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 Slovenia

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Executive Summary

1. Stage of development of EHRs in Slovenia

In Slovenia there is not yet an EHR system that allows the transfer of health data and their shared access to ensure the continuity of care of the patient. EHRs are set by each health providers that decide how their EHRs systems are designed and implemented.

Slovenia is currently implementing the project eHealth (*eZdravje*) and one of the components of the project is the establishment of national EHRs (*elektronski zdravstveni zapis –EZZ*).

As there is no specific legislation on EHRs, Slovenia is currently still relying on paper-era legislation. According to the Ministry, the expert group for preparation of starting points for the new legislation in the field of healthcare databases has been established. The adoption of the new law has also been included in the Government`s Legislative Work Programme, however the draft law has not been prepared yet.

2. Summary of legal requirements applying to EHRs

Health data to be included in EHRs

In Slovenia, there is currently no EHR national system that allows the transfer of health data. Even though there are plans to set such system, no proposal of law has been prepared yet. There is therefore currently no legal requirement related to health data to be included in EHRs.

The current legislation in the field of healthcare databases is more than 13 years old and had important issues even at the time of its adoption: the majority of important provisions were left to be resolved by implementing regulations, which were then never adopted and the law only contains very general provisions and the list of 75 different databases and its contents. It is not clear, whether all of these databases are necessary and even if they are all being implemented in practice. This current legislation does not give the legal basis for EHRs as there is no overview of the situation at each health care provider and there is no shared access to the data.

Requirements on the Institution Hosting EHRs Data

Nevertheless, legislation provides the possibility to establish EHRs at each individual healthcare provider. Whoever intends to capture or store materials in digital form, has to adopt internal rules in accordance with the provisions of the PDAAI, related implementing regulations (Decree on documentary and archival material custody), uniform technological requirements and rules of profession (e.g. archival profession, information security, etc.). Internal rules may be submitted for confirmation to the National Archives (*Državni arhiv*), which verifies their compliance with the requirements of PDAAI. However, entities governed by public law are obliged to submit their internal rules for confirmation to the National Archives.

Patient Consent

The general rule for collecting patient health data is that either patient consent is required or that collection of certain data is prescribed by the law. In Slovenia the data is mostly collected on the basis of the legal provisions – the law prescribes which health data is collected and in such case patient consent is not required. According to the Ministry of Health, the same approach will most probably be used once the EHR system is established – the law will prescribe the health data to be included in the EHRs without additional requirement of patient consent.

Creation, Access to and Update of EHRs

As national EHR system is at such early stage of development, the rules on creation, access to and update of EHRs are not yet clear. The currently valid legislation merely stipulates that the data prescribed for each individual healthcare database should be entered at medical examinations and other healthcare services.

Liability

In terms of liability, the laws governing the issues of personal data processing and hosting and management of electronic records provide criminal provisions in case of a breach of prescribed obligations.

Secondary Uses and Archiving Durations

Personal data may only be stored for as long as necessary to achieve the purpose for which they were collected or further processed. On completion of the purpose of processing, personal data shall be erased, destroyed, blocked or anonymised. The legislation also allows the possibility of data processing for the purpose of epidemiological and other studies, educational purposes, medical publications if the patient's identity is not definable.

Requirements on Interoperability of EHRs

But since the subproject documentation on EHRs is just being prepared and the legislation governing the EHR system has not been drafted yet, it is not possible to assess how interoperability of EHRs will be provided.

Links between EHRs and E-prescriptions

Within the activities of the eHealth project, the ePrescription will be one of the first solutions to be used in practice. As the EHR system is yet not in place, the two systems are not linked together at this point.

3. Good practices

At this stage it is impossible to identify possible good legal practices for the development of the EHRs as no national EHR scheme and its related legislation as been developed.

4. Legal barriers

The main legal barrier is that in the field of health records Slovenia entirely relies on paper-era legislation. The main piece of legislation in the field, the healthcare Database Act, is over 13 years old. This legislation does not provide the basis for electronic access to EHRs – it merely prescribes the list of healthcare databases. The legislation therefore does not cover situations that are present in e-services. This barrier should be overcome by adoption of new legislation. However no draft law has yet been published and legal and policy initiative on the deployment of EHRs are at a very early stage.

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List of abbreviations

EHRs	Electronic Health Records
HAD	Healthcare Database Act
IC RS	Information Comissioner of the Republic of Slovenia
PDAAI	Protection of Documents and Archives and Archival Institutions Act
PDPA	Personal Data Protection Act
PRA	Patient Rights Act
PDAAI	Protection of Documents and Archives and Archival Institutions Act

1. General context

1.1. EHR systems in place

In Slovenia there is not yet an EHR system that allows the transfer of health data and their shared access to ensure the continuity of care of the patient. EHRs are set by each health providers that decide how their EHRs systems are designed and implemented.

Slovenia is currently implementing eHealth project (*eZdravje*) including over 20 subprojects, which should be concluded by 2015. The project is implemented by the Ministry of Health (*Ministrstvo za zdravje*) and is partially funded by the European Social Fund (27,042,167 EUR) and partially by the budget of the Ministry of Health (25,967,468 EUR) and other public funds (14,551,000 EUR). One of the components of the project is the establishment of the EHRs (*elektronski zdravstveni zapis –EZZ*).[1]

According to the information on the eHealth project, available at the webpage of the Ministry of Health one of the subprojects is the standardization of the content of the EHR. The aim of this sub-project is to define health data and processes to be included in the Slovenian health informational model to provide for interoperability of the EHRs According to the documentation of the ministry, the standardization of the elements of the EHRs will be implemented in December 2015 when this subproject is to be concluded.[2]

The project also foresees the establishment of a central certified point for storing EHR, which will be fed by the health service provider. The process of creation, access to and update of EHRs shall also be defined.

One of the priorities of establishing of the central EHR is the establishment of the Patient Summary (EHR summary), as experiences in other countries show the necessity of a limited selection of essential health data, which are particularly important for health treatment and shall be available at all times. Such data could be blood group, allergic reactions, addictions, contagious diseases, medications and also disabilities, chronic illness, psycho-social issues, key elements of family and personal anamnesis, vaccinations, etc. In addition to these health data the data, expressing the will of the patient shall also be included, in particular for cases when the patient is not able to express his or her will. The selection of the type of data shall be provided by the medical professionals. According to the Ministry, the establishment of a central EHR system and the process of creation, access to and update of EHRs should have been concluded by July 2011

In order to better involve the patient, the eHealth project also foresees establishment of Personal Healthcare Record (PHR), through which individuals will be able to enter health data themselves, mostly on their life style and monitoring of their own health condition. The selection of data will be made by the medical professionals but the responsibility for creation and update of data will lie on each individual owning the PHR. This subproject of the eHealth was supposed to be concluded shortly after the establishment of a central EHR system.

However, the implementation of the project was seriously delayed and also received a lot of public criticism. In 2013 the Court of Audit of the Republic of Slovenia (*Računsko sodišče Republike Slovenije*) issued an audit report of the project,[3] in which it established that the content of the project is significantly different from the project documentation and that many of the subprojects were significantly changed, and while some were abolished, some new subprojects were introduced. The Court of Audit found that project tasks and responsibilities were not clearly defined and the

[1] Ministry of Health, Project e-Health , http://www.mz.gov.si/si/za_izvajalce_zdrav_storitev/ezdravje/
[2] Ministry of Health, Project e-Health , http://www.mz.gov.si/si/za_izvajalce_zdrav_storitev/ezdravje/
[3] revizijsko poročilo računsko sodišče

implementation was not properly coordinated and supervised. According to the audit report, the Ministry at the end of the audit period (26 September 2013) still has not defined the legal form and the date of establishment of the institution responsible for carrying out the solutions developed within the eHealth project. The court also found that individual subprojects were implemented with significant delays and that the ministry failed to establish an efficient system of monitoring of the implementation. The court also found that the management of the project funds was not successful as the Ministry did not have a comprehensive overview of the project expenditure.

Due to these findings of the Court of Audit, there were concerns whether the data on the eHealth project, available at the webpage of the Ministry were correct. Upon request, the Ministry replied that the EHR subproject is currently in the phase of development and project documentation is being prepared. According to the Ministry, the EHR system will be established in 2015.

1.2. Institutional setting

The national EHR framework has not been established yet and the institutional setting for the EHR scheme has not yet been created. The main institutions involved in the development of the EHR system and the functioning of the current system of health records are:

- The Ministry of Health

The Ministry of Health is responsible for matters relating to healthcare and health insurance, the setting-up of a network of healthcare services and health care activities at the primary, secondary and tertiary levels. Under the current legislation, the Ministry is also in charge of controlling health data systems and is carrying out the eHealth project.

- Institute of Public Health of the Republic of Slovenia (Inštitut za varovanje zdravja Republike Slovenije)

The institute is a central national institution for studying, protecting and increasing the level of health of Slovenia's population through awareness-raising and other preventive measures. The institute offers expert support to state decisions on the national and local level. The Institute is also the data controller of a number of health data filing systems

- Information Commissioner of the Republic of Slovenia (*Informacijski pooblaščenec Republike Slovenije*)

The Information Commissioner is independent body, established for the supervision of both the protection of personal data, as well as access to public information. The Commissioner is performing supervision over the implementation of the provisions of Personal data protection Act (PDPA), (handle cases of complaints, appeals, notifications and other applications, explaining possible breach of law), issuing supervision measures on prohibition to process personal data, anonymization, blocking, erasing or destroying personal data, when established that the data is not processed according to the law) and performing preventive supervision with personal data controllers in public and private sectors.

1.3. Legal setting and future legal development

The EHR project is not yet implemented and there is until now no specific legislation on EHR. The only legislation that applies to EHRs is the one for general records and the Personal Data Protection Act (PDPA) transposing Directive 95/46/EC.

Slovenia is currently still relying on paper-era legislation. In the past there were several attempts to pass legislation that would provide the legal basis for electronic services and exchange of data among different health service providers. Up until now all attempts were not successful, presumably due to the complexity of the field, and the need of substantial financial resources for the implementation of such systems.[4]

According to the Ministry, an expert group for the preparation of the new legal initiative in the field of healthcare databases has been established.[5] The adoption of the new law has also been included in the Government`s Legislative Work Programme, however the draft law has not been prepared yet.

List of relevant national legislation:

- Healthcare Databases Act (HDA) (*Zakon o zbirkah podatkov s področja zdravstvenega varstva*) of 11 July 2000 ;
- Health Care and Health Insurance Act (*Zakon o zdravstvenem varstvu in zdravstvenem zavarovanju*) of 12 February 1992 with subsequent modifications ;
- Patient Rights Act (PRA) (*Zakon o pacientovih pravicah*) of 29 January 2008 ;
- Personal Data Protection Act (PDPA) (*Zakon o varstvu osebnih podatkov*) of 15 July 2004 and subsequent modifications ;
- Protection of Documents and Archives and Archival Institutions Act (PDAAI) (*Zakon o varstvu dokumentarnega in arhivskega gradiva ter arhivih*) of 6 March 2006.

As the legislation providing national legal framework for EHRs does not yet exist, this report will provide information on the current 'paper-era' legal framework. The legislation will most probably be amended with the implementation of the national EHR system and at this moment it is not clear which elements of the current legal framework will be kept in the future EHR system.

[4] Interview with the IC RS on 26 March 2014
[5] Written response of the Ministry of Health

2. Legal requirements applying to EHRs Slovenia

2.1. Health data to be included in EHRs

2.1.1. Main findings

In Slovenia, the EHR national system for shared access has not been implemented yet. The new legislation in the field of healthcare databases is still at very early stages of development and information is not yet available on the health data that will be included in the EHRs once established.[6]

The current legislation in the field of healthcare databases is over 13 years old. Several provisions of this law had to be implemented by regulations. These regulations were however never adopted and the law only contains very general provisions and the list of 75 different databases and its contents.[7] It is not clear, whether all of these databases are necessary and even if they are all being implemented in practice. This current legislation does not give the legal basis for EHRs as there is no overview of the situation at each health care provider and there is no shared access to the data.[8]

The publicly available eHealth project documentation at the Ministry of Health describes EHRs as digitally kept clinical and administrative health information on the entire health care of an individual with required data confidentiality; the EHRs will be based on a shared national platform that will enable interoperability, the development of a patient summary and exchange of e-documentation.[9]

According to the eHealth project documentation, one of the priorities of establishing of the central EHR is the establishment of the Patient Summary (EHR summary), as experiences in other countries show the necessity of a limited selection of essential health data, which are particularly important for health treatment and shall be available at all times.

[6] Written response of the Ministry of Health
[7] Healthcare Databases Act (HDA) (*Zakon o zbirkah podatkov s področja zdravstvenega varstva*) of 11 July 2000
[8] Interview with the IC RS on 26 March 2014
[9] Ministry of Health, Project e-Health , http://www.mz.gov.si/si/za_izvajalce_zdrav_storitev/ezdravje/

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?)	Healthcare Databases Act (HDA), Art. 5	The HDA prescribes the types and the content of individual health care data filing systems/ databases, their purpose, the persons/institutions responsible for submitting data and the method for submitting the data, data controllers and archiving periods. This law is over 13 years old and contains general provisions that have never been implemented through regulations. [10] The HDA prescribes 75 different healthcare databases, each including a different set of data. It is not clear, whether all of these databases are necessary and even if they are all being implemented in practice.[11] The law does not require the health care providers to keep the data in the electronic form. This current legislation does not give the legal basis for EHRs as there is no overview of the situation at each health care provider and there is no shared access to the data.[12] Data sharing among health care providers is limited and it mostly takes place in paper form and in a limited form through the systems of compulsory health insurance. As mentioned above, the Ministry that is implementing the eHealth project is currently developing the project documentation concerning the EHR subproject. However the new legislation that is planned to be adopted to regulate EHRs has not been drafted yet. According to the Ministry, the decision on the content of the future EHRs has not

[10] The 2011 Draft Healthcare Database Law, which was not adopted; assessment of the current situation in the fields of healthcare databases
[11] Ibid.
[12] Interview with the IC RS on 26 March 2014

Questions	Legal reference	Detailed description
		been made, however EU recommendations shall be taken into account.
Are these data restricted to purely medical information (e.g. physical or mental health, well-being)?	Healthcare Databases Act (HDA), Art. 5	The EHR system is yet to be implemented and the relevant legislation has not been drafted and the content of the EHRs, once implemented, is not known at this point. However, the current legislation (see above) prescribes numerous healthcare databases with different content – 53 out of 75 healthcare databases contain personal data. The basic medical database (*Osnovna medicinska dokumentacija*), which is controlled by each healthcare provider has the following content: personal identification number (EMŠO), health insurance number, name, marital status, education, profession, permanent residence address, temporary residence address, phone number, diagnosis, date of contact, planned contacts, the number of the doctor, therapy, referral, the cause for temporary incapacity to work, health insurance status, the cause of treatment, social anamnesis o the family, the plan of healthcare. The Health Card database (*zdravstvena kartica*), controlled by the Ministry of Health and for which the data is submitted by individual healthcare providers, has the following content: personal identification number (EMŠO), health insurance number, name, marital status, education, profession, permanent residence address, temporary residence address, anamnesis, body measurements in different age periods, results of clinical examination, vaccination data, risk factors for development of chronic illnesses, data on allergies, results of laboratory and diagnostic tests, oral health data, diagnosis, injuries and poisonings, disabilities, addictions, data on surgical and non-surgical therapy, date of contact, the cause for temporary incapacity to work, prescribed and issued medical products and technical aids.
Is there a definition of EHR or patient's summary provided in the national legislation?		The publicly available eHealth project documentation at the Ministry of Health describes EHRs as digitally kept clinical and administrative health information on the entire health care of an individual with required data confidentiality; the EHRs will be based on a shared national platform that will enable interoperability, the

Questions	Legal reference	Detailed description
		development of a patient summary and exchange of e-documentation.[13] According to the eHealth project documentation, one of the priorities of establishing of the central EHR is the establishment of the Patient Summary (EHR summary), as experiences in other countries show the necessity of a limited selection of essential health data, which are particularly important for health treatment and shall be available at all times. Such data could be blood group, allergic reactions, addictions, contagious diseases, medications and also disabilities, chronic illness, psycho-social issues, key elements of family and personal anamnesis, vaccinations, etc. In addition to these health data the data, expressing the will of the patient shall also be included, in particular for cases when the patient is not able to express his or her will. The selection of the type of data shall be provided by the medical professionals.
Are there any requirements on the content of EHRs (e.g. detailed requirements on specific health data or general reference to health data)?		As explained above, The EHR system is yet to be implemented and the relevant legislation has not been drafted and the content of the EHRs, once implemented, is not known at this point.
Are there any specific rules on the use of a common terminology or coding system to identify diseases, disorders, symptoms and others?	Healthcare Databases Act (HDA), Art. 10	The HDA stipulates that for the purpose of unified system of healthcare databases, common methodological principles and standards shall apply. On the basis of this provision, the Order establishing uniform methodological principles, common standards and standard operating procedures to ensure uniformity of data collection management system in the field of health care was adopted by the Ministry of Health.[14] In accordance with this order, in Slovenia the Slovenian translation of the Australian modification of the international classification of deseases and other health problems (version 6) and the Slovenian translation of the classification of therapeutical and diagnostical procedures (version 6) are being used. However information is not yet available on whether this codification will be used for the future EHR system.

[13] Ministry of Health, Project e-Health , http://www.mz.gov.si/si/za_izvajalce_zdrav_storitev/ezdravje/

[14] Order establishing uniform methodological principles, common standards and standard operating procedures to ensure uniformity of data collection management system in the field of health care (*Odredba o določitvi enotnih metodoloških načel, enotnih standardov in standardnih postopkov za zagotovitev enotnosti sistema vodenja zbirk podatkov s področja zdravstvenega varstva*) of 12 January 2012.

Questions	Legal reference	Detailed description
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)?		The general rule for collecting patient health data is that either patient consent is required or that collection of certain data is prescribed by the law. In Slovenia the data is mostly collected on the basis of the legal provisions. However, paragraph 6 of Article 4 of the HDA stipulates, that in case of data pertaining to racial, national or other origin, political, religious or other beliefs or sexual conduct, data controllers may only obtain these data (directly from the patient or indirectly from other data controllers) on the basis of the patient's consent.
Are there any specific rules on identification of patients in EHRs?		As explained above, The EHR system is yet to be implemented and the relevant legislation has not been drafted and the rules on identification of patients are not known at this point.
Is there is a specific identification number for eHealth purposes?	Healthcare Databases Act (HDA), Art. 4	As explained above, The EHR system is yet to be implemented and the relevant legislation has not been drafted and the rules on possible identification number are not known at this point. The current legislation stipulates that the data controllers have the right to use the health insurance number that is listed on the Health Card (*zdravstvena kartica*), of each patient, as a connecting link for collection, processing and sharing of data in each of the prescribed healthcare databases.

2.2. Requirements on the institution hosting EHRs data

2.2.1. Main findings

As explained, the EHR system is currently still being developed and there are no specific rules pertaining to EHRs. When the system will be developed, it is possible that specific rules for hosting EHRs will be developed.
There are two main pieces of legislation that govern the issue of hosting and management of electronic records in general:

- The PDAAI is providing the provisions for electronic/digital preservation of data.
- The PDPA stipulates the organizational and technical measures for personal data protection.

In accordance with legislation, person/institution who process and host materials in the digital form, must adopt internal rules in accordance with the provisions of the PDAAI and related implementing regulations (Decree on documentary and archival material custody[15]), uniform technological requirements and rules of profession (e.g. archival profession, information security, etc.). Internal rules may be submitted for confirmation to the National Archives (*Državni arhiv*), which verifies their compliance with the requirements of PDAAI. However, entities governed by public law are obliged to submit their internal rules for confirmation to the National Archives.

No specific permit is necessary to host health data from EHRs However, the hosting institutions are required to register their activity to the National Archives at least eight days before the start of their activity.

The legislation prescribes an extensive minimal list of provisions that should be included in above mentioned internal rules.

According to PDPA security of personal data comprises organisational, technical and logical-technical procedures and measures to protect personal data, and to prevent accidental or deliberate unauthorised destruction, modification or loss of data, and unauthorised processing of such data as prescribed under Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data

[15] Decree on documentary and archival material custody (Uredba o varstvu dokumentarnega in arhivskega gradiva) of 27 July 2006

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?	Personal Data Protection Act (PDPA) Protection of Documents and Archives and Archival Institutions Act (PDAAI).	No specific legislation, only two main general pieces of legislation that govern the issue of hosting and management of electronic records in general. The PDAAI is providing the provisions for electronic/digital preservation of data. The PDPA stipulates the organizational and technical measures for personal data protection.
Is there a need for a specific authorisation or licence to host and process data from EHRs?	Protection of Documents and Archives and Archival Institutions Act (PDAAI)	No specific legislation. The PDAAI provides general rules for institutions hosting electronic data. Art. 18 of the PDAAI requires that any person/institution who hosts data digital form, must adopt internal rules in accordance with the provisions of the PDAAI and related implementing regulations (Decree on documentary and archival material custody[16]), uniform technological requirements and rules of profession (e.g. archival profession, information security, etc.). Internal rules may be submitted for confirmation to the National Archives (*Državni arhiv*), which verifies their compliance with the requirements of PDAAI. However, entities governed by public law are obliged to submit their internal rules for confirmation to the National Archives. The National Archives shall, upon confirmation or later, set a time-limit in which internal rules need to be amended and/or supplemented and submitted for a new confirmation, due to changes in legislation or technological progress. The adoption of the internal rules is necessary for the electronic data to be valid. After the confirmation the National Archives enters the confirmed internal rules in the register of confirmed internal rules. The National Archives shall review the submitted internal rules and shall issue a

[16] Decree on documentary and archival material custody (Uredba o varstvu dokumentarnega in arhivskega gradiva) of 27 July 2006

Questions	Legal reference	Detailed description
		decision confirming or not the accordance of the rules with the relevant legislation. No special permit is necessary for hosting data in electronic form However, the equipment and services providers are required to register their activity with the National Archives at least eight days before the start of their activity. On the basis of the application the National Archives must verify its completeness and order registration of the provider into the register of providers with an administrative decision. The National Archives shall supervise the activities of registered equipment and services providers as well as the implementation of the provisions of the relevant legislation. Providers that wish to gain a higher level of trust from their clients, may additionally acquire accreditation with the National Archives for the equipment or services offered to third parties (optional). You should also briefly mention the rules under the PDPA(?)
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)?		No specific legislation. The PDAAI and the implementing regulations provide general rules. Art. 5 of the Decree on documentary and archival material custody (adopted on the basis of the PDAAI) prescribes an extensive minimal list of provisions that should be included in above described internal rules, including: - Provisions on internal organization, roles, competencies and number and competence of the personnel– tasks and competencies of individual members of the personnel; - Provisions on management and handling of the documents - Provisions on the infrastructure of the information system for storage of the material in digital form, including provisions on the location and premises, personnel; - Provisions on physical security of the infrastructure - access to premises, handling of the hardware etc.

Questions	Legal reference	Detailed description
		- Provisions on software security - Provisions on internal supervision The Decree also prescribes the procedures for hosting data in digital form (actual capture, conversion during capture, capture control, capture registry, etc.) It also prescribes the conditions for ensuring safe long-term storage of materials in digital form: - Safe environment for data storage and functioning of the electronic medium - Access of the data only to authorized persons and physical accessibilities to the data support medium; - Mandatory usage of safe encrypted links when sending sensitive data (personal data, etc) - Appropriate number of backup copies on different locations; - Copying data to new data support medium before deterioration of existing ones; - Constant control of the data support medium; - Other measures for information security. In accordance with the PDAAI, in order to perform their obligations under the law, entities under public law must ensure appropriate material, personnel and financial conditions, and appoint a person to be responsible for carrying out those obligations. Employees dealing with documents must have at least secondary school qualifications and must have passed a qualification test at the competent archival institution. Rules on professional skills of the entities under public law employees and providers of equipment and services dealing with documents provides more detailed provisions on the required professional skils.[17]

[17] Rules on professional skills of the entities under public law employees and providers of equipment and services dealing with documents (Pravilnik o strokovni usposobljenosti uslužbencev javnopravnih oseb ter delavcev ponudnikov storitev, ki delajo z dokumentarnim gradivom)

Questions	Legal reference	Detailed description
		Under Article 24 of the PDPA security of personal data comprises organisational, technical and logical-technical procedures and measures to protect personal data, and to prevent accidental or deliberate unauthorised destruction, modification or loss of data, and unauthorised processing of such data: 1. by protecting premises, equipment and systems software, including input-output units; 2. by protecting software applications used to process personal data; 3. by preventing unauthorised access to personal data during transmission thereof, including transmission via telecommunications means and networks; 4. by ensuring effective methods of blocking, destruction, deletion or anonymisation of personal data; 5. by enabling subsequent determination of when individual personal data were entered into a filing system, used or otherwise processed, and who did so, for the period covered by statutory protection of the rights of an individual due to unauthorised supply or processing of personal data. No information is available on whether this procedure will be kept or a new specific procedure will be adopted for the hosting of EHRs.
In particular, is there any obligation to have the information included in EHRs encrypted?	Decree on documentary and archival material custody, Art. 16 and 22	Among the conditions for ensuring safe long-term storage of materials in digital form, the Decree prescribes mandatory usage of safe encrypted links when sending sensitive data (personal data, etc). At this moment it is not possible to assess whether such obligation will also apply to the future HER system.
Are there any specific auditing requirements for institutions hosting and processing EHRs?	Protection of Documents and Archives and Archival Institutions Act (PDAAI), Art 21	The Protection of Documents and Archives and Archival Institutions Act contains (to some extent) auditing obligations but that apply to all institutions hosting electronic data. Persons/institutions hosting electronic data must monitor the technical measures and internal rules set in place for the adequate hosting of data. Such monitoring must be done internally or externally based on the quantity of data hosted. Any verification should be properly documented. External verification shall be performed by an experienced information system auditor. Verifications of all information systems are performed every two years; and in cases of important data or large quantities of data at least once a year.

Questions	Legal reference	Detailed description

2.3. Patient consent

2.3.1. Main findings

It should be noted that the national EHR system with shared access to health data and its related legislation has not been developed and implemented yet. According to PDPA, personal data processing is allowed only if prescribed by the law or in case of consent of the individual. However, in the public sector (e.g. public health institutions), data processing on the basis of individual's consent is only allowed if specific law prescribes such option – one example is the provision of Article 4 of the HDA, stating that the data pertaining to racial, national or other origin, political, religious or other beliefs or sexual conduct, data controllers may only obtain (directly from the patient or indirectly from other data controllers) on the basis of the patient's consent.

In Slovenia the data is mostly collected on the basis of the legal provisions – the law prescribes which health data is collected and in such case patient consent is not required. According to the Ministry of Health, the same approach will most probably be used once the EHR system is established – the law will prescribe the health data to be included in the EHRs without additional requirement of patient consent.
As the national EHR system has not been established yet, there are no specific any opt-in/opt-out rules for patient consent with regard to processing and sharing of EHRs and concerning cross-border situations.

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?	Patient Rights Act (PRA), Art. 44 Personal Data Protection Act (PDPA), Art. 8 Healthcare Databases Act (HDA), Art. 4	It should be noted that national EHR system with shared access to health data has not been developed yet and that provided information concerns the rules on patient consent in general. According to PDPA, personal data processing is allowed only if prescribed by the law or in case of consent of the individual. However, in the public sector (e.g. public health institutions), data processing on the basis of individual's consent is only allowed if specific law stipulates such option – one example is the provision of Article 4 of the HDA, stating that the data pertaining to racial, national or other origin, political, religious or other beliefs or sexual conduct, data controllers may only obtain (directly from the patient or indirectly from other data controllers) on the basis of the patient's consent. In Slovenia the data is mostly collected on the basis of the legal provisions – the law prescribes which health data is collected and in such case patient consent is not required. According to the Ministry of Health, the same approach will most probably be used once the EHR system is established – the law will prescribe the health data to be included in the EHRs without additional requirement of patient consent..[18] Article 44 of the PRA stipulates that patients' health and other personal data for the purposes of medical treatment can also be processed on the basis of patient consent. If patient's personal data is being processed outside the procedures of medical treatment, processing is only possible on the basis of patient consent. However, paragraph 6 of Article 4 of the HDA stipulates, that in case of data pertaining to racial, national or other origin, political, religious or other beliefs or sexual conduct, data controllers may only obtain these data (directly from the patient or indirectly from other data controllers) on the basis of the patient's written consent.

[18] Written response of the Ministry of Health

Questions	Legal reference	Detailed description
Is a materialised consent needed?	Healthcare Databases Act (HDA), Art. 4 Personal Data Protection Act (PDPA), Art. 8	The rules on patient consent for the creation of EHRs have not been established yet. As for the current legal framework, the only provision requiring patient consent is Paragraph 6 of Article 4 of the HDA which stipulates, that in case of data pertaining to racial, national or other origin, political, religious or other beliefs or sexual conduct, data controllers may only obtain these data (directly from the patient or indirectly from other data controllers) on the basis of the patient's **written** consent. This is the only provision of the HDA enabling data processing on the basis of patient consent. The more general provisions of the PDPA stipulate that personal data may only be processed if the processing of personal data and the personal data being processed are provided by statute (law), or if the personal consent of the individual has been given for the processing of certain personal data. However, in the public sector (e.g. public health institutions), data processing on the basis of individual's consent is only allowed if specific law stipulates such option. According to the PDPA, personal consent is required a voluntary statement of the will of an individual that his personal data may be processed for a specific purpose, and this is given on the basis of information that must be provided to such individual by the data controller pursuant to this Act; personal consent of an individual may be written, oral or some other appropriate consent of the individual. For sensitive personal data (health data) the PDPA prescribes written consent as a rule.
Are there requirements to inform the patient about the purpose of EHRs and the consequences of the consent or withholding consent to create EHRs?	Personal Data Protection Act (PDPA), Art. 8	There are no specific rules regarding EHRs. Under general data protection rules, in cases of processing on the basis of personal consent of the individual, the individual must be informed in advance in writing or in another appropriate manner of the purpose of processing of personal data.
Are there specific national rules on consent from the patient to share data?	Patient Rights Act (PRA), Art. 44	Under PRA the patient consent for sharing of personal data among different healthcare providers is not required, as it is considered that by consenting to medical treatment, the patient also consented to processing of his/her personal

Questions	Legal reference	Detailed description
		data for the purpose of treatment.
Are there any opt-in/opt-out rules for patient consent with regard to processing of EHRs?		There are no particular rules with regard to processing.
Are there any opt-in/opt-out rules for patient consent with regard to sharing of EHRs?		There are no particular rules with regard to sharing.
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?		EHR system with shared access to health data has not been developed yet.
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)?		EHR system with shared access to health data has not been developed yet.
Are there specific rules on patient consent to share data on a cross-border situation?		EHR system with shared access to health data has not been developed yet.

2.4. Creation, access to and update of EHRs

2.4.1. Main findings

As there is not yet national EHR system in place, many of the requested information could not be provided in this section. Currently the only EHR systems are the ones kept by the individual healthcare providers without the purpose of being shared to ensure the continuity of care ; therefore the internal rules of each individual health care provider that has opted for capturing and storing materials in the digital form, apply (please, see section 2.2.)

The currently valid legislation prescribes the types and the content of individual health care data filing systems/ databases, their purpose, the persons/institutions responsible for submitting data and the method for submitting the data, data controllers and archiving periods.

However, the existing legislation clearly stipulates the right of patient to access all medical files and the data pertaining to him/her. When requesting for access, the patient is not required to state the purpose of his/her request and his/her motivation for access cannot be used by the health service provider to prevent or hinder access in any way.

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?	Healthcare Databases Act (HDA), Art. 5 and 8	The HDA prescribes the types and the content of individual health care data filing systems/ databases, their purpose, the persons/institutions responsible for submitting data and the method for submitting the data, data controllers and archiving periods. There is no national EHR system yet in place and the only EHR systems are the ones kept by the individual healthcare providers; therefore the internal rules of each individual health care provider that has opted for capturing and storing materials in the digital form, apply (please, see section 2.2.)
Are there specific national rules on access and update to EHRs?		Please see above.
Are there different categories of access for different health professionals?		Please see above.
Are patients entitled to access their EHRs?	Patient Rights Act (PRA), Art. 41	The national EHR system has not been established yet, however there are national rules on the patient's right to access to his/her medical files. This right is derived from the Constitution of the Republic of Slovenia and is more specifically covered in Article 41 of the PRA. The patient has the right to access and copy without any hindrance his/her medical documentation – the access is possible in the presence of a doctor or any other medical professional. Health care providers are obliged to enable photocopying and other reproduction of the medical files. Access must be enabled immediately or 5 days after the request has been made at the latest. With each individual healthcare provider the patient may request access to medical files maximum twice per month. Healthcare providers may charge material costs of photocopying or other reproduction of the medical files. Although the EHR system has not been established yet, the PRA explicitly states that with the application by analogy of the above described rules, the patient has the right to independent access to his/her EHR and the health care information system data if the health care system provides for that kind of access.

Questions	Legal reference	Detailed description
Can patient have access to all of EHR content?	Patient Rights Act (PRA), Art. 41	The law does not stipulate any limitations concerning access – the patient may access all medical documentations that pertaining to him/her.
Can patient download all or some of EHR content?	Patient Rights Act (PRA), Art. 41	The patient has the right to photocopy or otherwise reproduce the medical files.
Can patient update their record, modify and erase EHR content?	Patient Rights Act (PRA), Art. 41	The patient is not entitled to update records, modify and erase EHR contents, but he/she has the right to make a request to the healthcare provider that his/her comments are added to the records in his/her medical files.
Do different types of health professionals have the same rights to update EHRs?		There is no national EHR system yet in place and the only EHR systems are the ones kept by the individual healthcare providers; therefore the internal rules of each individual health care provider that has opted for capturing and storing materials in the digital form, apply (please, see section 2.2.)
Are there explicit occupational prohibitions? (e.g. insurance companies/occupational physicians…)		There is no national EHR system yet in place and the only EHR systems are the ones kept by the individual healthcare providers; therefore the internal rules of each individual health care provider that has opted for capturing and storing materials in the digital form, apply (please, see section 2.2.) However, on the basis of the Insurance Act (*Zakon o zavarovalništvu*)[19] health insurance companies have access to data on temporary injuries and health condition, types of injuries, duration of treatment and consequences for the patient and the costs of medical treatment.
Are there exceptions to the access requirements (e.g. in case of emergency)?	Healthcare Databases Act (HDA), Art. 8	The HDA stipulates that in case of emergency, with the purpose of protection in cases of life threatening situations, a doctor may access personal data.
Are there any specific rules on identification and authentication for health professionals? *Or are they aggregated?*		There is no national EHR system yet in place and the only EHR systems are the ones kept by the individual healthcare providers; therefore the internal rules of each individual health care provider that has opted for capturing and storing materials in the digital form, apply (please, see section 2.2.)

[19] Insurance Act (*Zakon o zavarovalništvu*) of 27 January 2000, with subsequent modifications.

Questions	Legal reference	Detailed description
Does the patient have the right to know who has accessed to his/her EHRs?	Healthcare Databases Act (HDA), Art. 5 and 8	There is no national EHR system yet in place and the only EHR systems are the ones kept by the individual healthcare providers; therefore the internal rules of each individual health care provider that has opted for capturing and storing materials in the digital form, apply (please, see section 2.2.)
Is there an obligation on health professionals to update EHRs?	Healthcare Databases Act (HDA), Art. 8	The HDA merely stipulates that the data prescribed for each individual healthcare system should be entered at medical examinations and other healthcare services. It further stipulates that the doctor and other healthcare professionals should with their signature verify the results of the examination or other services after each concluded daily work period.
Are there any provisions for accessing data on 'behalf of' and for request for second opinion?	Patient Rights Act (PRA), Art. 41	The PRA stipulates that in addition to the patient him/herself, a person authorised by the patient (and other persons that have the right to access) have the right to access medical files. Under the provisions of the PRA patients have the right to second opinion – in such cases the medical files have to be submitted to the provider of a second opinion.
Is there in place an identification code system for cross-border healthcare purpose?		According to the Ministry of Health there is no an identification code system for cross-border healthcare purpose in place.
Are there any measures that consider access to EHRs from health professionals in another Member State?		According to the Ministry of Health currently no measures that consider access to EHRs from health professionals in another Member State exist.

2.5. Liability

2.5.1. Main findings

No specific liability rules apply for EHRs. There is currently no national EHR system with shared access and no information available on whether there will be legal initiative in Slovenia to set specific liability rules on EHRs.

The laws governing the processing and hosting of personal data in electronic records provide criminal provisions in case of infringement of their requirement.

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?		There are no specific medical liability requirements related to the use of EHRs.
Can patients be held liable for erasing key medical information in EHRs?		As the national EHR system has not been established yet, the patients do not have digital access to electronic health records and cannot erase medical information.
Can physicians be held liable because of input errors?	Healthcare Databases Act (HDA), Art. 9 and 15	The HDA only stipulates that the person in charge of the data is held liable for completeness and accuracy of the data entered in the databases. The updates and changes of each data must be performed in a manner that allows access to the previous content of the data and traceability - so that the information on the person who made the change and the time of change are available.
Can physicians be held liable because they have erased data from the EHRs?	Healthcare Databases Act (HDA), Art. 9 and 15	Please see above.
Are hosting institutions liable in case of defect of their security/software systems?	Protection of Documents and Archives and Archival Institutions Act (PDAAI), Art 92	The institution that does not fulfil obligations and keep the documents in the manner prescribed for legal entities under the public law shall be punished by a fine between 2.986 EUR and 8.345 EUR. The person in charge at the institution can be issued a fine between 417 EUR and 2.086 EUR. Natural person can be issued a fine between 417 EUR and 1.252 EUR.
Are there measures in place to limit the liability risks for health professionals (e.g guidelines, awareness-raising)?		As the national EHR system has not been established yet, no such measures are in place.
Are there liability rules related to breach of access to EHRs (e.g. privacy breach)?	Personal Data Protection Act (PDPA), Art. 93 Patient Rights Act (PRA), Art. 87	In accordance to PDPA a fine from EUR 4.170 to 12.510 shall be imposed for a minor offence on a legal person, sole trader or individual independently performing an activity, if he processes personal data in accordance with this Act and fails to ensure security of personal data. In accordance to PRA a fine from EUR 400 to 4.100 shall be imposed for a minor offence on a legal person – healthcare provider if they do not act in accordance with the law in the case of an unallowed personal data processing.
Is there an obligation on health		As the national EHR system has not been established yet, no such obligations are

Questions	Legal reference	Detailed description
professionals to access EHRs prior to take a decision involving the patient?		in place.
Are there liability rules related to the misuse of secondary use of health data?	Personal Data Protection Act (PDPA), Art. 91	Art. 91 of the PDPA stipulates that a fine from EUR 4.170 to 12.510 shall be imposed for a minor offence on a legal person, sole trader or individual independently performing an activity, if they supply personal data in contravention / do not destroy personal data in accordance / do not publish the results of processing in accordance with Art. 17 PDPA (stipulates that personal data may be further processed for historical, statistical and scientific-research purposes; in such case it should be supplied in an anonymised form, unless otherwise provided by statute or if the individual to whom the personal data relate gave prior written consent for the data to be processed without anonymising; the data supplied shall on completion of processing be destroyed; the results of processing shall be published in anonymised form, unless otherwise provided by law or unless the individual to whom the personal data relate gave written consent for publication in a non-anonymised form or unless written consent for such publication has been given by the heirs to the deceased person).

2.6. Secondary uses and archiving durations

2.6.1. Main findings

The HDA prescribes archiving durations for each of the prescribed healthcare database.

The PDPA stipulates that personal data may only be stored for as long as necessary to achieve the purpose for which they were collected or further processed. On completion of the purpose of processing, personal data shall be erased, destroyed, blocked or anonymised.

The legislation also allows the possibility of data processing for the purpose of epidemiological and other studies, educational purposes, and medical publications if the patient's identity is not identifiable.

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?	Healthcare Databases Act (HDA)	Specific rules on archiving durations of EHRs have not been established yet. For health databases the annex of the HDA prescribes archiving durations for each of the prescribed healthcare database. For example, the archiving durations for the basic medical database (*Osnovna medicinska dokumentacija*), which is controlled by each healthcare provider are as follows: - Dental records: permanent - Patient record and list of illnesess: 10 years after the death of the patient - The rest of the basic medical database: 15 years
Are there different archiving rules for different providers and institutions?	Healthcare Databases Act (HDA)	The HDA only provides different archiving durations for different healthcare databases, but not for different providers and institutions.
Is there an obligation to destroy (…) data at the end of the archiving duration or in case of closure of the EHR?	Personal Data Protection Act (PDPA), Art. 21	Personal data may only be stored for as long as necessary to achieve the purpose for which they were collected or further processed. On completion of the purpose of processing, personal data shall be erased, destroyed, blocked or anonymised, unless pursuant to the statute governing archive materials and archives they are defined as archive material, or unless a statute otherwise provides for an individual type of personal data.
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?		No
Can health data be used for secondary purpose (e.g. epidemiological studies, national statistics...)?	Patient Rights Act (PRA), Art. 44 Personal Data Protection Act (PDPA), Art. 17	The PRA stipulates that there is no requirement for patient consent if the data are processed for the purpose of epidemiological and other studies, educational purposes, medical publications and the patient's identity is not identifiable. This provision allows collection of data from patient records. However they need to be processed in a manner that prevents an external researcher to identify whom these data are pertaining to. The data must be collected and processed in a form that does not allow the connection to the patient. If the research is conducted by the healthcare provider that is collecting the data in question, the anonymisation during the internal research is not necessary – however the published results of the research need to be anonymised.

Questions	Legal reference	Detailed description
Are there health data that cannot be used for secondary use?	Patient Rights Act (PRA), Art. 44 Personal Data Protection Act (PDPA), Art. 17	The PRA does not prescribe such limitations.
Are there specific rules for the secondary use of health data (e.g. no name mentioned, certain health data that cannot be used)?	Patient Rights Act (PRA), Art. 44 Personal Data Protection Act (PDPA), Art. 17	Please, see above.
Does the law say who will be entitled to use and access this data?		No
Is there an opt-in/opt-out system for the secondary uses of eHealth data included in EHRs?		No

2.7. Requirements on interoperability of EHRs

2.7.1. Main findings

Slovenia at this moment does not have a national EHR system and the only EHRs in place are the ones established at individual health care providers, However, these systems are not interoperable , and therefore there currently no shared access to patient EHRS by different health care providers.

The eHealth project documentation provides that one of the goals of the project is to standardize the elements of the EHR – in order to provide for interoperability of EHRs. But since the subproject documentation on EHRs is just being prepared and the legislation governing the EHR system has not been drafted yet, it is not possible to assess how interoperability of EHRs will be provided.

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?		Slovenia at this moment does not have a national EHR system and the only EHRs in place are the ones established at individual health care providers,
Are there any specific rules/standards on the interoperability of EHR?		See above.
Does the law consider or refer to interoperability issues with other Member States systems?		

2.8. Links between EHRs and ePrescriptions

2.8.1. Main findings

Within the activities of the eHealth project, the ePrescription will be one of the first solutions to be used in practice. As the EHR system is yet not in place, the two systems are not linked together at this point.

The ePrescription platform was developed in February 2014. The information systems of the healthcare providers at primary level and the pharmacies were upgraded and thus the delivery of medicines on the basis of e-prescriptions was enabled.[20]

According to the ministry, the process of writing prescription and the delivery of medicines received the necessary information support; by including necessary safety controls of interaction between doctors and pharmacists and additional sources of data, the Ministry believes that ePrescription will contribute to a higher level of security and quality of treatment.

In order to successfully include all pharmacies in the ePrescription system, the Ministry prepared a user manual. The plan is to enable the delivery of medicines on the basis of ePrescriptions by 20 April 2014. At the first stage of implementation – until all pharmacies are integrated into ePrescription system, a parallel system will be used during this phase the healthcare professionals will still issue prescriptions in paper form.

[20] Ministry of Health, *ePrescription*, http://recept.ezdrav.si/?p=149

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?		According to the Ministry of Health, the ePrescription system can be established before the establishment of the EHRs, as the Ministry is currently establishing this system and is in the process of linking all pharmacies into ePrescription.[21]
Can an ePrescription be prescribed to a patient who does not have an EHR?		Please, see above.

- ***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?	Healthcare Databases Act (HDA)	Healthcare professionals only have access to the basic medical database (*Osnovna medicinska dokumentacija*), which is controlled by each healthcare provider and the data available to them via Health Card database (*zdravstvena kartica*).
Can those health professionals write ePrescriptions without having access to EHRs?		Please, see above.

[21] Written response of the Ministry of Health

2.9. Other requirements

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

At this stage it is impossible to identify good practices and legal barriers since there is not yet a system in place that allows the shared access of health data by different health providers and a specific legislation to regulate it. For the moment Slovenia entirely relies on paper-era legislation – the main piece of legislation in the field, the healthcare Database Act, is over 13 years old and has had several issues even at the time of its adoption. This legislation does not provide the basis for electronic access to EHRs – it merely prescribes the list of healthcare databases.[22] This barrier should be overcome by adoption of new legislation. But as the process of preparation of new legislation has come to a halt several times and is again in early stages, it is clear that preparation of the legal foundation for EHRs is a difficult task and it is very questionable, whether the EHRs will in fact be established by 2015.

On the other hand, the absence of efficient legislation does not block the development of EHRs at individual healthcare providers – they are free to decide whether they wish to keep health records in electronic form, which enables interesting solutions of individual health service providers. One of such initiatives is a probationary preparation of EHRs for the patients with lung illnesses at the Hospital Golnik (*Bolnišnica Golnik*). Their EHRs would also include the cross-border aspect on the basis of patient consent. [23]

[22] Interview with the IC RS on 26 March 2014
[23] Interview with the IC RS on 26 March 2014