Table on secondary uses and archiving durations

Questions	Legal reference	Detailed description
<i>Are there specific national rules on the archiving durations of EHRs?</i>		<p>The Romanian legislation does not include any specific provisions with regard to the archiving durations of EHRs.</p> <p>Under the Data Protection Law, there is no maximum period of time during which the personal data may be processed. However, the personal data must be archived for a period of time proportional with the purpose of the data processing. The proportionality will be reviewed upon the registration of the processing with the DPA.</p> <p>CNAS mentioned that the general archiving rules²³ applicable to paper documents and electronic documents will also be applicable to EHRs.</p>
<i>Are there different archiving rules for different providers and institutions?</i>		<p>Given that the current legislation does not include any specific provision with regard to the archiving durations of EHRs, there are no differences between different providers regarding the archiving.</p>
<i>Is there an obligation to destroy data at the end of the archiving duration or in case of closure of the EHR?</i>		<p>There is no specific provision regarding the obligation to destroy the data at the end of the archiving duration or in case of closure of the EHR.</p> <p>However, according to the provisions of the Data Protection Law, the data controller must mention in the Notification filed with the DPA whether the data will be deleted or will be transferred to another controller at the end of the archiving duration.</p>
<i>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?</i>	Data Protection Law, Art. 6 (last amended 2012)	<p>There are no rules about the use of data at the end of the archiving duration or in case of closure of the EHR.</p> <p>However, the Notification which the data controller must file with the DPA prior to the start of the data collection and processing provides that at the end of the data processing, the data can be either:</p> <p>(i) deleted;</p>

²³ Law no. 16 of 1996 on National Archives, and Law no. 135 of 2007 regarding the Archiving of Documents in Electronic Format

Questions	Legal reference	Detailed description
		(ii) further processed for a different purpose; (iii) transferred to a different data controller; (iv) transformed into anonymous data for statistics, historical or technical research purposes.
<i>Can health data be used for secondary purpose (e.g. epidemiological studies, national statistics...)?</i>	Data Protection Law, Art. 4 (last amended in 2012)	Although, there are no specific legal provisions in respect thereof, one of the purposes of the EHRs is to create a database which facilitates national statistics, epidemiological studies. Moreover, the Data Protection Law provides that further processing of personal data for statistics, historical or scientific research will not be considered incompatible with the purpose they were initially collected for. CNAS confirmed that the health data will be used for secondary purposes.
<i>Are there health data that cannot be used for secondary use?</i>		There are specific provisions regarding health data that cannot be used for secondary use. CNAS advised that they did not identify so far such data.
<i>Are there specific rules for the secondary use of health data (e.g. no name mentioned, certain health data that cannot be used)?</i>	Data Protection Law, Art. 5 (last amended in 2012)	According to the Data Protection Law when the processing is performed exclusively for statistical purposes, historical or scientific research the data must remain anonymous throughout the entire processing. Pursuant to CNAS's Responses, the health data can be extracted from the EHR for a secondary use only with the express consent of the patient.
<i>Does the law say who will be entitled to use and access this data?</i>		There are no specific provisions on who is entitled to use and access this data. However, CNAS advised that the data are accessed and used by physicians. The patients can view the health data included in their own EHR.
<i>Is there an opt-in/opt-out system for the secondary uses of eHealth data included in EHRs?</i>		There are no provisions regarding an opt-in/opt-out system for the secondary uses of eHealth data included in EHRs.

2.7. Requirements on interoperability of EHRs

2.7.1. Main findings

As mentioned above, EHRs are currently at the technical testing stage, and there are few specific provisions regarding the implementation of EHRs. According to the information posted on the CNAS Discussions Group, EHRs will be stored in a database managed by CNAS, at a national level. The Romanian EHR will be implemented in a national database accessible to doctors and patients throughout the country. Consequently, the EHR database which in Romania will be implemented at national level will ensure the interoperability of EHRs.

Art. 270 of the Health Law provides that CNAS organizes and manages the Health Insurance Information Platform which consists of: the integrated sole information database, the national database of the social health insurance card, the national database of electronic prescription, and the database of the electronic health records of the patients, ensuring the interoperability thereof with the e-Health solutions at the national level for an efficient use of the information for the purpose of the formulation of the health policies, and the management of the health system.

Recent amendments of the Health Law include specific provisions regarding the cross-border medical care, which also refer to the possibility of a Romanian patient who wish to benefit or who benefit from cross-border medical assistance to have the right to access their medical records from distance or have the right to receive at least a copy thereof.

The current Romanian legislation does not specifically refer to interoperability in case of EHRs. However, there are certain provisions of the Health Law recently included²⁴ which refer to the cooperation and exchange of information between the Romanian authorities and the relevant authorities of other Member States.

²⁴ The Health Law was amended on February 21, 2014 in order to include, among others, new chapters on cross-border medical assistance, partially transposing the EU Directive no. 2011/24/EU on the Application of Patients' Rights in Cross-Border Healthcare.

2.7.2. Table on interoperability of data requirements

Questions	Legal reference	Detailed description
<p><i>Are there obligations in the law to develop interoperability of EHRs?</i></p>	<p><i>Art. 29 and 270 of the Health Law</i></p>	<p>The Romanian EHR will be implemented through a national database, accessible to doctors and patients throughout the country. Consequently, the national EHR database 1 will ensure the interoperability of EHRs.</p> <p>Art. 270 of Health Law provides that CNAS organizes and manages the system of the patient's electronic health record, providing the interoperability thereof with the e-Health solutions at the national level, for an efficient use of the information for the purpose of formulation of the health policies, and for the management of the health system.</p> <p>The Romanian legislation provides the obligation of keeping the medical data in electronic format, by using the patient's electronic health record.</p> <p>Thus, Art. 29 of the Health Law provides the obligation of the following entities to provide conditions for medical information mobility in electronic format by using the patient's electronic health record:</p> <ul style="list-style-type: none"> (a) offices of the family doctors and of other specialized doctors, diagnosis and treatment centres, medical centres, labs, as well as other public and private medical units; (b) public and private medical units with beds. <p>If another information system is used, it must be compatible with the system in the health insurance information platform of CNAS, in which case the suppliers must ensure the security and confidentiality conditions in the data transmission process.</p>
<p><i>Are there any specific rules/standards on the interoperability of EHR?</i></p>		<p>Except for the above-mentioned Arts. 29 and 270 of the Health Law, there are no other specific rules on the interoperability of EHRs pursuant to the Romanian legislation.</p>

Questions	Legal reference	Detailed description
<p><i>Does the law consider or refer to interoperability issues with other Member States systems?</i></p>	<p>Arts. 872, 881 and 883 of the Health Law</p>	<p>Pursuant to Art. 872 (4) of the Health Law, the Romanian patients who wish to benefit or who benefit from cross-border medical assistance have the right to access from distance their medical records, or have the right to receive at least a copy thereof, according to the norms approved by Government decision.</p> <p>Art. 881 of the Health Law provides that the Health Ministry supports the development of European networks by connecting medical services suppliers within the national territory, and by encouraging medical services suppliers to participate to the relevant European networks.</p> <p>Art. 883 of the Health Law provides that the Health Ministry and CNAS cooperate and participate in exchanges of information with other Member States which operate within a voluntary network which connects the national authorities responsible for eHealth.</p> <p>The provisions of the above-mentioned Articles were included in the Health Law in February 2014.</p> <p>The current version of the Health Law does not specifically refer to interoperability in case of EHRs.</p> <p>Pursuant to the CNAS's Responses, the interoperability with foreign EHRs will be provided in the legislation after the national implementation of the EHRs.</p>

2.8. Links between EHRs and ePrescriptions

2.8.1. Main findings

EPrescriptions were implemented in Romania pursuant to the Order no. 674 of 2012 of the Health Ministry regarding the Approval of the Form of Electronic Medical Prescription with regard to Drugs with and without Personal Contribution in the Ambulatory Treatment and the Methodological Norms regarding the Use and Filling in Manner of the Form of Electronic Medical Prescription with regard to Drugs with and without Personal Contribution in the Ambulatory Treatment (“**Order no. 674**”).

Pursuant to Order no. 674, ePrescription is an electronic form which has two parts, one of which is filled in by the doctor prescribing the drug, and one which is filled in by the pharmacist. The ePrescription can be either online, or offline.

The form approved by Order no. 674 is used for prescribing medicine for patients. The ePrescription system was implemented in Romania prior to EHR system. Consequently, ePrescription is functional without having to interconnect with EHR system.

Although both ePrescription and EHR are part of the eHealth strategy of Romania, currently there is no interconnection between the two systems. Once EHRs will be functional in Romania, doctors accessing the EHR of a patient will have the possibility to review the ePrescriptions issued for the said patient, which will be available in the system.

2.8.2. Table on the links between EHRs and ePrescriptions

- *Infrastructure*

Questions	Legal reference	Detailed description
<i>Is the existence of EHR a precondition for the ePrescription system?</i>		<p>The ePrescription system was implemented prior to the EHR.</p> <p>Although, both ePrescription and EHR are part of the eHealth strategy of Romania, currently there is no interconnection between the two systems.</p> <p>During the interview with CNAS, Mr. Bogdan advised that the two systems will not be connected. However, when accessing EHR, the doctor will view the ePrescriptions issued for the patient in the system.</p>
<i>Can an ePrescription be prescribed to a patient who does not have an EHR?</i>		<p>Given that Romania already implemented the ePrescription system, while EHR is only at the stage of developing the software, ePrescriptions are prescribed to patients who do not have an EHR.</p> <p>According to the information currently available, the two programs are completely independent.</p>

- *Access*

Questions	Legal reference	Detailed description
<i>Do the doctors, hospital doctors, dentists and pharmacists writing the ePrescription have access to the EHR of the patient?</i>		<p>Currently such access is not possible, given that EHR is not operational yet.</p> <p>After the EHR will become operational, family doctors and hospital doctors will have access to EHR, and will insert medical data in EHR. The access of dentists and pharmacists was not subject to discussions so far according to the publicly available information.</p>
<i>Can those health professionals write ePrescriptions without having access to EHRs?</i>		<p>As ePrescription system is already implemented in Romania, while EHR is only at the stage of developing the software, doctors are currently issuing ePrescriptions without any access to EHR.</p>

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

Good practices for the development of EHRs in Romania

ePrescription was implemented in Romania the second half of 2012. ePrescription has been functioning across Romania, being one of the eHealth components which were successfully implemented.

In addition to the ePrescription program, CNAS intends to issue and distribute the Health Insurance Cards during 2014. Once the EHRs will be implemented and the Health Insurance Cards will be distributed to Romanian citizens, the doctors will be able to access the EHRs based on the Health Insurance Card provided by the patient.

The current data protection legislation, which reflects the EU directive, regulates the collection and processing of health-related data, and the transfer of such data to a foreign country. The procedure provided by the Data Protection Law for the filing by the data controller of the Notification regarding the collection and processing of health-related data is not complex. A standard template of the Notification must be filled in with the relevant data and filed with the DPA.

The obligation of certain entities to provide conditions for medical information mobility in electronic format, by using the patient's electronic health record was introduced pursuant to the most recent amendments of the Health Law, of February 21, 2014. Thus, the Health Law obliges hospitals and family doctors to use the EHRs. Including such obligation in the Health Law represents an assurance of the development of the use of EHRs in Romania.

The EHRs will include data considered necessary and relevant for a faster and correct diagnosis. Legal requirements and obligations of the authorities hosting the health data will be developed in order to ensure the best functioning of the EHR system.

Potential legal barriers for the development of EHRs in Romania

At present, the most important barrier in the development of EHRs in Romania is the lack of specific legislation in respect thereof.

As mentioned throughout this Report, CNAS, which is the authority in charge with the development and implementation of the EHRs, confirmed that the EHR system is currently in technical tests. The development of the EHRs was carried out by CNAS without a pre-existing specific legal framework.

As advised by the representative of CNAS, prior to the implementation of the pilot of the EHRs system, CNAS and the Health Ministry will issue jointly an Order which will provide the specific rules for the EHRs. Thus it appears that the specific rules on EHRs will be tailored after the finalization of the actual system.

Note that some of the stakeholders²⁵ are opposing the CNAS initiative, while others²⁶ expressed their concerns regarding the rules planned on consent for the creation and access to EHRs.

²⁵ The President of the Romanian College of Physicians mentioned in the interview of February 21, 2014 that the Romanian College of Physicians opposes to the implementation of EHRs as long as it will not have the confirmation that safety measures were taken in order to make sure that the personal and medical data of the patients are secured, and cannot be disclosed for purposes other than medical ones.

²⁶ Romanian National Society of Family Medicine during the interview of February 18, 2014, National Supervisory Authority for Personal Data Processing - DPA during the interview of February 24, 2014