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 Finland

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Executive Summary

1. Stage of development of EHRs in Finland

In the Finnish health care, national electronic data system services are currently under development and implementation. Such national data system services are called as "*Kanta"* services ("Kanta"-palvelut) and include:

- ePrescription;
- medicine database;
- data repository;
- patient data management service (including for example the most relevant EHRs derived from the national data repository); and
- electronic portal for patients ("Omakanta").

Kanta as such is not an EHR system but a data transmission and archiving service. Kanta does not replace regional EHR systems, but health care units joining Kanta services must ensure interoperability of their EHR system with Kanta services.

The core functions of Kanta are already in use but other services are currently under implementation. Implementation occurs in phases. According to Act on EHRs, public health care service providers (e.g municipalities) are obliged to join the national data system services (latest on 1 September 2014). Private health care service providers are obliged to join the national data system services, if the long-term storage of their health records is carried out electronically (latest on 1 September 2015).[1] Also ePrescription is used.

Kela (Finnish Social Insurance Institution, "Kansaneläkelaitos") is responsible for technical implementation and maintenance of Kanta services. Kela implements Kanta services in collaboration with health care service providers, health record system providers and health care authorities.

The main regulation governing EHRs in Finland is the Act on EHRs[2]. In addition, Decree on National EHR System Services specifically regulates EHRs. Also other general legislation relating for example to health care, health records and data protection are relevant to EHRs, including both general and specific provisions applicable to EHRs.

2. Summary of legal requirements applying to EHRs

- *Health data included in EHRs*: The main rule (and the aim) is that all original copies of health records are recorded to the national data repository by health care service providers who are connected to Kanta services. However, in the current transition phase this aim will not yet be met, and exceptions to the main rule (to narrow down the required content of EHRs) are regulated to enable implementation of the national data repository in phases.
- *Requirements on the institution that hosts EHRs; interoperability of data requirements*: New provisions have recently been added to the Act on EHRs concerning essential requirements of health care data systems, requirements relating to interoperability, information security, data protection and functionality.
- *Consent:* According to Kanta website (www.kanta.fi), a patient does not have a right to forbid storing his/her EHRs in the national patient data repository after the health care unit in question has started using the repository. As regards to sharing health data, the basic rule of thumb is that health data may not be shared without a written consent of the patient. Also

[1] Details of transition phases are set forth in Decree on National EHR System Services.
[2] After the completion of report, the Act on EHR was amended with effect as of 1 April 2014.

sharing of EHRs between health care service providers connected to the national data system services is subject to patient's consent (subject to certain exceptions). Once the consent is given, the consent covers all EHRs in the national data repository. The patient may, however, prohibit sharing of specific EHRs as determined by the patient. The consent (as well as any prohibitions) is given by a document signed by the patient or via an electronic portal ("Omakanta").

- *Creation, access to and update of EHRs:* EHR systems must include a management system for user rights, through which user rights to EHRs and different functions of the EHR system are specified for each user on the basis of his/her duties. The user must be identified in a reliable way, including authentication.
- *Liability:* The Finnish legislation does not set specific medical liability requirements (e.g relating to medical malpractice) related to the use/non-use of EHRs. However, specific provisions are set forth for example in relation to responsibility over accuracy of EHRs.
- *Secondary use and archiving duration:* Archiving durations are specified in detail for different groups of health records, based on their nature, in Decree on Health Records (applicable both to physical and electronic health records). Health data may be used for secondary purposes such as historical, scientific or statistical research subject to certain conditions set forth in Data Protection Act.
- *Links between EHRS and ePrescriptions:* ePrescription service is part of Kanta services. Prescription of ePrescriptions has required use of EHR system. In a recent legislative reform it has been enacted that Kela shall, at the latest on 1 January 2017, implement a service that enables prescribing ePrescriptions also by using Internet browser and portable devices.

3. Good practices

[N/A]

4. Legal barriers

Certain features are identified as specific to the Finnish EHRs, for example:

- Patients are identified by their personal identity code ("henkilötunnus" or "HETU"), which is a national general identification code. The Finnish EHR system is based on using this national code for identification.
- Electronic signatures are used in the processing, transfer and storing of EHRs.

It is recognised that various issues, also described in this report, would need to be considered in more detail as regards to cross-border transfer of EHRs (for example the scope of patient's consent, responsibility over preparation of "patient's summary" and the right / obligation to archive EHRs).

As regards to medicine databases, it is already recognised that different countries have different kinds of databases (for example different names of medicinal products), which leads to certain challenges.

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List of abbreviations

EHRs	Electronic Health Records
Kela	Finnish Social Insurance Institution ("Kansaneläkelaitos")
Valvira	National Supervisory Authority for Welfare and Health ("Sosiaali- ja terveysalan lupa- ja valvontavirasto")
Act on EHRs	Act on Electronic Processing of Client Data in Social and Health Care
Decree on Health Records	Decree issued by the Ministry of Social Affairs and Health on Health Records
Decree on National EHR System Services	Decree issued by the Ministry of Social Affairs and Health on National Health Care Data System Services

1. General context

1.1. EHR systems in place

The national health care data system services are called "*Kanta*" services ("Kanta-palvelut") and include:

- ePrescription;
- medicine database;
- data repository;
- patient data management service (including for example the most relevant EHRs derived from the national data repository); and
- electronic portal for patients ("Omakanta").

Kanta as such is not an EHR system but a data transmission and archiving service. Kanta does not replace regional EHR systems, but health care units joining Kanta services must ensure interoperability of their EHR system with Kanta services.

The core functions of Kanta are already in use but other services are currently being implemented. Implementation occurs in phases. The patient data repository is a service in which healthcare units enter patient records from their own data systems in a secure way and which is being developed in stages. Therefore the information will accumulate in the archive gradually, as the use of the archive becomes more widespread. According to the Act on EHRs, public health care service providers (e.g. municipalities) are obliged to join the national data system services (at the latest on 1 September 2014). Private health care service providers are obliged to join the national data system services, if the long-term storage of their health records is carried out electronically (at the latest on 1 September 2015).[3]

Also ePrescription is already used. In the public health care the usage of ePrescriptions is over 90 %. For all prescriptions, including private health care providers, the usage of ePrescriptions is estimated around 70 %. Private health care providers will have to adopt the Kanta services and prescribe only ePrescriptions from 31 December 2014 if the amount of prescriptions is more than 5000 prescriptions per year, and from 31 December 2016 when there are less than 5000 prescriptions per year.

1.2. Institutional setting

The Ministry of Social Affairs and Health is responsible for general planning, directing and supervising the processing of EHRs and related data management.

The National Institute for Health and Welfare is responsible for planning, directing and following the processing of EHRs as well as related data management and national data system services.

The Data Protection Ombudsman has the competence for data protection issues.

Regional State Administrative Agencies have certain controlling and supervising-related competences in their regions.

Kela is responsible for technical implementation and maintenance of the Kanta services. Kela implements the Kanta services in collaboration with health care service providers, health record system providers and health care authorities. Kela is also responsible for data protection and data security of its service. Kela shall take actions in case of illegal processing of health records.

[3] Details of transition phases are set forth in Decree on National EHR System Services.

In addition, for example the following authorities are relevant:

- Population Register Centre (e.g. authentication and identification; data protection and data security of its service)
- Information security inspection body (e.g. assessment of data security and data protection of data systems)
- Valvira (e.g. access rights to national health care data system services; data protection and data security of its service; supervision and enhancement of conformance with requirements of data systems; inspections)

1.3. Legal setting and future legal development

The main and specific regulation governing EHRs in Finland is the Act on EHRs ("*Laki sosiaali- ja terveydenhuollon asiakastietojen sähköisestä käsittelystä*", 159/2007)[4]. Certain provisions of the said Act only govern EHRs in the national data system services. Certain provisions governing EHR systems differ based on whether the data system is connected to Kanta or not. Certain provisions govern all EHRs and EHR systems (whether or not connected to Kanta).

In addition, the Decree on National EHR System Services ("*Sosiaali- ja terveysministeriön asetus terveydenhuollon valtakunnallisista tietojärjestelmäpalveluista*", 165/2012) specifically regulates EHRs.

The Act on ePrescription ("*Laki sähköisestä lääkemääräyksestä*", 61/2007)[5] is the specific Act governing ePrescriptions.

Also for example the following general legislation relating, among others, to health care, health records and data protection is relevant in relation to EHRs, as it includes both general and specific provisions applicable to EHRs:

- Decree on Health Records ("*Sosiaali- ja terveysministeriön asetus potilasasiakirjoista*", 298/2009)
- Act on Position and Rights of a Patient ("*Laki potilaan asemasta ja oikeuksista*", 785/1992)
- Act on Health Care ("*Terveydenhuoltolaki*", 1326/2010)
- Data Protection Act ("*Henkilötietolaki*", 523/1999)
- Act on Population Information System and Certification Services of the Population Register Centre ("*Laki väestötietojärjestelmästä ja Väestörekisterikeskuksen varmennepalveluista*", 661/2009)
- Act on National Person Data Files in Health Care ("*Laki terveydenhuollon valtakunnallisista henkilörekistereistä*", 556/1989)

[4] After the completion of report, the Act on EHR was amended with effect as of 1 April 2014.
[5] After the completion of report, the Act on ePrescriptions was amended with effect as of 1 April 2014.

2. Legal requirements applying to EHRs in Finland

2.1. Health data to be included in EHRs

2.1.1. Main findings

The main rule (and objective) is that all original copies of health records are transmitted to the national data repository by health care service providers who have joined the national data system services.

However, at least during the transition period when Kanta services are being taken into use, this objective will not yet be achieved. The Decree on National EHR System Services includes a list of data that does not (yet) have to be recorded in the national data repository. The purpose of this list of exceptions is to enable implementing the national data repository in phases so that in the first stage the most essential data is recorded and later more data is recorded (even the data in the list of exceptions may already be recorded in the national data repository, but there is no obligation to do so).

In addition, the Decree on National EHR System Services includes a list of data that is essential for the health care of a patient. Such data will be visible via the patient data management service to health care service providers (subject to patient's consent). Such essential data is collected from the national data repository.

2.1.2. Table on health data

Requirements on health data to be included in EHRS		
Questions	**Legal reference**	**Detailed description**
Are there specific rules on the content of EHRs? (or regional provisions, agreements, plans?)	Sec. 14 a and 15 of Act on EHRs Sec. 2 of Act on Position and Rights of a Patient E.g. Sec. 2 of Decree on Health Records Sec. 2 of Decree on National EHR System Services	The main rule (and objective) is that health care service providers who have joined the national data system services must transmit *all original copies of health records*, which are produced after joining the said services, to the national data repository.[6] According to the general definition set forth in the Act on Position and Rights of a Patient, *health records* mean documents or technical recordings used, created or appeared in organising and carrying out the treatment of a patient containing data relating to his/her state of health or other personal data. The content of health records is further detailed in the Decree on Health Records. In accordance with the above-said, the content of EHRs is mainly determined based on general health records -related legislation (see specific provisions on the content of EHRs below). However, the Decree on National EHR System Services includes a list of exceptions to the main rule. The purpose of this list of exceptions is to enable implementing the national data repository in phases so that in the first stage the most essential data is recorded and later more data are recorded (even the listed data may be recorded to the data repository, but there is no obligation to do so). In addition, the Decree on National EHR System Services includes a list of data that are essential for the health care of a patient.[7] Such data must be visible via the patient data management service (to such health care units that have a right to access such data for example on the basis of the patient's consent). Such data are collected from the national data repository.
Are these data restricted to purely medical information (e.g. physical or mental health, well-being)?		Also 'other personal data' may be included. See above; detailed list of data is described in Decree on Health Records, with the exceptions of the Decree on National EHR System Services.
Is there a definition of EHR or patient's summary provided in the		See above; the Finnish legislation does not directly define "EHR" but a reference is made to the general definition of health records.

[6] In addition to health records, also other documents relating to data management and organising health care may be stored in the data repository.
[7] Such essential data may also include data that is essential for services relating to the health care of a patient (Sec. 14 a of Act on EHRs).

Requirements on health data to be included in EHRS		
Questions	**Legal reference**	**Detailed description**
national legislation?		
Are there any requirements on the content of EHRs (e.g. detailed requirements on specific health data or general reference to health data)?		See above, first question.
Are there any specific rules on the use of a common terminology or coding system to identify diseases, disorders, symptoms and others?	Sec. 7 of Decree on Health Records Sec. 14 of Act on EHRs	EHRs recorded in the national data repository must include markings in accordance with the coding service. The National Institute for Health and Welfare is responsible for the content of the coding service, whereas Kela is responsible for the technical implementation of the said service. The coding service includes all codes needed for processing EHRs via the national data system services.
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)?	Sec. 4 of Decree on Health Records Sec. 6 of Act on EHRs	EHRs requiring special protection (such as certain psychiatry or genetics-related recordings) must be protected by the health care service provider with a separate confirmation request.
Are there any specific rules on identification of patients in EHRs?	Sec. 8 of Act on EHRs	Patients must be identified in a reliable way.
Is there is a specific identification number for eHealth purposes?		Patients are identified by their personal identity code ("*henkilötunnus*" or "HETU", a national general identification code in Finland).

2.2. Requirements on the institution hosting EHRs data

2.2.1. Main findings

New provisions have recently been added to the Act on EHRs regarding essential requirements of health care data systems. Such essential requirements relate to interoperability, information security, data protection and functionality. New provisions also prescribe to demonstrate conformity with such requirements ("certification"). Further, also health care service providers are required to ensure data security and data protection when using EHR systems.

Already earlier, some requirements including auditing have applied to national EHR systems but they were not regulated in the legislation. One of the main changes resulting from the new legislation is that requirements will apply to all EHR systems, not just those joining Kanta services (some requirements, however, differ based on whether the data system is joining Kanta services or not).

Currently, auditing requirements regarding EHR systems connected to Kanta are referred to at the Kanta website (www.kanta.fi).

2.2.2. Table on requirements on the institutions hosting EHRs data

Requirements on the institution hosting EHRs data		
Questions	**Legal reference**	**Detailed description**
Are there specific national rules about the hosting and management of data from EHRs?	Sec. 19 a–19 i of Act on EHRs	New provisions have been added to the Act on EHRs regarding essential requirements of data systems and demonstrating conformity with such requirements (certification). Such essential requirements include requirements relating to interoperability, information security, data protection and functionality. The National Institute for Health and Welfare may order more detailed rules on the content of essential requirements (and Kela may order such rules regarding interoperability). Data systems will be classified either as class A or B. Class A includes Kanta services maintained by Kela as well as data systems to be connected to Kanta services (as well as certain transmission services). Class B includes other data systems. Certain requirements differ based on the class of a data system. Requirements for class A are partly stricter, e.g. requiring a certificate of conformity issued by the information security inspection body and participating testing in collaboration with Kela, whereas self-certification is sufficient for class B data systems.
Is there a need for a specific authorisation or licence to host and process data from EHRs?	Sec. 19 d–19 f of Act on EHRs	As regards data systems in class A, conformity with essential requirements is demonstrated by declaration of the producer of the data system, by testing in collaboration with Kela (in order to demonstrate interoperability), and by a certificate of conformity issued by the information security inspection body. (Data systems maintained by Kela do not need to participate the testing with Kela). Data systems in class A may be taken into use after the information security inspection body has given the certificate of conformity. As regards data systems in class B, compliance with essential requirements is demonstrated by declaration of the producer of the data system for the said conformity ("self-certification"). Data systems in class B may be taken into use after providing the said declaration. Producers must notify data systems to Valvira which maintains a public register of the data systems.
Are there specific obligations that apply to institutions hosting and	Sec. 19 a of Act on EHRs	See above, first question.

Requirements on the institution hosting EHRs data		
Questions	**Legal reference**	**Detailed description**
managing data from EHRs (e.g. capacity, qualified staff, or technical tools/policies on security confidentiality)?		
In particular, is there any obligation to have the information included in EHRs encrypted?		It is stated at Kanta website (www.kanta.fi) that all data transfers between a health care data system and patient data repository are encrypted.
Are there any specific auditing requirements for institutions hosting and processing EHRs?	Sec. 19 a–19 i of Act on EHRs	New specific provisions have been added to the Act on EHRs on auditing; see above what is said about the new regulation on essential requirements of data systems. Also provisions regarding self-auditing are included. (According to the government bill (HE 219/2013 vp. p. 5), the starting point has been already earlier that all data systems and organisation joining the national data system services must be audited. However, auditing has not been regulated in the legislation (in practice, auditing requirements have been available at Kanta website (www.kanta.fi), established by the Ministry of Social Affairs and Health.))

2.3. Patient consent

2.3.1. Main findings

According to the website of Kanta (www.kanta.fi), a patient does not have a right to forbid storing his/her EHRs in the national patient data repository after the health care service provider in question has joined the national data repository.

A health care service provider, which has joined the national data system services, must inform the patient of such services and other relevant information, such as rights of the patient, at the latest in connection with the first service event (unless the patient has already previously been informed).

The basic rule of thumb is that health data may not be shared without a written consent of the patient. Also as regards sharing EHRs by using the national data system services, sharing of EHRs between health care service providers is subject to patient's consent (subject to certain exceptions). Once the consent is given, the consent covers all EHRs in the national data system services. The patient may, however, prohibit sharing of certain EHRs as determined by the patient. The consent and prohibitions are valid until further notice. The consent (as well as any prohibitions) is given by a document signed by the patient or via an electronic portal ("Omakanta").

2.3.2. Table on patient consent

Requirements on the patient consent		
Questions	**Legal reference**	**Detailed description**
Are there specific national rules on consent from the patient to set-up EHRs?		According to Kanta website (www.kanta.fi), a patient does not have a right to forbid storing EHRs in the patient data repository after the health care service provider in question has started using the repository. (No similar explicit provision exists in the legislation but as (certain) health care service providers are obliged to set up EHRs, the legislation can be interpreted accordingly.)
Is a materialised consent needed?		See above.
Are there requirements to inform the patient about the purpose of EHRs and the consequences of the consent or withholding consent to create EHRs?	Sec. 17 of Act on EHRs	A health care service provider, which has joined the national data system services, must inform the patient of such services and other relevant information, such as related rights of the patient, at the latest in connection with the first service. The information can be provided to the patient orally, in writing or via an electronic service. Provision of information is recorded in the patient data management service. If the patient has already been provided the information, it does not have to be provided again.
Are there specific national rules on consent from the patient to share data?	Sec. 13 of Act on Position and Rights of a Patient Sec. 10–13, 14 a and 19 of Act on EHRs	The basic rule of thumb is that health data may not be shared without a written consent of the patient. Sharing of EHRs between different health care service providers connected to the national data system services is subject to patient's consent (subject to certain exceptions). The consent (as well as any prohibitions) is given by a document signed by the patient. The consent may also be given by the patient via an electronic portal ("Omakanta"). The consent (and prohibitions) are recorded in the patient data management service.
Are there any opt-in/opt-out rules for patient consent with regard to processing of EHRs?		According to Kanta website (www.kanta.fi), a patient does not have a right to forbid storing EHRs in the patient data repository after the health care service provider in question has joined the repository.
Are there any opt-in/opt-out rules for patient consent with regard to sharing	Sec. 10–13 and 19 of Act on EHRs	See above. Further, once the consent is given, the consent covers all EHRs in the national data system services. The patient may, however, prohibit sharing of specific

Requirements on the patient consent		
Questions	**Legal reference**	**Detailed description**
of EHRs?		EHRs as determined by the patient. The consent and prohibitions are valid until further notice.
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?		See above.
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)?		The Finnish EHRs cannot currently be accessed outside Finland (i.e. the current EHR-related legislation and the structure of national data system services are national and do not recognize cross-border transfers.)
Are there specific rules on patient consent to share data on a cross-border situation?		No specific rules are set forth as regards to EHRs. General provisions of the Data Protection Act (for example) apply to sharing of data. In addition, a specific provision (Sec. 13 of Act on Position and Rights of a Patient) apply to sharing of health data in cross-border situations in certain (exceptional) circumstances (such as unconsciousness).

2.4. Creation, access to and update of EHRs

2.4.1. Main findings

In general, health records may be used only by persons taking part in the treatment of the patient or related tasks and to the extent necessary, taking into account their duties and responsibilities. User rights must be specified in detail.

As regards specific rules on EHRs, an EHR system must include a management system for user rights, through which user rights to EHRs and different functions of the EHR system are specified for each user on the basis of his/her duties. The user must be identified in a reliable way, including authentication.

The Act on EHRs includes specific provisions regarding sharing of EHRs by using the national data system services. Sharing of EHRs between different health care service providers requires that the treatment relationship between the patient and the data recipient is electronically ensured. Sharing is also subject to patient's consent. EHRs requiring special protection (such as certain psychiatry or genetics-related recordings) must be protected by a separate confirmation request.

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

Requirements on creation, access to and update of EHRs and update of data		
Questions	**Legal reference**	**Detailed description**
Are there any specific national rules regarding who can create and where can EHRs be created?	Sec. 2 and 6 of Decree on Health Records Sec. 14 of Act on EHRs	EHRs recorded in the national data repository may include recordings made by different persons taking part in the treatment of the patient or related tasks. In general, health records may include recordings made by health care professionals and according to their instructions, also other persons to the extent they take part in the treatment of the patient. Specific rules apply to students, emergency transport personnel, dictation and medical devices. According to the explanations to the government bill (HE 219/2013 vp. p. 12), currently EHRs (in the national data system services) can be created only by using EHR systems of health care service provider organisations. A new provision of the Act on EHRs describes that Kela shall, at the latest on 1 January 2017, implement a service that enables use of national data system services also by using Internet browser and portable devices .
Are there specific national rules on access and update to EHRs?	Sec. 4 and 7 of Decree on Health Records Sec. 6 and 9 of Act on EHRs	In general, health records may be used only by persons taking part in the treatment of the patient or related tasks and to the extent necessary, taking into account their duties and responsibilities, and user rights must be specified in detail. As regards specific rules on EHRs, an EHR system must include a management system for user rights, through which user rights to EHRs and different functions of the EHR system are specified for each user on the basis of his/her duties. Electronic signatures are used to ensure wholeness and consistency of EHRs. Sharing of EHRs between different health care service providers requires that the treatment relationship between the patient and the data recipient is electronically ensured. EHRs requiring special protection (such as certain psychiatry or genetics-related recordings) shall be protected by the health care service provider with a separate confirmation request. No specific provisions are set forth as regards to updating EHRs.

Requirements on creation, access to and update of EHRs and update of data		
Questions	**Legal reference**	**Detailed description**
Are there different categories of access for different health professionals?		See above; user rights are specified for each user on the basis of his/her duties.
Are patients entitled to access their EHRs?	Sec. 18–19 of Act on EHRs Sec. 26–28 of Data Protection Act	The principles of access to data of the Data Protection Act apply: everyone has the right of access, after having supplied sufficient search criteria, to the data on him/her in a personal data file. Certain restrictions apply. For example, there is no right if providing access to the data would cause serious danger to the health or treatment of the data subject or to the rights of someone else. Patients may access certain data (as specified in the Act on EHRs) recorded in the national data repository via an electronic portal ("Omakanta").
Can patient have access to all of EHR content?	Sec. 18–19 of Act on EHRs Sec. 26–28 of Data Protection Act	See above. Act on EHRs includes a (limited) list of data that is accessible by patients via an electronic portal ("Omakanta").
Can patient download all or some of EHR content?	Sec. 19 of Act on EHRs	According to government bill (HE 253/2006 vp. p. 62), a patient may see the data and print the data to which he or she has access.
Can patient update their record, modify and erase EHR content?		According to government bill (HE 253/2006 vp. p. 62), a patient does not have a right to process the data but the patient may only see the data and print the data.
Do different types of health professionals have the same rights to update EHRs?		No specific provisions are set forth as regards to EHRs.
Are there explicit occupational prohibitions? (e.g. insurance companies/occupational physicians…)		No specific provisions on such prohibitions are set forth as regards to EHRs.
Are there exceptions to the access requirements (e.g. in case of emergency)?	Sec. 13 of Act on Position and Rights of a Patient	As regards to sharing EHRs, EHRs may be shared only on the basis of the consent of the patient or a legal provision (for example if the patient is unconscious).
Are there any specific rules on identification and authentication for health professionals? *Or are they aggregated?*	Sec. 8 of Act on EHRs Sec. 4 of Decree on Health Records	Health professionals must be identified in a reliable way. Identification also requires authentication. Electronic processing, sharing and hosting data requires electronic signature (Act on Strong Electronic Identification and Electronic Signatures, 617/2009).

Requirements on creation, access to and update of EHRs and update of data		
Questions	**Legal reference**	**Detailed description**
Does the patient have the right to know who has accessed to his/her EHRs?	Sec. 18–19 of Act on EHRs Sec. 28 of Data Protection Act	Subject to a written request, the patient has a right to know who has accessed his/her EHRs or with whom his/her EHRs has been shared, including grounds for the access or sharing. Patients may access this information via an electronic portal. Exceptions of the Data Protection Act apply.[8]
Is there an obligation on health professionals to update EHRs?	E.g. Sec. 7–19 of Act on EHRs	There is no specific regulation as regards the updating of EHRs but general provisions of the Decree on Health Records can be presumed to apply (including e.g. obligations to enter necessary and sufficient data and to enter the data without delay). A memorandum of the Ministry of Social Affairs and Health[9] states that the current regulation does not regulate updating EHRs in the data management service, and thus this issue may be modelled as part of the technical implementation of the patient data management service in accordance with how the relevant data is available via Kanta services. (See above what is explained about the content of EHRs in the implementation phase of Kanta and adding more content to Kanta in phases.)
Are there any provisions for accessing data on 'behalf of' and for request for second opinion?		No specific provisions are available as regards EHRs.
Is there in place an identification code system for cross-border healthcare purpose?		
Are there any measures that consider access to EHRs from health professionals in another Member State?		

[8] Among others, there is no right of access (1) if providing access to the data could compromise national security, defence or public order or security, or hinder the prevention or investigation of crime; (2) if providing access to the data would cause serious danger to the health or treatment of the data subject or to the rights of someone else.
[9] Memorandum of 11 April 2012 ("*STM asetus terveydenhuollon valtakunnallisista tietojärjestelmäpalveluista*")

2.5. Liability

2.5.1. Main findings

The Finnish legislation does not contain any specific medical liability requirements related to the use of EHRs. General rules governing health care and proper patient care apply.

A health care service provider, which has joined the national data repository, is responsible as the controller of EHRs for the content and accuracy of EHRs stored in the system.

A person entering data in the patient data management system is responsible for the accuracy of the data.

New provisions describe that a person entering data in the patient data management system is also responsible for correction of incorrect data in the system.

2.5.2. Table on liability

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 provisions as regards EHRs.
Can patients be held liable for erasing key medical information in EHRs?		Patients cannot modify EHRs.
Can physicians be held liable because of input errors?	Sec. 14 a and 16 of Act on EHRs	A health care service provider which has joined the national data repository is responsible as the controller of EHRs for the content and accuracy of EHRs stored in the system. A person entering data in the patient data management system is responsible for the accuracy of the data. According to a new provision the person entering data in the patient data management system is also responsible for correction of faulty data in the system.
Can physicians be held liable because they have erased data from the EHRs?		No specific provisions are set forth as regards to EHRs.
Are hosting institutions liable in case of defect of their security/software systems?	Sec. 16, 19 c, 20 d and 20 e of Act on EHRs	National data system services and EHRs must be accessible 24 hours per day. Services must include necessary emergency systems for malfunctions and states of emergency. Specific responsibilities are also imposed on Kela as it manages the national data repository. New provisions describe liability of the producer: The producer of a health data system is responsible for designing, producing and classifying the data system (irrespective of whether actions are made by the producer or a third party such as a subcontractor). The producer must on its own initiative take reparatory actions if the data system does not fulfil the essential requirements. Furthermore, Valvira may order the producer of the data system, health care service provider, transmission service provider and Kela to fulfil their obligations.
Are there measures in place to limit		No specific provisions are set forth as regards EHRs (the Act on EHRs includes new

Liability		
Questions	**Legal reference**	**Detailed description**
the liability risks for health professionals (e.g guidelines, awareness-raising)?		obligations on health care units to provide written instructions on processing of health records and related procedures as well as to take care of personnel's expertise on processing of health records (Sec. 20) but no (direct) reference is made to limiting liability risks).
Are there liability rules related to breach of access to EHRs (e.g. privacy breach)?	Sec. 5 and 23 of Act on EHRs Sec. 1, 2, 8 and 9 of Ch. 38 and Sec. 5 of Ch. 40 of Criminal Code Sec. 47–48 of Data Protection Act	According to the Act on EHRs, the health care service provider must maintain a register of the users of its EHR system and their user rights. According to the government bill (HE 176/2010 vp. p. 5), sharing of EHRs differs from sharing physical documents by the fact that the disclosing party does not choose the shared data and is not in any way involved in the sharing process. Thus the recipient requesting the information as well as the electronic system which processes the sharing is responsible for the appropriate sharing. The Act on EHRs includes provisions on criminal sanctions. A person who intentionally or by gross negligence breaches obligations of identification or authentication, unlawfully shares search data or EHRs or fails to comply with information obligations, shall be sentenced with a fine (unless a more severe penalty is provided elsewhere). The Criminal Code includes penalties (fine/imprisonment) for computer break-in, data protection offence and secrecy offence. The Data Protection Act includes provisions governing both liability in damages (controller's liability for economic and other loss) and penalties (fine) for personal data violation.
Is there an obligation on health professionals to access EHRs prior to take a decision involving the patient?		No specific provisions are set forth as regards to EHRs (but it cannot be presumed that such obligation does not exist).
Are there liability rules related to the misuse of secondary use of health data?		See above regarding general liability rules.

2.6. Secondary uses and archiving durations

2.6.1. Main findings

Archiving durations are set forth in the Decree on Health Records. The Decree applies both to physical health records as well as EHRs. Archiving durations are specified in detail in the appendix to the said Decree for different groups of health records based on their nature.

Health data may be used for secondary purposes such as historical, scientific or statistical research subject to certain conditions set forth in the Data Protection Act.

2.6.2. Table on secondary uses and archiving durations

Requirements on secondary uses and archiving durations		
Questions	**Legal reference**	**Detailed description**
Are there specific national rules on the archiving durations of EHRs?	Sec. 12 of Act on Position and Rights of a Patient Sec. 23–24 of Decree on Health Records	The main rule is that general archiving durations set forth in the Decree on Health Records also apply to EHRs (with some exceptions). Durations are detailed in the referred Decree and differ depending on the nature of the health record (varying from 12 years from production of the health record / death of a patient to a permanent period). Log files relating to use and sharing of EHRs shall be stored at least 12 years.
Are there different archiving rules for different providers and institutions?	Sec. 23 of Decree on Health Records	The main rule is that the rules differ based on the nature of the health record and not based on the provider/institutions.
Is there an obligation to destroy (…) data at the end of the archiving duration or in case of closure of the EHR?	Sec. 12 of Act on Position and Rights of a Patient Sec. 23 of Decree on Health Records	Health records shall be destroyed immediately after the end of the archiving duration. Kela is responsible on its own behalf for technical destruction of the EHRs/log files stored in the national data repository after the end of the archiving duration specified by the health care service provider (based on the EHR in question and the respective appropriate archiving duration). Kela shall inform the health care service provider before the destruction.
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?	Sec. 12 of Act on Position and Rights of a Patient	Data may be stored even after the archiving durations if storing is necessary for the treatment of the patient.
Can health data be used for secondary purpose (e.g. epidemiological studies, national	Sec. 7 and 10 of Act on EHRs	The Data Protection Act includes general provisions on processing sensitive data such as health data. In short, such data may be processed for example for historical, scientific or statistical research subject to certain conditions set forth in the said Act.[10]

[10] Section 14 — Research

1. Personal data may be processed for purposes of historical or scientific research also for a reason not referred to in section 8(1) [consent of data subject], if: (1) the research cannot be carried out without data identifying the person and the consent of the data subjects cannot be obtained owing to the quantity of the data, their age or another comparable reason; (2) the use of the personal data file is based on an appropriate research plan and a person or a group of persons responsible for the research have been designated; (3) the personal data file is used and data are disclosed therefrom only for purposes of historical or scientific research and the procedure followed is also otherwise such that the data pertaining to a given individual are not disclosed to outsiders; and (4) after the personal data are no longer required for the research or for the verification of
the results achieved, the personal data file is destroyed or transferred into an archive, or the data in it are altered so that the data subjects can no longer be identified.

Requirements on secondary uses and archiving durations		
Questions	**Legal reference**	**Detailed description**
statistics...)?	Sec. 13 of Act on Position and Rights of a Patient Sec. 11–15 of Data Protection Act	The Act on EHRs includes the following provision on planning, research and statistical information: the following information may be produced from the EHR system: own planning, management and statistics of the health care service provider as well as necessary information for the national research and statistics activities and information regarding the assessment of the need for treatment and the timing of getting the treatment. Data may be shared, in accordance with further requirements, to national health care personal data files by using national data system services (this relates to certain national registers maintained by certain authorities for statistical (etc.) purposes).
Are there health data that cannot be used for secondary use?		No explicit exceptions are set forth.
Are there specific rules for the secondary use of health data (e.g. no name mentioned, certain health data that cannot be used)?	Sec. 11–15 of Data Protection Act	Specific provisions are set forth in Data Protection Act as regards processing personal data for the purpose of research and statistics. For example as regards to research, identifiable data should not be used if carrying out the research would be possible without using such data. If the research, however, requires using identifiable data, the use should primarily be based on the consent of the data subject.
Does the law say who will be entitled to use and access this data?	Sec. 14–15 of Data Protection Act Sec. 2 of Act on National Person Data Files in Health	See above. Also, as regards research, for example, the use of personal data is to be based on an appropriate research plan and a person or a group of persons responsible for the research are to be designated.

2. The provision in paragraph (1)(3) does not apply if the procedure in that paragraph is manifestly unnecessary for the protection of the privacy of the data subjects owing to the age or quality of the data in the personal data file.
3. The provisions in paragraph (1) apply in a supplementary manner where the processing of the personal data is based in section 8(1).
Section 15 — Statistics
Personal data may be processed for statistical purposes also for a reason not referred to in section 8(1) [consent of data subject], if: (1) the statistics cannot be compiled or the underlying data requirements fulfilled without using personal data; (2) the compilation of statistics is an activity where the controller is engaged in; and (3) the file is used for statistical purposes only and data are not disclosed from it in a way allowing for the identification of a given individual, except where the data are disclosed for official statistics.

Requirements on secondary uses and archiving durations		
Questions	**Legal reference**	**Detailed description**
	Care	As regards statistics, personal data may be processed for statistical purposes (even without the consent of data subject) when the compilation of statistics is part of the line of business of the controller. According to the Act on National Person Data Files in Health Care, the National Institute for Health and Welfare as well as the Finnish Medicines Agency have the right to maintain national data files relating to patient's health care to be used for purposes of planning, research and surveillance.
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

The national data system services are called Kanta services. Such services include for example national data repository, ePrescriptions and patient data management service (including the most essential data of the patient).

Kanta as such is not an EHR system but a data transmission and archiving service. Kanta does not replace regional EHR systems, but health care service providers joining Kanta services must ensure interoperability of their EHR system with Kanta services. Each health care service provider / unit will acquire such EHR system that best fulfils their own needs.

All EHR systems (as well as data systems used in connection with ePrescriptions) connected to Kanta services shall comply with technical specifications maintained by the competent authority. Compliance with the specifications is verified in the auditing procedure.

There are no provisions referring to the interoperability of national EHRs with other Member States' EHR systems.

2.7.2. Table on interoperability of data requirements

Requirements on interoperability of data		
Questions	**Legal reference**	**Detailed description**
Are there obligations in the law to develop interoperability of EHRs?	Sec. 19 a of Act on EHRs	According to the new provisions, health data systems must follow essential requirements regarding interoperability, data security, data protection and functionality. The National Institute for Health and Welfare may order more detailed rules on the content of essential requirements, and Kela may order rules on procedures used in verifying the interoperability of data systems joining the national data system services.
Are there any specific rules/standards on the interoperability of EHR?		Specifications and other information relating to interoperability are currently available (at least) at Kanta website (www.kanta.fi).
Does the law consider or refer to interoperability issues with other Member States systems?		No specific provisions are set forth as regards to EHRs.

2.8. Links between EHRs and ePrescriptions

2.8.1. Main findings

The ePrescription service is part of the national Kanta services. All data system services (including those relating to ePrescriptions) joining Kanta services must be interoperable with the centralised data system services maintained by Kela.

ePrescriptions are saved in a centralised database called as prescription centre ("*reseptikeskus*"). Kela is the controller of the prescription centre. The prescription centre includes all ePrescriptions. Information in the prescription centre is used via EHR systems and pharmacy systems. An ePrescription is written in the EHR system, from which the ePrescription is sent to the prescription centre. In the future, ePrescriptions may be written also by other means than using an EHR system: Kela shall, at the latest on 1 January 2017, implement a new service that enables prescribing ePrescriptions by using Internet browser and portable devices.

Information included in the prescription centre may be accessed by pharmacists as well as certain health care professionals (subject to certain conditions). Patients may also access their own information in the prescription centre.

As a result of a recent legislative reform, the main rule is all prescriptions should be issued electronically (transition periods apply).

Further, new provisions have recently been added to Act on ePrescription which relate to cross-border transfer of ePrescriptions between the Member States (for example, ePrescriptions in accordance with the Finnish requirements may be sent to other Member States, and ePrescriptions written in other Member States may be accepted and supplied in Finland (subject to certain requirements); reference is made to Directive 2011/24/EU).

A currently ongoing epSOS project between Finland and Sweden includes cross-border use of ePrescription.

2.8.2. Table on the links between EHRs and ePrescriptions

- ***Infrastructure***

Requirements on the link with ePrescriptions (infrastructure)		
Questions	**Legal reference**	**Detailed description**
Is the existence of EHR a precondition for the ePrescription system?	Sec. 20 and 22 a of Act on ePrescreption	ePrescriptions have been written in the EHR system, and writing ePrescriptions in practice has required health care service providers to join Kanta services at least as regards to ePrescriptions. This will, however, change in the future: following a recent legislative reform, Kela shall, at the latest on 1 January 2017, implement a new service that enables prescribing ePrescriptions by using Internet browser and portable devices. New provisions describe that data systems and supporting software as well as prescription centre and medicine database shall meet the requirements set forth in the Act on EHRs.
Can an ePrescription be prescribed to a patient who does not have an EHR?		EHR of a patient in question is not a condition for prescribing ePrescription for the said patient.

- ***Access***

Requirements on the link with ePrescriptions (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?	Sec. 13 of Act on ePrescreption	Not necessary. Access rights to EHR of a patient are not directly linked to ePrescriptions but they are determined on other grounds. Information in the prescriptions centre, however, is accessible (subject to patient's consent).
Can those health professionals write ePrescriptions without having access to EHRs?		Writing ePrescriptions does not require access to the EHR of the patient.

2.9. Other requirements

[N/A]

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

Note that it is difficult to identify legal barriers and good practices in Finland since the system is just being implemented and partly also still under development.

Certain features are identified as specific to the Finnish EHRs that could be a barrier for the cross-border transfer of health data from EHRs, for example:

- Patients are identified by their personal identity code ("henkilötunnus" or "HETU"), which is a national general identification code. The Finnish EHR system is based on using this national code for identification.
- Electronic signatures are used in the processing, transfer and storing of EHRs.

It is recognised that various issues, also described in this report, would need to be considered in more detail as regards to cross-border transfer of EHRs (for example the scope of patient's consent, responsibility over preparation of "patient's summary" and the right / obligation to archive EHRs).

As regards to medicine databases, it is already recognised that different countries have different kinds of databases (for example different names of medicinal products), which leads to certain challenges.