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 the Czech Republic

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Executive Summary

1. Stage of development of EHRs in the Czech Republic

The Czech Republic has not developed an eHealth system yet. A strategy proposal was prepared by the Department of Informatics in Medicine of the Ministry of Health at the end of 2013 and discussed internally, but it was not yet approved. The stakeholders interviewed refer the low motivation of doctors, patients and state institutions, insufficient legislation and lack of finances as the main risks for a successful implementation of an eHealth system in the Czech Republic. There are however a series of pilot projects, some of which quite successful

2. Summary of legal requirements applying to EHRs

There is no such thing as an EHR system in place in Czech Republic or specific legislation applying to EHRs. Therefore, the general rules from data protection law or health data (i.e. not specific for electronic records but applying to all types of health records) apply.

Health data

There is no express definition of EHR in the Czech legislation, however, the definition of "medical documentation" contained in Article 54 para. 1 of the Act No. 372/2011 Coll., on Health Services covers also documentation in "electronic form". There are also no legal provisions defining what the content of an EHR should be i.e. what must and must not be covered

Requirements on the Institutions hosting EHRs

Article 55 of Act No. 372/2011 Coll., on Health Services sets the conditions that need to be fulfilled for medical documentation to be kept in an electronic form. Apart from this provision, there are no rules setting requirements for the institutions hosting and managing EHRs.

Patient Consent

Czech legislation does not require the patient to give his consent for the processing of his electronic health data. There are also no general rules on consent for health records in paper. Therefore the general rules of the Act on Personal Data Protection are applicable. There is no consent needed for the purposes of health care. This exception follows from Article 9 letter c) Act No. 101/2000 Coll., on Personal Data Protection.

Creation, access to and update of EHRs

There are no specific national rules regarding who can create, access to or update EHRs. Likewise, there are also no specific rules regarding the patient's access to EHRs, however, in this case the provisions of Article 66 para. 4 of the Act No. 372/2011 Coll., on Health Services would apply. There are also no explicit occupational prohibitions but Article 65 para. 2 of the Act No. 372/2011 Coll., on Health Services provides a list of those who can access medical documentation (both in paper and in electronic form).

Liability

The national legislation does not set specific medical liability rules related to the use of EHRs and therefore the general medical liability rules would apply. There are also no specific liability rules for institutions hosting EHRs, although these would be covered by the provisions of Act No. 101/2000 Coll., on Personal Data Protection.

Secondary uses and archiving durations

There are no specific national rules on the archiving durations of EHRs however the general rules on health documentation would apply. There are also no specific rules for the secondary use of health data from EHRs. The existing rules on secondary use of health data from National Health Registers on

certain diseases can be indicative of the approach the legislator will choose for EHRs

Interoperability
There are no centralised nor regional databases of EHRs. The law also does not refer to the interoperability of national EHRs with other Member States EHRs. The current EHRs are set by different health providers or private companies and they are not interoperable

EHRs and ePrescriptions
A ePrescriptions system was established in the Czech Republic in 2008. In practice it is used mostly on voluntary basis.

3. Good practices and legal barriers

There is still no EHR system in place in the Czech Republic or specific legislation on EHRs. Therefore, it was not possible to identify any legal barriers, apart from the absence of specific legislation, or good practices.

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List of abbreviations

CzMA	the Czech Medical Association of J.E.Purkyně
EHRs	Electronic Health Records
IHIS	Institute of Health Information and Statistics
IZIP	System of electronic health records of IZIP Inc.
KSRZIS	Coordination Centre for Departmental Health Information Systems
NHIS	National Health Information System
ÚOOÚ	Office of the Personal Data Protection

1. General context

The Czech Republic has not developed an eHealth system yet. A strategy proposal was prepared by the Department of Informatics in Medicine of the Ministry of Health at the end of 2013[1] and discussed internally, but it was not yet approved. According to all stakeholders interviewed there are no specific rules referring to a eHealth system but rather first attempts to include electronic health vocabulary into legislation.

1.1. EHR systems in place

The first steps towards the implementation of a Czech eHealth system were based not on initiatives by governmental organisations but on the National plan of the eHealth development,[2] which was laid down by the civic association Czech National Forum for eHealth[3] and ICT Union[4] composed of companies in ICT industry. Although at the beginning these activities were not coordinated, in December 2013, five private and civic initiatives formally signed a general memorandum for cooperation in the process of creation of a National Plan of eHealth Development[5].

The Ministry of Health is an important agent for the civic and business associations promoting eHealth, although there remain different opinions between the different groups of health professionals and associations in the health system and the ministry itself on the implementation process. These differences are discussed on different roundtables and seminars organised over the years.

A working group of the Czech Medical Association of J.E.Purkyně (CzMA) focused on eHealth was also established.[6] CzMA is a voluntary independent association of natural persons – physicians, pharmacists and other personnel in healthcare and affiliated fields - or legal entities.

The non-governmental institutions see as key areas of eHealth development:

- National politics, legislation and standards
- Electronic health documentation
- Electronic patient and health worker identification
- Health information network
- Electronic education for citizens and health workers[7]

The stakeholders interviewed refer the low motivation of doctors, patients and state institutions, insufficient legislation and lack of finances as the main risks for a successful implementation of an eHealth system in the Czech Republic.

In order to develop eHealth the Ministry of Health allegedly[8] wants to use existing information systems. According to the proponents of eHealth improvements from above mentioned non-governmental institutions, the newly appointed government of January 2014 did not prioritize the coverage of the Czech Republic by high speed internet and necessary building of access networks of

[1] Interview with the Director of IHIS.
[2] http://www.ictu.cz/fileadmin/docs/Akce_Spis/Pracovni_skupiny/ehealth/ICTU-brozura-eHealth-10-08-16-osvit.pdf
[3] A non-governmental non-profit organization established to support the development of eHealth. Goal of this forum is to focuse especially on expanding and raising of awareness of eHealth, support of development of eHealth and support of communication in the field of eHealth. See: http://www.ehealthforum.cz/en
[4] ICTU is a professional association of companies from the area of information and telecommunication technologies partly represents ICT industry of the Czech Republic and promotes effective ICT use in all spheres of life in the Czech Republic. See http://www.ictu.cz/index.php?id=6
[5] http://www.ehealthforum.cz/files/memorandum_ehealth_2013.pdf
[6] Information based on the interview with the health informatics expert from the Faculty of Electrical Engineering, Czech Technical University in Prague.
[7] http://www.ezdrav.cz/ehealth-v-cr/
[8] Interview with the Director of IHIS as well as http://www.ezdrav.cz/ehealth-v-cr/.

the new generation. There is also no mention about the development of eHealth[9].

A regional eHealth pilot project took place in Vysočina and Karlovy Vary region. This project served to prove the advantages of IT devices for the work of general practitioners, ambulance specialists, hospitals, pharmacies and health emergency. Emergency service in Vysočina region capital Jihlava implemented as the first in the country the system of electronic health records in its ambulance cars.

The flagship of the eHealth should have been[10] the system of electronic health records implemented by IZIP Company for the General Health Insurance[11] clients. They should have compiled together the data about patients, their diagnosis and treatment. The purpose of the system was to prevent the useless repetition of some examinations, the use of several drugs with the same effect as well as to speed up the determination of diagnosis. However, the project, which had been functioning just for the patients of the General Health Insurance (and not for patients of other private insurances in the Czech Republic), had never been really functional.[12] The General Health Insurance has invested 1,8 billion crowns from public fund into this project in 10 years, but the Ministry of Health decided to end the project as it was not used by both the doctors and patients.

Another project which deserves mentioning is the current eHealth project run by the Czech Ministry of Social Affaires– 'eNeschopenka (eSicknote)'. It enables to send the decision on temporary sick leave and announcement of nursing doctor. These documents previously completed by hand can be sent by the doctors via data box or Czech Social Security Administration application in an electronic way since January 2011.

One of the more successful projects is ePACS[13]. It is a system enabling the exchange of photographic documentation between particular facilities in electronic form. A project that started between 3 Prague hospitals now connects more than 200 entities in the health system.

A project on ePrescription is in place for several years supervised by the State Institute for Drugs Control,[14] but it is rarely used in the practice according to the stakeholders.[15]

1.2. Institutional setting

The **Ministry of Health** is responsible for setting the healthcare policy agenda, supervising the health system and health legislation. The Ministry also administers some of the healthcare institutions and bodies.

The '**Coordination Centre for Departmental Health Information Systems (KSRZIS)**' ensures the implementation, development and operation of health information systems. It operates under the direct supervision of the Ministry of Health. It is one of the institution that theoretically could administer a future EHR system according to stakeholders interviewed.[16]

The **Institute of Health Information and Statistics (IHIS)** of the Czech Republic is an

[9] http://www.ezdrav.cz/ehealth-v-cr/
[10] Interview with the Director of IHIS, http://www.ezdrav.cz/ehealth-v-cr/
[11] With more than 6.5 million clients, General Health Insurance is the biggest health insurance company in the Czech Republic. VZP ČR has been operating for over 15 years and has been one of the basic pillars of the Czech health care system for a long time. http://www.vzp.cz/en/index.php
[12] This project has been many times evaluated among the experts as well as in the media as a total failure. Interviews with all stakeholders, dozens of critical articles from the Czech press (such as here in a respectable economic media with a title: Dysfunctional IZIP project stops, minister Heger wants to turn to the police: http://ekonom.ihned.cz/c1-55820760-nefunkcni-izip-konci-ministr-heger-se-chce-obratit-na-policii) or general summary at http://www.ezdrav.cz/ehealth-v-cr/.
[13] http://www.epacs.cz/
[14] http://www.sukl.cz/erecept
[15] Interview with the health informatics expert from the Faculty of Electrical Engineering, Czech Technical University in Prague.
[16] Interview with the Director of IHIS

organisational component of the State, functioning under the supervision of the Ministry of Health. The basic purpose and objective of IHIS is the management and coordination of tasks of the 'National Health Information System (NHIS)', including activities related to the development and improvement of the NHIS aimed at the collection and corroboration of health information, management of national health registers, provision of information in the extent determined by legal acts an in respect of the personal data protection rules, as well as the use of information in the frame of health research.

The **Office of Data Protection** has an overall competence over the processing of personal data.

1.3. Legal setting and future legal development

There is no specific legislation on EHRs and therefore the more general rules would apply. These stem from data protection legislation, health legislation and liability rules of administrative and criminal nature.

As mentioned above, a strategy proposal was prepared by the Department of Informatics in Medicine of the Ministry of Health at the end of 2013 and discussed internally, but it was not yet approved.

List of relevant national legislation:

- Act No. 372/2011 Coll., on Health Services
- Act No. 101/2000 Coll., on Personal Data Protection
- Act No. 378/2007 Coll., on Drugs
- Bylaw No. 98/2012 Coll., on Medical Documentation

2. Legal requirements applying to EHRs Czech Republic

2.1. Health data to be included in EHRs

2.1.1. Main findings

There is no such thing as an EHR system in place in Czech Republic or specific legislation applying to EHRs. A strategy proposal was prepared by the Department of Informatics in Medicine of the Ministry of Health at the end of 2013; however this document has not been published yet. There is no express definition of EHR in the Czech legislation, however, the definition of "medical documentation" contained in Article 54 para. 1 of the Act No. 372/2011 Coll., on Health Services covers also documentation in "electronic form". There are also no legal provisions defining what the content of an EHR should be i.e. what must and must not be covered

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?)		The Czech Republic has not developed an eHealth system yet. According to all stakeholders interviewed there are no specific rules referring to a eHealth system but rather first attempts to include electronic health vocabulary into legislation. A strategy proposal was prepared by the Department of Informatics in Medicine of the Ministry of Health at the end of 2013[17], however this document has not been published yet.
Are these data restricted to purely medical information (e.g. physical or mental health, well-being)?		According to the additional information acquired from interviews with stakeholders[18] there are different data stored in hospitals due to differences in software systems and solutions provided by different companies to particular hospitals. These data concern only medical information.
Is there a definition of EHR or patient's summary provided in the national legislation?	Article 54 para. 1 of the Act No. 372/2011 Coll., on Health Services	No definition was identified. It should be noted however that according to Article 54 para. 1 of the Act No. 372/2011 Coll., on Health Services, medical documentation can be registered in paper or electronic form or in a combination of the two. According to the law, "electronic form" means that medical documentation is taken, processed, stored and intermediated in digital form with the use of information technologies.
Are there any requirements on the content of EHRs (e.g. detailed requirements on specific health data or general reference to health data)?		None identified.
Are there any specific rules on the use of a common terminology or coding system to identify diseases, disorders, symptoms and others?		None identified.
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)?		There are no specific national rules prescribing different categories of health data with different levels of confidentiality.

[17] Interview with the Director of IHIS.
[18] Namely with the health informatics expert from the Faculty of Electrical Engineering, Czech Technical University in Prague.

Questions	Legal reference	Detailed description
Are there any specific rules on identification of patients in EHRs?		None identified.
Is there a specific identification number for eHealth purposes?		There is no specific identification number just for eHealth purposes.

2.2. Requirements on the institution hosting EHRs data

2.2.1. Main findings

Although there is no HER system in place in Czech Republic or specific legislation regulating EHRs, Article 55 of Act No. 372/2011 Coll., on Health Services sets the conditions that need to be fulfilled for medical documentation to be kept in an electronic form. Apart from this provision, there are no rules setting requirements for the institutions hosting and managing EHRs.

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?	Article 55 of Act No. 372/2011 Coll., on Health Services	Article 55 of Act No. 372/2011 Coll., on Health Services lays down the conditions for keeping medical documentation in an electronic form. The technical means used for records' storage in electronic form should ensure that it is not possible to modify data stored in the data entries and that such data is accessible remotely. Copies for long term preservation are created at least once a year.
Is there a need for a specific authorisation or licence to host and process data from EHRs?		There is no specific authorisation or license to host and process data from EHRs.
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)?		There are no specific obligations that apply to institutions hosting and managing data from EHRs.
In particular, is there any obligation to have the information included in EHRs encrypted?		None identified.
Are there any specific auditing requirements for institutions hosting and processing EHRs?		None identified.

2.3. Patient consent

2.3.1. Main findings

Czech legislation does not require the patient to give his consent for the processing of his electronic health data. There are also no general rules on consent for health records in paper. Therefore the general rules of the Act on Personal Data Protection are applicable. There is no consent needed for the purposes of health care. This exception follows from Article 9 letter c) Act No. 101/2000 Coll., on Personal Data Protection. This interpretation was confirmed by the Office for the Personal Data Protection.[19]

[19] Written response of the legal experts of the Office for the Personal Data Protection.

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?		None identified. There is no consent needed for the purposes of health care (please see below).
Is a materialised consent needed?		There is no consent needed for the purposes of health care (please see below).
Are there requirements to inform the patient about the purpose of EHRs and the consequences of the consent or withholding consent to create EHRs?		There is no consent needed for the purposes of health care (please see below).
Are there specific national rules on consent from the patient to share data?	Article 9 letter c) of the Act No. 101/2000 Coll., on Personal Data Protection	There are no specific national rules on consent from the patient to set-up EHRs and therefore the general rules of the Act on Personal Data Protection are applicable. According to Office of the Personal Data Protection the consent of the data subject will be necessary solely in the case where the data is used for other than the immediate medical care. If the data are used solely for the purpose of medical care, it is not necessary to have the consent of data subjects.[20] According to Article 9 of the Act No. 101/2000 Coll., on Personal Data Protection, sensitive data may be processed only if the processing in question is in relation with ensuring health care, public health protection, health insurance, and the exercise of public administration in the field of the health sector pursuant to a special Act, or it is related to assessment of health in other cases provided by a special Act (i.e. Act on Health Services for the area of health care).
Are there any opt-in/opt-out rules for patient consent with regard to processing of EHRs?		There is no consent needed for the purposes of health care (please see below).
Are there any opt-in/opt-out rules for patient consent with regard to sharing of EHRs?		There is no consent needed for the purposes of health care (please see below).
Are there requirements to inform the patient about the purpose of EHRs and the consequences of consent or withholding consent on the sharing of		There is no consent needed for the purposes of health care (please see below).

[20] Written response of the legal experts of the Office for the Personal Data Protection.

Questions	Legal reference	Detailed description
EHRs?		
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)?		There are no specific national rules on consent from the patient to EHRs being accessed by a health practitioner or health institution outside of the Member State.
Are there specific rules on patient consent to share data on a cross-border situation?		None identified.

2.4. Creation, access to and update of EHRs

2.4.1. Main findings

There is no such thing as an EHR system in place in Czech Republic or specific legislation applying to EHRs. There are no specific national rules regarding who can create, access to or update EHRs. Likewise, there are also no specific rules regarding the patient's access to EHRs, however, in this case the provisions of Article 66 para. 4 of the Act No. 372/2011 Coll., on Health Services would apply. There are also no explicit occupational prohibitions but Article 65 para. 2 of the Act No. 372/2011 Coll., on Health Services provides a list of those who can access medical documentation (both in paper and in electronic form).

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?		There are no specific national rules regarding who can create EHRs and where can these be created.
Are there specific national rules on access and update to EHRs?		There are no specific national rules regarding who can access and update EHRs.
Are there different categories of access for different health professionals?		No
Are patients entitled to access their EHRs?	Article 66 para. 4 of the Act No. 372/2011 Coll., on Health Services	In case the medical documentation is kept only in electronic form, the patient or another person authorised according to Article 65 has the right to look via remote access or to acquire its copy.
Can patient have access to all of EHR content?		There are no specific national rules regarding the extent of the patient's access to EHRs. However, Article 66 para. 4 of the Act No. 372/2011 Coll., on Health Services, which would apply to medical data in electronic form, does not expressly exclude the access to specific types of information, referring only to "medical documentation".
Can patient download all or some of EHR content?	Article 66 para. 4 of the Act No. 372/2011 Coll., on Health Service	There are no specific national rules regarding the extent of the patient's access to EHRs. However, Article 66 para. 4 of the Act No. 372/2011 Coll., on Health Services, which would apply to medical data in electronic form, does not expressly exclude the access to specific types of information, referring only to "medical documentation". The patient has the right to acquire a copy of this information.
Can patient update their record, modify and erase EHR content?		No explicit rules have been found.
Do different types of health professionals have the same rights to update EHRs?		No explicit rules have been found on EHR updating rights.
Are there explicit occupational prohibitions? (e.g. insurance companies/occupational physicians…)		There are no explicit occupational prohibitions but Article 65 para. 2 provides a list of those who can access medical documentation (both in paper and in electronic form). These are health professionals and authorized personnel of the healthcare providers.
Are there exceptions to the access requirements (e.g. in case of		No explicit rules have been found.

Questions	Legal reference	Detailed description
emergency)?		
Are there any specific rules on identification and authentication for health professionals? *Or are they aggregated?*		None identified.
Does the patient have the right to know who has accessed to his/her EHRs?		No explicit rules have been found.
Is there an obligation on health professionals to update EHRs?		No explicit rules have been found.
Are there any provisions for accessing data on 'behalf of' and for request for second opinion?		No explicit rules have been found.
Is there in place an identification code system for cross-border healthcare purpose?		None identified.
Are there any measures that consider access to EHRs from health professionals in another Member State?		None identified.

2.5. Liability

2.5.1. Main findings

The national legislation does not set specific medical liability rules related to the use of EHRs and therefore the general medical liability rules would apply. There are also no specific liability rules for institutions hosting EHRs, although these would be covered by the provisions of Act No. 101/2000 Coll., on Personal Data Protection.

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?		The national legislation does not set specific medical liability rules related to the use of EHRs and therefore the general medical liability rules would apply. These include liability for violation of the duty to maintain secrecy in relation to health services pursuant to Article 51 para. 1 of the Act 372/2011 Coll., on health services.
Can patients be held liable for erasing key medical information in EHRs?		No explicit rules have been found.
Can physicians be held liable because of input errors?		There are no express rules on the liability of physicians because of input of errors when including information into medical records both electronic and paper ones. However, inputting information in an erroneous way (whether this input was negligent, reckless, or intentional) could be considered a professional fault triggering medical liability.
Can physicians be held liable because they have erased data from the EHRs?		There are no specific rules on the liability of physicians for the erasure of data from the EHRs. However, withholding information necessary for an adequate provision of health services could be considered a professional fault triggering medical liability.
Are hosting institutions liable in case of defect of their security/software systems?	Articles 13 and 44 of the Act No. 101/2000 Coll., on Personal Data Protection	According to the Article 13 the controller and the processor shall be obliged to adopt measures preventing unauthorised or accidental access to personal data, their alteration, destruction or loss, unauthorised transmission, other unauthorised processing, as well as other misuse of personal data. This obligation shall remain valid after the termination of the processing of personal data. Pursuant to Article 44 para. 2 the natural person with responsibility in the control and process of data commits an offence if s/he fails to adopt or implement measures for ensuring security of personal data processing (Article 13). According to Article 44 para. 5 a fine up to CZK 1 000 000 (EUR 37 000) may be imposed for an offence pursuant to para. 2.
Are there measures in place to limit the liability risks for health professionals (e.g guidelines, awareness-raising)?		None identified.
Are there liability rules related to breach of access to EHRs (e.g. privacy breach)?		None identified.
Is there an obligation on health		None identified.

Questions	Legal reference	Detailed description
professionals to access EHRs prior to take a decision involving the patient?		
Are there liability rules related to the misuse of secondary use of health data?	Article 5 and Article 44 of the Act No. 101/2000 Coll., on Personal Data Protection	There are no specific liability rules related to the misuse of secondary use of health data. Therefore the rules of the Act on Personal Data Protection would apply. According to Article 5 para. 1 d) the controller shall collect personal data corresponding exclusively to the specified purpose and in an extent that is necessary for fulfilment of the specified purpose. A fine up to CZK 1,000,000 (EUR 37 000) may be imposed for an offence pursuant to this Article.

2.6. Secondary uses and archiving durations

2.6.1. Main findings

There are no specific national rules on the archiving durations of EHRs however the general rules on health documentation would apply. There are also no specific rules for the secondary use of health data from EHRs. The existing rules on secondary use of health data from National Health Registers on certain diseases can be indicative of the approach the legislator will choose for EHRs.

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?		None identified, however the general rules on health documentation would apply (please see below).
Are there different archiving rules for different providers and institutions?	bylaw No. 98/2012 Coll., on Health Documentation	There are general rules for archiving of medical documentation and these would also apply to EHRs. Supplement No. 3 of the bylaw No. 98/2012 Coll., on Health Documentation lays down different rules for archiving medical documentation. There are different archiving period for different type of health care providers as 10 years for general practitioner or pediatrist, 5 years for ambulance care, 40 years for cases of accommodation in hospitals etc. In case there is no specific mention in this Supplement No. 3 of the bylaw, a general rule in Article 5 para. 2 of the bylaw says that it is kept for 5 years.
Is there an obligation to destroy data at the end of the archiving duration or in case of closure of the EHR?	bylaw No. 98/2012 Coll., on Health Documentation	Supplement No. 2 of this bylaw specifies the proceedings on destroying medical documentation. There is an obligation in Article 6 para. 2 of this supplement to destroy the documentation proposed for destruction marked by letter "S" after the archiving period is over. Medical documentation marked by letter "V" should be assessed firstly if there is a need to preserve it as a whole or in part. The parts that are assessed as not important for preservation should be destroyed.
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?		None identified.
Can health data be used for secondary purpose (e.g. epidemiological studies, national statistics...)?		There are no rules on EHRS. *However, the following might be relevant:* There are data collected in National Health Registers on certain diseases which can be provided for statistical and scientific purposes by the Ministry of Health or authorised legal person, but only in anonymous form.
Are there health data that cannot be used for secondary use?		The law does not refer expressly to any type of data that cannot be used for secondary uses.
Are there specific rules for the secondary use of health data (e.g. no name mentioned, certain health data that cannot be used)?		There are no rules on EHRS. *However, the following might be relevant:* The data from National Health Registers provided for statistical and scientific purposes should be used in anonymous form.

Questions	Legal reference	Detailed description
Does the law say who will be entitled to use and access this data?		There are no rules on EHRS. *However, the following might be relevant:* The access to non-anonymous data according to Article 73 para. 2 shall have only the person which inserts data and then the appointed representative of the data administrator, which is IHIS or a representative of KSRZIS which process the data based on agreement.
Is there an opt-in/opt-out system for the secondary uses of eHealth data included in EHRs?		None identified.

2.7. Requirements on interoperability of EHRs

2.7.1. Main findings

There are no centralised nor regional databases of EHRs. The law also does not refer to the interoperability of national EHRs with other Member States EHRs. The current EHRs are set by different health providers or private companies and they are not interoperable, which was a subject of criticism by stakeholders interviewed[21]. There is currently no legal initiative to oblige them to be interoperable.

[21] Interview with the Director of IHIS and with the health informatics expert from the Faculty of Electrical Engineering, Czech Technical University in Prague

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?		None identified.
Are there any specific rules/standards on the interoperability of EHR?		None identified.
Does the law consider or refer to interoperability issues with other Member States systems?		None identified.

2.8. Links between EHRs and ePrescriptions

2.8.1. Main findings

A ePrescriptions system was established in the Czech Republic in 2008. In practice it is used mostly on voluntary basis.

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?		The ePrescription system is still not in full operation and there is no such thing as an EHR system at the time being.
Can an ePrescription be prescribed to a patient who does not have an EHR?		The ePrescription system is still not in full operation and there is no such thing as an EHR system at the time being.

- ***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?		The ePrescription system is still not in full operation and there is no such thing as an EHR system at the time being.
Can those health professionals write ePrescriptions without having access to EHRs?		The ePrescription system is still not in full operation and there is no such thing as an EHR system at the time being.

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

There is still no EHR system in place in the Czech Republic or specific legislation on EHRs. Therefore, it was not possible to identify any legal barriers, apart from the absence of specific legislation, or good practices.