

*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*

Contract 2013 63 02

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

**National Report for Austria**



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This report was completed by Erich Schweighofer and Walter Hötendorfer from the Centre for Computers and Law at the University of Vienna/Vienna Centre for Legal Informatics. The views expressed herein are those of the consultants alone and do not necessarily represent the official views of the Executive Agency for Health and Consumers.

Milieu Ltd. (Belgium), rue Blanche 15, B-1050 Brussels, tel: +32 2 506 1000; fax: +32 2 514 3603; florent.pelsy@milieu.be; web address: [www.milieu.be](http://www.milieu.be)

# Executive Summary

## 1. Stage of development of EHRs in Austria

The “*Elektronische Gesundheitsakte*” (Electronic Health Record) - ELGA - is the Austrian national electronic health record scheme set in place by the Federal Act on Data Security Measures when using personal electronic Health Data (Health Telematics Act 2012 – HTA 2012), which in turn was enacted by Electronic Health Record File Act (ELGA Act).

ELGA is the only EHR scheme in Austria including the following four elements: the objective of creating a national framework, formalities on data-hosting institutions, modalities concerning the patient (consent and identification), and identification of health professionals.

Austria institutionalised the discussion on eHealth already in 2003 by setting up the so called STRING-Commission as an advisory group for the Minister of Health. In this Commission the acronym “ELGA” was created, which nowadays stands synonymous for eHealth in the Austrian public.

The part of the ELGA Act referring to the storage of health records will become effective on 1 July 2015. Until then, the Framework Act of ELGA will have to be supplemented and clarified by Ordinances of the Minister of Health.

## 2. Summary of legal requirements applying to EHRs

Many matters regarding EHRs were already regulated in these acts of legislation before ELGA was established with the Health Telematics Act 2012. There was also a preceding Health Telematics Act which was repealed by the new act and which already regulated some aspects of eHealth. Data protection issues related to the use of health data are laid down in the Data Protection Act 2000 and in the Physicians Act 1998. The Hospitals and Sanatoriums Act and the Physicians Act 1998 regulate duties in relation to the storage of patient histories and to the issuance of medical documents.

With the Electronic Health Record File Act (ELGA Act), in 2012 a new era in the field of eHealth in Austria began. The ELGA Act is what could be called a ‘framework act’ which enacted the Health Telematics Act 2012 and amended several other acts of legislation, including some of the acts mentioned above. Subject matter of the Health Telematics Act 2012 is the usage of personal electronic health data by healthcare providers. ELGA is an information system that provides ELGA health data to ELGA health service providers and ELGA participants (i.e. the persons of whom health data is stored) in electronic form independent of time and place. Hence, what is called “*Elektronische Gesundheitsakte*, ELGA”, which literally translates to Electronic Health Record is actually the information system for the exchange of EHRs. It is not an EHR or a central data store for EHRs or anything of that kind.

The fourth part of the Health Telematics Act 2012 deals with ELGA in particular and is restricted to the usage of ELGA Health Data only. ELGA Health Data is only a subset of all possible health data. It is the health data which currently is subject to ELGA and hence subject to electronic exchange amongst health service providers within the ELGA information system. Pursuant to Sec. 2 no. 9 Health Telematics Act 2012, ELGA Health Data (“*ELGA-Gesundheitsdaten*”) are:

- a) Medical documents including image data (excluding data the sole purpose of which is accounting/charging), such as
  - a. Hospital discharge reports
  - b. Laboratory findings
  - c. Results of diagnostic imaging
  - d. Other medical reports;

- b) Medication data (“e-medication”);
- c) Living wills;
- d) Health care proxies;
- e) Data from the registers of implanted devices such as cardiac pacemakers, ICDs and loop recorders;
- f) Patient summaries according to Art. 14(2) (b)(i) of Directive 2011/24/EU.

The Health Telematics Act 2012 defines Healthcare Providers and the sub-set of the so called ELGA Healthcare Providers as including physicians and dentists (with certain exceptions), hospitals, pharmacies and nursing institutions. Only ELGA Healthcare Providers are allowed and obliged to host ELGA Health Data. The data must be stored in the territory of the European Union. The Health Telematics Act 2012 also imposes IT security obligations onto institutions hosting and managing data from EHRs.

Regarding patient consent in ELGA, Austria opted for an opt-out approach. This means that a person is by default ‘ELGA participant’ unless he/she objects.

ELGA participants have the following options:<sup>1</sup>

- General opt out: No participation in ELGA
- Partial opt-out: No participation in a particular ELGA application, e.g. eMedication
- Case-specific opt-out: No participation in ELGA only regarding a particular case/treatment.

There is the possibility to opt-in again.

ELGA participants can also exclude the access of a particular ELGA healthcare provider to a particular piece of or all of their ELGA data.

The system of identification, authentication and authorisation under the Health Telematics Act 2012 is complex. The Act defines a particular group of healthcare providers, the “ELGA Healthcare Providers” who are exclusively entitled to create and access EHRs. The Health Telematics Act 2012 defines different roles and different access rights for different health professionals..

Patients are entitled to access their own EHRs on ELGA. They can access all their data and they can also download them in pdf files and hence also print them. Furthermore, patients can keep track on which person accessed which particular piece of their data.

With ELGA, no new liability legislation was enacted. The existing liability regime did not change. There is no provision which explicitly stipulates that health professionals must access ELGA prior to taking a decision involving the patient. However, a duty to access ELGA prior to taking a decision involving the patient can follow from professional duties of the health professional.

So the legal situation regarding liability has not changed with ELGA but factually ELGA is a new source of information for health professionals and not taking into account such a source of information may be considered as professional negligence.

Persons who enter information into ELGA are liable for that information being accurate. ELGA provides for the possibility to be always able to find out who (which natural person) entered a particular piece of information.

The obligation for hospitals to establish clinical files and to archive them for at least 30 years has already been laid down in the Hospitals and Sanatoriums Act for a long time.

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<sup>1</sup> Cf. *Auer/Militsits/Reimer*, ELGA-Handbuch, Manz, Wien, 2014, pp. 18 ff.

Similarly, the Physicians Act 1998 defines what information physicians in private practice have to store about their patients and defines a minimum archiving duration of ten years.

Both are only minimum durations. There is no defined maximum and we know that, for example, the largest hospital in Austria (AKH) does not delete any clinical files.<sup>2</sup>

However, it is important to note that neither of these Acts defines the medium which has to be used by hospitals and doctors to store the files. Hence these are not necessarily EHRs but could also be paper files, micro films etc.

As far as ELGA Health Data is concerned, the Health Telematics Act 2012 defines an archiving duration of ten years, which is also a maximum and hence the data must be deleted after that period.

Secondary uses are not foreseen. ELGA data should not be used for other purposes.

The Austrian EHR system contains only the minimum requirements: identification of patients and EHR providers, minimum requirements of repositories and restrictions on storage of data. The link to the repositories is not yet defined.

There are no rules on interoperability of national EHRs with other Member States EHRs systems. However, the registration of other EHRs seems to be properly envisaged and also tested in projects like epSOS. Patients from other Member States are already registered if they ask for health services in Austria.

In Austria, an ePrescription system does not exist and is not planned. For the time being prescriptions are and remain to be paper-based.

### **3. Good practices**

The ELGA rules are very detailed and strict on data privacy. As the patient can opt-out – in general or on every data entry (e.g. by deleting certain entries) – the ELGA record is designed as being under the patient's control, whilst only health professionals can enter data.

The Health Telematics Act 2012 defines Healthcare Providers and the sub-set of the so called ELGA Healthcare Providers as including only physicians and dentists (with certain exceptions), hospitals, pharmacies and nursing institutions. Only ELGA Healthcare Providers are allowed and obliged to host ELGA Health Data.

### **4. Legal barriers**

So far, important implementation details are still not regulated.

No provisions for cross-border transfer in other EU Member States exist so far.

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<sup>2</sup> See Interview 2 (AKH).

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## List of abbreviations

ASVG	General Social Insurance Law ( <i>Bundesgesetz vom 9. September 1955 über die Allgemeine Sozialversicherung (Allgemeines Sozialversicherungsgesetz)</i> ), Federal Law Gazette ( <i>BGBl.</i> ) no. 189/1955
ATC	Anatomical Therapeutic Chemical Classification System
bPK	sector specific personal identifier („ <i>Bereichsspezifisches Personenkennzeichen</i> “). A bPK is derived from the sourcePIN, a unique identification number in Austria. For data protection reasons, 26 different special bPKs are used in the different contexts of administration.
E-GovG	E-Government Act ( <i>Bundesgesetz über Regelungen zur Erleichterung des elektronischen Verkehrs mit öffentlichen Stellen (E-Government-Gesetz)</i> ), Federal Law Gazette ( <i>BGBl.</i> ) I no. 10/2004
EHRs	Electronic Health Records
ELGA	“Electronic Health Record” “ <i>Elektronische Gesundheitsakte</i> ”) is an electronic information system that provides ELGA health data to ELGA health service providers and ELGA participants.
GTelG	Federal Act on data security measures when using personal electronic health data (Health Telematics Act 2012 – HTA 2012) ( <i>Bundesgesetz betreffend Datensicherheitsmaßnahmen bei der Verwendung elektronischer Gesundheitsdaten (Gesundheitstelematikgesetz 2012 – GTelG 2012)</i> ), Federal Law Gazette ( <i>BGBl.</i> ) I no. 111/2012
Sec.	Section
WHO	World Health Organization

# 1. General context

## 1.1. EHR systems in place

Austria is a federal republic. Major stakeholders in the Austrian health care system are

- the federal ministry of health,
- the 22 different social insurance carriers (“*Sozialversicherungsträger*”) in Austria (19 of which are health insurance carriers) under its umbrella organisation called Main Association of Austrian Social Security Organisations (“*Hauptverband der österreichischen Sozialversicherungsträger*”) and
- the federal states (“*Länder*”) which are the main operators of the hospitals.

Section 1.2 below provides a more detailed description of the institutional setting in the Austrian health care system.

Austria institutionalised the discussion on eHealth already in 2003 by setting up the so called STRING-Commission as an advisory group for the minister of health. In this Commission the acronym “ELGA” (“*Elektronische Gesundheitsakte*” - electronic health record) was created, which nowadays stands synonymous for eHealth in the Austrian public. ELGA is now defined in Sec. 2 no. 6 Health Telematics Act 2012<sup>3</sup> as an information system that provides ELGA health data to ELGA health service providers and ELGA participants (the persons of whom health data is stored) in electronic form independent of time and place.

In 2005, a so called “Article-15a-Treaty” (under Article 15a of the Austrian Federal Constitutional Law) between the Republic of Austria and its nine federal states included the mandate to develop ELGA in Austria. ELGA was then developed by the ELGA working group, including the major stakeholders in the field. In 2009, ELGA GmbH was founded, which is a private company with limited liability that is owned by public-sector stakeholders responsible for delivering e-health services and for launching and implementing the electronic health record (ELGA) in Austria.

Currently (as of March 2014) ELGA is regularly on the media and subject of intense public discussion. The major opponents of ELGA in Austria are parts of the physicians in private practice and their representatives, in particular the Austrian Medical Chamber, and privacy advocates.

The current state of development is as follows: The legal framework of ELGA, or at least of its first phase of implementation is in place, the centrepiece of which being the Health Telematics Act 2012. At the moment, nothing but the mechanism for data subjects to opt-out is practically in operation. This was the first part of ELGA which was practically implemented. The next step will be the start of operation of ELGA proper, i.e. the use of EHRs as laid down in the Health Telematics Act 2012 and described within this report.

## 1.2. Institutional setting

The main institutions involved in the development and deployment of the ELGA scheme in Austria are:

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<sup>3</sup> Federal Act on Data Security Measures when using personal electronic Health Data (Health Telematics Act 2012 – HTA 2012); Bundesgesetz betreffend Datensicherheitsmaßnahmen bei der Verwendung elektronischer Gesundheitsdaten (Gesundheitstelematikgesetz 2012 – GTelG 2012), Federal Law Gazette (BGBl.) I no. 111/2012, as amended BGBl. I no. 83/2013. English working translation available at [https://www.ris.bka.gv.at/Dokumente/ErV/ERV\\_2012\\_1\\_111/ERV\\_2012\\_1\\_111.html](https://www.ris.bka.gv.at/Dokumente/ErV/ERV_2012_1_111/ERV_2012_1_111.html).



- The Ministry of Health (*Gesundheitsminister*)

The Ministry of Health is responsible for public health and the organisation of the healthcare system. As such, it is responsible for overseeing the implementation of the ELGA scheme in Austria. It is in charge of monitoring the incremental development of the scheme throughout the territory by the ELGA GmbH (see below).

- Statutory Insurance Providers

The 22 statutory insurance providers (*Sozialversicherungsträger*) in Austria (19 of which are health insurance carriers) under their umbrella organisation called Main Association of Austrian Social Security Organisations (“Hauptverband der österreichischen Sozialversicherungsträger”) are responsible for health, pension and accident insurance. The Main Association of Austrian Social Security Organisations undertakes a number of important coordination functions. The Main Association is under the regulatory supervision of two federal ministries, the Minister of Labour, Social Affairs and Consumer Protection and the Minister of Health. The Federal Minister of Finance also has a regulatory capacity in order to protect the financial interests of the Austrian federation.

- Austrian Data Protection Authority (*Österreichische Datenschutzbehörde*)

The Austrian Data Protection Authority is a governmental authority charged with data protection. The data protection authority is the Austrian supervisory authority for data protection, the equivalent of a national data protection commissioner in other countries.

The Data Protection Authority replaces the Data Protection Commission, which held this position until 31 December 2013.

### 1.3. Legal setting and future legal development

The following pre-existing national legislation is relevant to eHealth and ELGA:<sup>4</sup>

- Constitutional law, in particular the fundamental right to data protection
- The Data Protection Act 2000<sup>5</sup>
- The Physicians Act 1998<sup>6</sup>
- Hospitals and Sanatoriums Act<sup>7</sup>

Many matters regarding EHRs were already regulated in these acts of legislation before ELGA was established by the Health Telematics Act 2012. There was also a preceding Health Telematics Act which was repealed by the new act and which already regulated some aspects of eHealth. Data protection issues of the use of health data are laid down in the Data Protection Act 2000 and in the Physicians Act 1998. The Hospitals and Sanatoriums Act and the Physicians Act 1998 regulate duties in relation to the storage of patient histories and to the issuance of medical documents.<sup>8</sup> However, currently there is no interoperability between the data which is electronically stored by the various

<sup>4</sup> Cf. *Auer/Milisits/Reimer*, ELGA-Handbuch, Manz, Wien, 2014, p. 52 et seq. The legal translations of the names of these and other legislative acts are taken from the English working translation of the Health Telematics Act 2012, available at: [https://www.ris.bka.gv.at/Dokumente/ErV/ERV\\_2012\\_1\\_111/ERV\\_2012\\_1\\_111.html](https://www.ris.bka.gv.at/Dokumente/ErV/ERV_2012_1_111/ERV_2012_1_111.html).

<sup>5</sup> Federal Act concerning the Protection of Personal Data (DSG 2000), (*Bundesgesetz über den Schutz personenbezogener Daten (Datenschutzgesetz 2000 - DSG 2000)*), Federal Law Gazette (BGBl.) I no. 165/1999 as amended BGBl. I no. 83/2013. English working translation available at [https://www.ris.bka.gv.at/Dokumente/ErV/ERV\\_1999\\_1\\_165/ERV\\_1999\\_1\\_165.pdf](https://www.ris.bka.gv.at/Dokumente/ErV/ERV_1999_1_165/ERV_1999_1_165.pdf).

<sup>6</sup> Federal Act concerning the practice of medical profession and the professional representation of doctors (Physicians Act 1998) (*Bundesgesetz über die Ausübung des ärztlichen Berufes und die Standesvertretung der Ärzte (Ärztegesetz 1998 – ÄrzteG 1998)*), Federal Law Gazette (BGBl.) I no. 169/1998 as amended BGBl. I no. 81/2013.

<sup>7</sup> Federal Act concerning Hospitals and Sanatoriums Act (*Bundesgesetz über Krankenanstalten und Kuranstalten (KAKuG)*), Federal Law Gazette (BGBl.) no. 1/1957 as amended BGBl. I no. 81/2013.

<sup>8</sup> Cf. *Auer/Milisits/Reimer*, ELGA-Handbuch, Manz, Wien, 2014, p. 53.

players, such as physicians and hospitals.

With the ELGA Act, in 2012 a new era in the field of eHealth in Austria began. The ELGA Act is what could be called a ‘framework act’ which enacted the Health Telematics Act 2012 and amended several other acts of legislation, including some of the acts mentioned above.

Subject matter of the Health Telematics Act 2012 is, pursuant to its Sec. 1 (1), the usage of personal electronic health data by healthcare providers. In relation to the Data Protection Act and other acts of legislation mentioned above it is therefore a *lex specialis* regarding the use of personal health data which is processed electronically.<sup>9</sup>

ELGA is defined in Sec. 2 no. 6 Health Telematics Act 2012 as an information system that provides ELGA health data to ELGA health service providers and ELGA participants (i.e. the persons on which health data is stored) in electronic form independent of time and place. Hence, what is called “*Elektronische Gesundheitsakte, ELGA*”, which literally translates to Electronic Health Record is actually the information system for the exchange EHRs. It is not an EHR or a central data store for EHRs or anything of that kind.

The fourth part of the Health Telematics Act 2012 deals with ELGA in particular and is restricted to the usage of ELGA Health Data only. ELGA Health Data is only a subset of all possible health data. It is the health data which currently is subject to ELGA and hence subject to electronic exchange amongst health service providers within the ELGA information system. Pursuant to Sec. 2 no. 9 Health Telematics Act 2012, ELGA Health Data (“*ELGA-Gesundheitsdaten*”) are:

- a) Medical documents including image data (excluding data the sole purpose of which is accounting/charging), such as
  - a. Hospital discharge reports
  - b. Laboratory findings
  - c. Results of diagnostic imaging
  - d. Other medical reports.
  - e.
- b) Medication data (“e-medication”)
- c) Living wills
- d) Health care proxies
- e) Data from the registers of implanted devices such as cardiac pacemakers, ICDs and loop recorders
- f) Patient summaries according to Art. 14. (2) (b) (i) of Directive 2011/24/EU

This definition therefore limits the data which is exchanged within ELGA.<sup>10</sup> However the list referred to under (a) above is non-exhaustive.<sup>11</sup>

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<sup>9</sup> Cf. Auer/Milisits/Reimer, ELGA-Handbuch, Manz, Wien, 2014, p. 74.

<sup>10</sup> Cf. Auer/Milisits/Reimer, ELGA-Handbuch, Manz, Wien, 2014, p. 88.

<sup>11</sup> Cf. Auer/Milisits/Reimer, ELGA-Handbuch, Manz, Wien, 2014, p. 86.

## 2. Legal requirements applying to EHRs in Austria

### 2.1. Health data to be included in EHRs

#### 2.1.1. Main findings

Only ELGA Health Data, as referred to in Sec. 2 no. 9 Health Telematics Act 2012 can be used within ELGA. Such data are personal data which could be essential for the treatment, care or for safeguarding the continuity of service. They include the following:

- a) Medical documents including image data (excluding data the sole purpose of which is accounting/charging), such as
  - a. Hospital discharge reports
  - b. Laboratory findings
  - c. Results of diagnostic imaging
  - d. Other medical reports.
- b) Medication data (“e-medication”)
- c) Living wills
- d) Health care proxies
- e) Data from the registers of implanted devices such as cardiac pacemakers, ICDs and loop recorders
- f) Patient summaries according to Art. 14. (2) (b) (i) of Directive 2011/24/EU

A special identification number (sector specific personal identifier - *bereichsspezifische Personenkennung - bPk*) of the health sector is used for identification purposes.

## 2.1.2. Table on health data

Questions	Legal reference	Detailed description
<i>Are there specific rules on the content of EHRs? (or regional provisions, agreements, plans?)</i>	Sec. 2 no. 9 Health Telematics Act 2012	<p>Sec. 2 no. 9 Health Telematics Act 2012 defines the term “ELGA Health Data” (“<i>ELGA-Gesundheitsdaten</i>”) as personal data which could be essential for the treatment, care or for safeguarding the continuity of service. Pursuant to Sec. 2 no. 9 Health Telematics Act 2012 ELGA health data are:</p> <ul style="list-style-type: none"> <li>g) Medical documents including image data (excluding data the sole purpose of which is accounting/charging), such as <ul style="list-style-type: none"> <li>a. Hospital discharge reports</li> <li>b. Laboratory findings</li> <li>c. Results of diagnostic imaging</li> <li>d. Other medical reports.</li> </ul> <p>The specific data format of these data is defined in an ordinance pursuant to Sec. 28 (2) Health Telematics Act 2012.</p> </li> <li>h) Medication data (“e-medication”)</li> <li>i) Living wills</li> <li>j) Health care proxies</li> <li>k) Data from the registers of implanted devices such as cardiac pacemakers, ICDs and loop recorders</li> <li>l) Patient summaries according to Art. 14. (2) (b) (i) of Directive 2011/24/EU</li> </ul> <p>ELGA health data is one of the key definitions of the Health Telematics Act 2012. Only these data may be used within ELGA.<sup>12</sup></p>
<i>Are these data restricted to purely medical information (e.g. physical or mental health, well-being)?</i>	Sec. 2 no. 9 Health Telematics Act 2012	Within ELGA only the aforementioned data may be stored/interlinked.
<i>Is there a definition of EHR or patient’s summary provided in the national legislation?</i>	Sec. 2 no. 6 Health Telematics Act 2012 Sec. 2 no. 9 Health Telematics Act 2012	See above, first question.
<i>Are there any requirements on the</i>	Sec. 2 no. 9 Health	Already the definition of ELGA health data contains some specific

<sup>12</sup> Cf. Auer/Milisits/Reimer, ELGA-Handbuch, Manz, Wien, 2014, p. 88.

Questions	Legal reference	Detailed description
<i>content of EHRs (e.g. detailed requirements on specific health data or general reference to health data)?</i>	Telematics Act 2012 Sec. 12 ELGA Ordinance Sec. 14 ELGA Ordinance	requirements. Pursuant to Sec. 28 (2) Health Telematics Act 2012 a specific data format of medical documents is defined in an ordinance, the ELGA Ordinance (“ <i>Verordnung des Bundesministers für Gesundheit zur Implementierung von ELGA (ELGA – Verordnung – ELGA - VO)</i> ”). It lays down structure, format and standards of ELGA health data. Sec. 12 ELGA Ordinance lays down structure and format of medication data. Sec. 14 ELGA Ordinance names several implementation guidelines defined by the Minister of Health on which content, structure, format and coding of medical documents have to follow. The guidelines define fields which the medical documents are required to include.
<i>Are there any specific rules on the use of a common terminology or coding system to identify diseases, disorders, symptoms and others?</i>	Sec. 15 ELGA Ordinance Sec. 12 (2) ELGA Ordinance	Pursuant to Sec. 15 ELGA Ordinance, terminology is defined by the Minister of Health and published on his website, and the use of this terminology is obligatory. Regarding pharmaceutical products Sec. 12 (2) ELGA Ordinance requires the storage of the registered trade name and under certain circumstances also the ATC code (defined by the WHO).
<i>Are EHRs divided into separate categories of health data with different levels of confidentiality (e.g. data related to blood type is less confidential than data related to sexual diseases)?</i>		No
<i>Are there any specific rules on identification of patients in EHRs?</i>	Sec. 4, Sec. 14 (1) no.1 and Sec. 18 (4) Health Telematics Act 2012	Pursuant to Sec. 4 (1) Health Telematics Act 2012 the identity of persons of which health data is passed on has to be determined (Sec. 14 (1) no.1. Health Telematics Act 2012 is very similar to that). Sec. 18 (4) Health Telematics Act 2012 states: The ELGA-Participants’ (Sec. 14 para. 1 no. 1) identity shall be verified in electronic form and through their participation. Thereby the identity data registered with the Patient Index needs to be compared with the identity data collected during identification. The identity data can be collected 1. electronically verifying the validity of the e-card and reading data from the e-card via the e-card system (sects. 31a et sqq. ASVG) or 2. using a citizen card (Sec. 2 no. 10 E-GovG or

Questions	Legal reference	Detailed description
		<p>3. using identity data of an unambiguously identified natural person according to Sec. 4 para. 2, which are stored at a ELGA-Healthcare Provider pursuant to Sec. 2 no. 10 lit. d and e, provided that the IT-Security Policy according to Sec. 8 technically assures that ELGA-Health Data is only used for purposes laid down in Sec. 14 para. 2 no. 1 and identification of ELGA-Participants is verified or</p> <p>4. using data of an electronic or otherwise unique prescription or referral (Sec. 14 para. 2 no. 1 lit. b), if the identity data are not collected according to nos. 1 to 3.</p>
<i>Is there is a specific identification number for eHealth purposes?</i>	Sec. 18(1), (2) Health Telematics Act 2012	<p>According to Sec. 18 (1), the Main Association shall establish and operate a Patient Index. A bPK of the health area is used for identification purposes (Sec. 18 (2)).</p> <p>Note: A bPK is derived from the sourcePIN, a unique identification number in Austria. For data protection reasons, 26 different special bPKs are used in the different contexts of administration.</p>

## **2.2. Requirements on the institution hosting EHRs data**

### **2.2.1. Main findings**

The Health Telematics Act 2012 defines Healthcare Providers and the sub-set of the so called ELGA Healthcare Providers, as including physicians and dentists (with certain exceptions), hospitals, pharmacies and nursing institutions. Only ELGA Healthcare Providers are allowed and obliged to host ELGA Health Data. According to Sec. 20 Health Telematics Act 2012, the data must be stored in the territory of the European Union. Sec. 8 Health Telematics Act 2012 imposes IT security obligations onto institutions hosting and managing data from EHRs. A general obligation to store EHRs in encrypted form does not exist.

## 2.2.2. Table on requirements on the institutions hosting EHRs data

Questions	Legal reference	Detailed description
<p><i>Are there specific national rules about the hosting and management of data from EHRs?</i></p>	<p>Sec. 2 no. 10, Sec. 20, Sec. 28 para 2 no. 5, Sec.13(5) Health Telematics Act 2012 Health Telematics Act 2012</p>	<p>Only ELGA Healthcare Providers as defined in Sec. 2 no. 10 Health Telematics Act 2012 (see next question for details) are allowed and obliged to host ELGA Health Data. According to Sec. 20 para. 1 Health Telematics Act 2012 they have to store the data in stores according to Sec. 28 para. 2 no. 5, which need to be located in the territory of the European Union. Already saved ELGA Health Data may not be altered. If circumstances emerge that could cause significant changes in the course of treatment, updated versions have to be saved additionally. ELGA Healthcare Providers are data controllers of the storage.</p> <p>Regarding storage time requirements, see Table 2.6.2.</p> <p>Sec. 28 para. 2 no. 5 Health Telematics Act 2012 lays down that standards for the search function pursuant to Sec. 13 para. 5, the temporal availability, security requirements and access protection of the ELGA components, while it must be ensured that maintenance is logged and allows personal data only to be displayed in encrypted form or in accordance with a four-eye-principle, have to be defined by the Minister of Healthcare in an ordinance.</p> <p>Pursuant to Sec.13(5) Health Telematics Act 2012,the ‘ELGA system partners’ must provide ELGA ‘while taking the appropriate security requirements into consideration’. The ‘ELGA system partners’ are the Federation, the Länder, and the Main Association of Austrian Social Security Organisations.</p>
<p><i>Is there a need for a specific authorisation or licence to host and process data from EHRs?</i></p>	<p>Sec. 2 no. 10 Health Telematics Act 2012</p>	<p>Only ELGA Healthcare Providers are allowed to host and process ELGA Health Data.</p> <p>ELGA Healthcare Providers are only a sub-set of all healthcare providers in Austria. They are exhaustively listed (by function, not individually) in the definition of the Sec. 2 no. 10 Health Telematics Act 2012. ELGA Healthcare Providers are physicians and dentists (with certain exceptions), hospitals, pharmacies and nursing institutions.</p>



Questions	Legal reference	Detailed description
		Apart from belonging to these groups, the Health Telematics Act 2012 does not require any additional authorisation or licence to host and process data from EHRs.
<p><i>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)?</i></p>	<p>Sec. 8 para. 1 Health Telematics Act 2012</p>	<p>Sec. 8 para. 1 Health Telematics Act 2012 reads:  “On the basis of an IT-security concept Healthcare Providers have to document all data security measures taken in accordance with Sec. 14 Data Protection Act 2000 and the provisions of this Act. This documentation shall give evidence that both access and disclosure of the data are performed in accordance with the law and that data are not accessible to unauthorized persons.”</p> <p>Institutions hosting and managing ELGA data have to have an IT-security concept and – as every data controller – have to comply with Sec. 14 Data Protection Act 2000 which in its para. 2 lays down the following data security requirements:</p> <ul style="list-style-type: none"> <li>- The distribution of functions between the organisational units as well as the operatives regarding the use of data [<i>Datenverwendung</i>] shall be laid down expressly,</li> <li>- The use of data must be tied to valid orders of the authorised organisational units or operatives,</li> <li>- every operative is to be instructed about his duties according to this Federal Act and the internal data protection regulations, including data security regulations,</li> <li>- The right of access to the premises of the data controller or processor is to be regulated,</li> <li>- The right of access to data and programs is to be regulated as well as the protection of storage media against access and use by unauthorised persons,</li> <li>- The right to operate the data processing equipment is to be laid down and every device is to be secured against unauthorised operation by taking precautions for the machines and programs used,</li> <li>- Logs shall be kept in order that the processing steps that were actually performed, in particular modifications, consultations and</li> </ul>

Questions	Legal reference	Detailed description
		<p>transmissions, can be traced to the extent necessary with regard to their permissibility,</p> <ul style="list-style-type: none"> <li>- Documentation shall be kept on the measures taken pursuant to sub-paras. 1 to 7 to facilitate control and conservation of evidence.</li> </ul>
<i>In particular, is there any obligation to have the information included in EHRs encrypted?</i>	Sec. 6 Health Telematics Act 2012	<p>A general obligation to store the information in encrypted form does not exist,<sup>13</sup> only in the following cases:</p> <ul style="list-style-type: none"> <li>- Health data must be encrypted when stored in cloud computing storage environments (Sec. 6 para. 3 Health Telematics Act 2012).</li> <li>- Transfer of health data is only allowed on closed networks or in encrypted form (Sec. 6 para. 1 Health Telematics Act 2012).</li> </ul>
<i>Are there any specific auditing requirements for institutions hosting and processing EHRs?</i>		No

<sup>13</sup> Cf. Auer/Milisits/Reimer, ELGA-Handbuch, Manz, Wien, 2014, p. 39.

## 2.3. Patient consent

### 2.3.1. Main findings

Regarding patient consent in ELGA, Austria opted for an opt-out approach. This means that a person is by default ‘ELGA participant’, unless he/she objects.

ELGA participants have the following options:<sup>14</sup>

- General opt out: No participation in ELGA
- Partial opt-out: No participation in a particular ELGA application, e.g. eMedication
- Case-specific opt-out: No participation in ELGA only regarding a particular case/treatment.

There is the possibility to opt-in again.

ELGA participants can also prevent the access of a particular ELGA healthcare provider to a particular piece of or all of their ELGA data (sec. 16 para. 1 no. 2 Health Telematics Act 2012 and sec. 21 para. 3. no. 1 Health Telematics Act 2012).

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<sup>14</sup> Cf. *Auer/Milisits/Reimer*, ELGA-Handbuch, Manz, Wien, 2014, pp. 18 et seq.

### 2.3.2. Table on patient consent

Questions	Legal reference	Detailed description
<i>Are there specific national rules on consent from the patient to set-up EHRs?</i>	Sec. 15 para. 2 Health Telematics Act 2012  Sec. 16 para. 2 Health Telematics Act 2012	Pursuant to sec. 15 para. 2 Health Telematics Act 2012, ELGA implements an opt-out approach regarding consent: “The participation in ELGA may be generally objected at any time (Opt-out). Objecting ELGA-Participants have to indicate, whether this objection relates to all or just some kinds of ELGA Health Data (Sec. 2 no. 9). The general objection may be given <ol style="list-style-type: none"> <li>1. in writing to Opt-out Offices according to Sec. 28 para. 7 no. 2 or</li> <li>2. electronically via the e-Health Access Point (Sec. 23),”</li> </ol> Sec. 16 para. 2 Health Telematics Act 2012 lays down an opt-out in individual cases in the context of treatment.
<i>Is a materialised consent needed?</i>	Sec. 15 para. 2 Health Telematics Act 2012	A person is by default ‘ELGA participant’ unless he/she objects.
<i>Are there requirements to inform the patient about the purpose of EHRs and the consequences of the consent or withholding consent to create EHRs?</i>		
<i>Are there specific national rules on consent from the patient to share data?</i>		No
<i>Are there any opt-in/opt-out rules for patient consent with regard to processing of EHRs?</i>	See above	See above.
<i>Are there any opt-in/opt-out rules for patient consent with regard to sharing of EHRs?</i>	See above	There are no specific opt-in/opt-out rules on sharing of EHRs but the rules explained above apply to sharing as well.  ELGA participants can prevent the access of a particular ELGA healthcare provider to a particular piece of or all of their ELGA data (sec. 16 para. 1 no. 2 Health Telematics Act 2012 and sec. 21 para. 3. no. 1 Health Telematics Act 2012)
<i>Are there requirements to inform the</i>		No

Questions	Legal reference	Detailed description
<i>patient about the purpose of EHRs and the consequences of consent or withholding consent on the sharing of EHRs?</i>		
<i>Can the patient consent to his/her EHRs being accessed by a health practitioner or health institution outside of the Member State (cross-border situations)?</i>		Cross-border situations are not implemented in Austrian EHR legislation yet.
<i>Are there specific rules on patient consent to share data on a cross-border situation?</i>		See above.

## **2.4. Creation, access to and update of EHRs**

### **2.4.1. Main findings**

The Health Telematics Act 2012 defines a particular group of healthcare providers, the “ELGA Healthcare Providers” who are exclusively entitled to create and access EHRs. Sec. 21 para. 2 Health Telematics Act 2012 defines different roles and different access rights for different health professionals. The system of identification, authentication and authorisation is complex.

Patients are entitled to access their own EHRs on ELGA. They can access all their data stored there and they can also download them as pdf file and hence print them as well. Patients can also keep track on what person accessed what particular piece of their data.

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

Questions	Legal reference	Detailed description
<i>Are there any specific national rules regarding who can create and where can EHRs be created?</i>	Sec. 2 no. 10 Health Telematics Act 2012 Sec. 13 (2) Health Telematics Act 2012	For inter organisational exchange of EHRs (ELGA), ELGA Healthcare Providers (Sec. 2 no. 10 Health Telematics Act 2012) have the right to create and store ELGA Health Data in ELGA, pursuant to Sec. 13 para. 2 Health Telematics Act 2012. This is only allowed for one of the purposes defined in Sec. 14 para. 2 Health Telematics Act 2012.  For their own use, hospitals and physicians in private practice are allowed to create their own EHRs, as already explained above.
<i>Are there specific national rules on access and update to EHRs?</i>	Sec. 2 no. 10 Health Telematics Act 2012 Sec. 13 (2) Health Telematics Act 2012	ELGA Healthcare Providers have the right to access and update ELGA Health Data in ELGA pursuant to Sec. 13 (2) Health Telematics Act 2012. This is only allowed for one of the purposes defined in Sec. 14 (2) Health Telematics Act 2012.
<i>Are there different categories of access for different health professionals?</i>	Sec. 21 para. 2 Health Telematics Act 2012	Sec. 21 para. 2 Health Telematics Act 2012 lays down ‘general access authorizations’ for different groups of health professionals:  “(2) According to the general access authorizations that determine which standard requests shall be allowed, access is granted to: <ol style="list-style-type: none"> <li>1. members of the medical profession (Sec. 2 no. 10 lit. a) for all ELGA-Health Data (Sec. 2 no. 9),</li> <li>2. members of the dental profession (Sec. 2 no. 10 lit. b) for ELGA-Health Data according to Sec. 2 no. 9 lit. a and b,</li> <li>3. pharmacies (Sec. 2 no. 10 lit. c) for medication data according to Sec. 2 no. 9 lit. b,</li> <li>4. hospitals (Sec. 2 no. 10 lit. d) for all ELGA-Health Data (Sec. 2 no. 9),</li> <li>5. nursing institutions (Sec. 2 no. 10 lit. e) for all ELGA-Health Data (Sec. 2 no. 9),</li> <li>6. representatives pursuant to Sec. 14 para. 2 no. 2 lit. b for all ELGA-Health Data (Sec. 2 no. 9) as well as</li> <li>7. employees of the EHR-Ombudsman for all ELGA-Health Data (Sec. 2 no. 9).”</li> </ol>

Questions	Legal reference	Detailed description
<i>Are patients entitled to access their EHRs?</i>	Sec. 16 para. 1 no. 1 Health Telematics Act 2012	Patients are entitled to access all their ELGA health data through a front-end (“ELGA-Portal”) which is operated for this purpose.
<i>Can patients have access to all of EHR content?</i>	Sec. 16 para. 1 no. 1 Health Telematics Act 2012	See above.
<i>Can patients download all or some of EHR content?</i>	Sec. 16 para. 1 no. 1 Health Telematics Act 2012	The ELGA-Portal provides an option to download all data from ELGA that is related to the specific patient and to save it as a pdf file. <sup>15</sup>
<i>Can patients update their record, modify and erase EHR content?</i>	Sec. 15 para. 2 Health Telematics Act 2012 Sec. 16 para. 1 no. 2 Health Telematics Act 2012	Patients can delete any of their ELGA health data. They can do that generally when opting-out (see above, Sec. 15 para. 2 Health Telematics Act 2012) or individually with regard to particular pieces of data (Sec. 16 para. 1 no. 2 Health Telematics Act 2012)  If deletion of the data is inhibited by legal documentation requirements, only the links to the data are deleted.  Patients cannot update or modify their data on ELGA.
<i>Do different types of health professionals have the same rights to update EHRs?</i>	Sec. 13 para. 2 and 3 Health Telematics Act 2012	Sec. 13 para. 3 Health Telematics Act 2012 lists the data which must be stored in ELGA and by which persons. The Healthcare Providers listed there can be called ‘Source ELGA Healthcare Providers’ <sup>16</sup> . They create the ELGA Health Data and are allowed to store it.  All the other ELGA Healthcare Providers are ‘Consumer ELGA Healthcare Providers’ <sup>17</sup> . They have only reading access to the data.  Regarding the differentiated system of reading rights see below.
<i>Are there explicit occupational prohibitions? (e.g. insurance companies/occupational physicians...)</i>	Sec. 14 in conjunction with Sec. 2 no. 10 and 14 Health Telematics Act 2012	In reverse to the provision in Sec.14(3) Health Telematics Act 2012, only ELGA Healthcare Providers (as defined in Sec. 2 no. 10 Health Telematics Act 2012) and the ELGA ombudsman (as defined in Sec.2 no.14 Health Telematics Act 2012) are allowed to access ELGA health data. The definition of ELGA Healthcare Providers in Sec. 2 no. 10 Health Telematics Act 2012 is an exhaustive list. In addition,

<sup>15</sup> Cf. Auer/Milisits/Reimer, ELGA-Handbuch, Manz, Wien, 2014, p. 24.

<sup>16</sup> Cf. Auer/Milisits/Reimer, ELGA-Handbuch, Manz, Wien, 2014, p. 30.

<sup>17</sup> Cf. Auer/Milisits/Reimer, ELGA-Handbuch, Manz, Wien, 2014, p. 30.



Questions	Legal reference	Detailed description
		occupational physicians are explicitly exempted in Sec. 2 no. 10 (a) (cc) Health Telematics Act 2012. Pursuant to Sec.14(3) Health Telematics Act 2012, employers, human resource consultants and insurance companies are prohibited to access or use the ELGA Health Data.
<i>Are there exceptions to the access requirements (e.g. in case of emergency)?</i>		Pursuant to sec. 1 para. 2 Data Protection Act 2000, the use of personal data is permitted in cases of medical emergency. However, in the Health Telematics Act 2012 no exceptions to the access requirements can be found.
<i>Are there any specific rules on identification and authentication for health professionals? Or are they aggregated?</i>	<p>Sec. 14 para. 1 no. 1 Health Telematics Act 2012</p> <p>Sec. 4 para. 4 Health Telematics Act 2012</p> <p>Sec. 5 Health Telematics Act 2012</p> <p>Appendix 1 of the Health Telematics Ordinance 2013</p> <p>Sec. 2 and 3 Health Telematics</p>	<p>Pursuant to sec. 14 para. 1 no. 1 Health Telematics Act 2012 the use of ELGA Health Data is only legitimate if ELGA Healthcare Providers were unambiguously identified.</p> <p>Sec. 4 para. 4 Health Telematics Act 2012 defines how the identity of Healthcare Providers is verified:  “Proof and verification of the unique identity (Sec. 2 no. 2 E-Government Act) of Healthcare Providers shall be done</p> <ol style="list-style-type: none"> <li>1. by using electronic signatures that have to be traceable to qualified certificates, as well as sector-specific personal identifiers (Sec. 9 E-Government Act) or</li> <li>2. by matching of the identification data with the data of the eHealth Directory Service (Sec. 9) or</li> <li>3. by matching of the identification data with the data of the Healthcare Provider Index (Sec. 19).” <p>Sec. 5 Health Telematics Act 2012 deals with roles:  “(1) Proof and verification of the role of Healthcare Providers shall be performed according to Sec. 4 para. 4.  (2) The Federal Minister of Health shall lay down the roles to use by means of ordinance according to Sec. 28 para. 1 no. 1.”</p> <p>Appendix 1 of the Health Telematics Ordinance 2013 defines 23 roles for persons and 32 roles for organisations.</p> <p>Sec. 2 and 3 Health Telematics Ordinance 2013 lays down further</p> </li></ol>

Questions	Legal reference	Detailed description
<p><i>Does the patient have the right to know who has accessed to his/her EHRs?</i></p>	<p>Ordinance 2013</p> <p>Sec. 22 Health Telematics Act 2012</p> <p>Sec. 16 para. 1 no. 1 Health Telematics Act 2012</p>	<p>details on obtaining roles etc.</p> <p>Sec. 22 Health Telematics Act 2012 defines a “Logging System” which serves the documentation and traceability of the use of ELGA Health Data.</p> <p>According to Sec. 16 para. 1 no. 1, EHR-Participants are entitled to access and use the log data relating to them. The log data shall be presented in a simple and clearly arranged manner, pursuant to Sec. 22 para. 4 Health Telematics Act 2012.</p>
<p><i>Is there an obligation on health professionals to update EHRs?</i></p>	<p>Sec. 13 para. 3 Health Telematics Act 2012</p>	<p>Sec. 13 para. 3 Health Telematics Act 2012 lays down what ELGA Health Data must be stored in ELGA by whom until what point in time (in the course of the roll-out of ELGA).</p> <p>Sec. 13 para. 3 Health Telematics Act 2012 provides:</p> <p>“(3) To achieve the objectives referred to in para. 1 the following data shall not be stored prior to the dates laid down in Sec. 27 para. 2 to 6 and not later than laid down in Sec. 28 para. 2 no. 4:</p> <ol style="list-style-type: none"> <li>1. clinical discharge reports (Sec. 2 no. 9 lit. a sub lit. aa) from hospitals (Sec. 2 no. 10 lit. d),</li> <li>2. laboratory findings (Sec. 2 no. 9 lit. a sub lit. bb) by members of the medical profession (Sec. 2 no. 10 lit. a) provided that they are specialized in “medicinal chemistry laboratory diagnostics” or “hygiene and microbiology”, as well as laboratory findings by hospitals (Sec. 2 no. 10 lit. d) in the context of outpatient treatment,</li> <li>3. findings of diagnostic imaging by members of the medical profession (Sec. 2 no. 10 lit. a) provided that they are specialized in radiology, as well as laboratory findings by hospitals (Sec. 2 no. 10 lit. d) in the context of outpatient treatment,</li> <li>4. medication data (Sec. 2 no. 9 lit. b), in so far as they relate to trade name or active ingredient, by members of the medical profession (Sec. 2 no. 10 lit. a) at prescription,</li> <li>5. medication data (Sec. 2 no. 9 lit. b), in so far as they relate to</li> </ol>

Questions	Legal reference	Detailed description
		trade name or active ingredient, by pharmacies (Sec. 2 no. 10 lit. c) or drug dispensing doctors at dispensation as well as 6. other findings (Sec. 2 no. 9 lit. a sub lit. dd) pursuant to Sec. 28 para. 2 no. 3 and 4.”
<i>Are there any provisions for accessing data on ‘behalf of’ and for request for second opinion?</i>		The general rules for acting on behalf of another person with regard to the Austrian Citizen Card apply. To be able act on behalf of another person the person or entity must be registered on the Citizen Card of the acting person which is bound to strict requirements. <sup>18</sup>
<i>Is there in place an identification code system for cross-border healthcare purpose?</i>		No
<i>Are there any measures that consider access to EHRs from health professionals in another Member State?</i>		No

<sup>18</sup> Cf. Auer/Militsits/Reimer, ELGA-Handbuch, Manz, Wien, 2014, p. 11 sq.

## 2.5. Liability

### 2.5.1. Main findings

With ELGA, no new liability legislation was enacted.<sup>19</sup> The existing liability regime did not change. There is no provision which explicitly stipulates that health professionals must access ELGA prior to taking a decision involving the patient. However, a duty to access ELGA prior to taking a decision involving the patient can follow from professional duties of the health professional.<sup>20</sup>

So the legal situation has not changed with ELGA but factually ELGA is a new source of information for health professionals and not taking into account such a source of information can be considered as professional negligence.

On the other hand persons who enter information into ELGA are liable for that information being accurate. ELGA provides for the possibility to be always able to find out who (which natural person) entered a particular piece of information.

Austria has a comprehensive body of pre-existing as well as ELGA-specific provisions against the misuse of health data and other personal data.

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<sup>19</sup> Cf. Auer/Milisits/Reimer, ELGA-Handbuch, Manz, Wien, 2014, p. 37.

<sup>20</sup> Cf. Auer/Milisits/Reimer, ELGA-Handbuch, Manz, Wien, 2014, p. 30.

## 2.5.2. Table on liability

Questions	Legal reference	Detailed description
<i>Does the national legislation set specific medical liability requirements related to the use of EHRs?</i>		With ELGA, no new liability legislation was enacted. <sup>21</sup> The liability regime did not change.
<i>Can patients be held liable for erasing key medical information in EHRs?</i>		The patient is responsible for his actions regarding his medical data on ELGA. If the patient erases important information on ELGA and receives the wrong treatment because of that, it is his own responsibility. However, health professionals using ELGA must act in a way taking into account that the information on ELGA might not be complete.
<i>Can physicians be held liable because of input errors?</i>		The person who stores information on ELGA can be held liable for the information being accurate. <sup>22</sup> The name of the natural person who stored a piece of information on ELGA is always stored with this piece of information.
<i>Can physicians be held liable because they have erased data from the EHRs?</i>	Sec. 20 para. 1 Health Telematics Act 2012	Physicians are not able to erase data from ELGA but can update data. Sec. 20 para. 1 Health Telematics Act 2012: “Already saved ELGA-Health Data may not be altered. If circumstances emerge that could cause significant changes in the course of treatment, updated versions have to be saved additionally.”
<i>Are hosting institutions liable in case of defect of their security/software systems?</i>	Sec. 3 to 8 Health Telematics Act 2012  Sec. 25 para. 1 Health Telematics Act 2012	Sec. 3 to 8 Health Telematics Act 2012 lay down several responsibilities for the hosting institutions regarding security and other aspects.  Sec. 25 para. 1 Health Telematics Act 2012 lays down a penal provision for not complying with these responsibilities: “Anyone who <ol style="list-style-type: none"> <li>1. fails contrary to Sec. 3 para. 3 to technically ensure that Health Data can only be used in legitimate roles, or</li> <li>2. fails contrary to Sec. 4 to identify the Healthcare Providers or individuals whose health information should be disclosed, or</li> <li>3. fails contrary to Sec. 5 para. 1 to verify or proof the Role(s) of Healthcare Providers, or</li> </ol>

<sup>21</sup> Cf. Auer/Milisits/Reimer, ELGA-Handbuch, Manz, Wien, 2014, p. 37.

<sup>22</sup> Cf. Auer/Milisits/Reimer, ELGA-Handbuch, Manz, Wien, 2014, p. 36.

Questions	Legal reference	Detailed description
		<ol style="list-style-type: none"> <li>4. fails contrary to Sec. 6 to ensure the confidentiality of Health Data by data security measures, or</li> <li>5. fails contrary to Sec. 7 to verify or proof the integrity of electronic Health Data, or</li> <li>6. places persons contrary to Sec. 16 para. 3 at a disadvantage regarding the access to healthcare or in terms of cost apportionment, or</li> <li>7. makes use of the facilitated conditions as laid down in Sec. 27 para. 10 or 12, without meeting their requirements, or</li> <li>8. in his role as an ELGA-Healthcare Provider intentionally uses ELGA-Health Data, without being entitled to,</li> </ol> <p>commits an administrative offence and shall be subject to a financial penalty of up to EUR 10 000, provided that the deed does not fulfil the conditions for a criminal offence or is subject under a legal specification to the threat of penalty of greater severity.”</p>
<p><i>Are there measures in place to limit the liability risks for health professionals (e.g. guidelines, awareness-raising)?</i></p>		<p>No</p>
<p><i>Are there liability rules related to breach of access to EHRs (e.g. privacy breach)?</i></p>	<p>Sec. 25 para. 1 in conjunction with Sec. 3 to 8 Health Telematics Act 2012</p>	<p>Sec. 3 to 8 Health Telematics Act 2012 lays down several responsibilities for the hosting institutions regarding security and other aspects.</p> <p>Sec. 25 para. 1 Health Telematics Act 2012 lays down a penal provision for not complying with these responsibilities:  “Anyone who</p> <ol style="list-style-type: none"> <li>1. fails contrary to Sec. 3 para. 3 to technically ensure that Health Data can only be used in legitimate Roles, or</li> <li>2. fails contrary to Sec. 4 to identify the Healthcare Providers or individuals whose health information should be disclosed, or</li> <li>3. fails contrary to Sec. 5 para. 1 to verify or proof the Role(s) of Healthcare Providers, or</li> <li>4. fails contrary to Sec. 6 to ensure the confidentiality of Health Data by data security measures, or</li> <li>5. fails contrary to Sec. 7 to verify or proof the integrity of electronic Health Data, or</li> </ol>

Questions	Legal reference	Detailed description
		<p>6. places persons contrary to Sec. 16 para. 3 at a disadvantage regarding the access to healthcare or in terms of cost apportionment, or</p> <p>7. makes use of the facilitated conditions as laid down in Sec. 27 para. 10 or 12, without meeting their requirements, or</p> <p>8. in his role as an ELGA-Healthcare Provider intentionally uses ELGA-Health Data, without being entitled to,</p> <p>commits an administrative offense and shall be subject to a financial penalty of up to EUR 10 000, provided that the deed does not fulfil the conditions for a criminal offence or is subject under a legal specification to the threat of penalty of greater severity.”</p> <p>In addition the general rules on privacy breach apply, depending on the intention and success of the breach.</p>
<p><i>Is there an obligation on health professionals to access EHRs prior to take a decision involving the patient?</i></p>		<p>There is no provision which explicitly stipulates that health professionals must access ELGA prior to taking a decision involving the patient. However, a duty to access ELGA prior to taking a decision involving the patient can follow from professional duties of the health professional.<sup>23</sup> The fact that the legislator assumed such an obligation to exist can be derived from Sec.13(7) which provides that the ELGA Healthcare Provider is exceptionally not obligated to consult ELGA if that is technically impossible or if it takes so long that the life or health of the patient would be endangered.</p> <p>So the legal situation has not changed with ELGA but factually ELGA is a new source of information for health professionals and not taking into account such a source of information can be a breach of their legal duties.</p>
<p><i>Are there liability rules related to the misuse of secondary use of health data?</i></p>	<p>Sec. 51 Data Protection Act 2000</p> <p>Sec. 52 para. 1 Data Protection Act 2000</p> <p>Sec. 25 para. 1 Health Telematics Act 2012</p>	<p>Misuses of health data falls within the following penal provisions:</p> <p>Sec. 51 Data Protection Act 2000:  “Use of Data with the Intention to make a Profit or to Cause Harm  Sec. 51. Whoever with the intention to enrich himself or a third person unlawfully or to harm someone in his entitlement guaranteed according to Sec. 1 para 1 deliberately uses personal data that have been entrusted to or made accessible to him solely because of professional reasons, or that he has</p>

<sup>23</sup> Cf. Auer/Militsits/Reimer, ELGA-Handbuch, Manz, Wien, 2014, p. 30.

Questions	Legal reference	Detailed description
	Sec. 118a Penal Code	<p>acquired illegally, for himself or makes such data available to others or publishes such data with the intention to make a profit or to harm others, despite the data subject's interest in secrecy deserving protection, shall be punished by a court with imprisonment up to a year, unless the offence shall be subject to a more severe punishment pursuant to another provision.”</p> <p>Sec. 52 para. 1 Data Protection Act 2000:  “ Insofar as the act does not realise the legal elements of a criminal offence subject to the jurisdiction of the courts of law and is not subject to more severe penalties according to another administrative provision, an administrative offence punishable by a fine of up to 25 000 Euro is committed by anyone who</p> <ol style="list-style-type: none"> <li>1. intentionally and illegally gains access to a data application [Datenanwendung] or maintains an obviously illegal means of access or</li> <li>2. transmits data intentionally in violation of the rules on confidentiality (Sec. 15), and in particular anybody who uses data entrusted to him according to Sec. 46 and 47 for other purposes or</li> <li>3. uses or fails to grant information, to rectify or erase data in violation of a final judicial decision or ruling [Bescheid],</li> <li>4. intentionally erases data in violation of Sec. 26 para. 7;</li> <li>5. by pretending incorrect facts intentionally obtains data according to Sec. 48a.”</li> </ol> <p>Also Sec. 25 para. 1 and para. 2 Health Telematics Act 2012 are relevant here:  “(1) Anyone who</p> <ol style="list-style-type: none"> <li>1. fails contrary to Sec. 3 para. 3 to technically ensure that Health Data can only be used in legitimate roles, or</li> <li>2. fails contrary to Sec. 4 to identify the Healthcare Providers or individuals whose health information should be disclosed, or</li> <li>3. fails contrary to Sec. 5 para. 1 to verify or proof the role(s) of Healthcare Providers, or</li> <li>4. fails contrary to Sec. 6 to ensure the confidentiality of Health Data by data security measures, or</li> </ol>



Questions	Legal reference	Detailed description
		<p>5. fails contrary to Sec. 7 to verify or proof the integrity of electronic Health Data, or</p> <p>6. places persons contrary to Sec. 16 para. 3 at a disadvantage regarding the access to healthcare or in terms of cost apportionment, or</p> <p>7. makes use of the facilitated conditions as laid down in Sec. 27 para. 10 or 12, without meeting their requirements, or</p> <p>8. in his role as an ELGA-Healthcare Provider intentionally uses ELGA-Health Data, without being entitled to,</p> <p>commits an administrative offense and shall be subject to a financial penalty of up to EUR 10 000, provided that the deed does not fulfil the conditions for a criminal offence or is subject under a legal specification to the threat of penalty of greater severity.</p> <p>(2) Provided that the deed does not fulfil the conditions for a criminal offence or is subject under a legal specification to the threat of penalty of greater severity, similar punishment shall be imposed on anyone who</p> <ol style="list-style-type: none"> <li>1. intentionally uses ELGA-Health Data as a staff member of the ELGA-Ombudsman without being entitled to, or</li> <li>2. uses ELGA-Health Data as a servant of the Federal Ministry of Health without being entitled to.”</li> </ol> <p>In addition, the misuse of health data could also fall within sec. 118a Penal Code which penalises the unlawful access to a computer system under certain circumstances.</p>

## 2.6. Secondary uses and archiving durations

### 2.6.1. Main findings

The obligation for hospitals to establish clinical files and to archive them for at least 30 years has already been laid down in the Hospitals and Sanatoriums Act for a long time.

Similarly, the Physicians Act 1998 defines what information physicians in private practice have to store about their patients and defines a minimum archiving duration of ten years.

Both are only minimum durations. There is no defined maximum and we know that, for example, the largest hospital in Austria (AKH) does not delete any clinical files.<sup>24</sup>

However, it is important to note that both provisions do not define the medium which has to be used by hospitals and doctors to store the files. Hence these are not necessarily EHRs but could also be paper files, micro films etc.

As far as ELGA Health Data is concerned, the Health Telematics Act 2012 defines an archiving duration of ten years, which is also a maximum, and hence the data must be deleted after that period, unless they have to be maintained under other provisions, such as the Act referred to above.

Secondary uses are not foreseen. ELGA data should not be used for other purposes.

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<sup>24</sup> See Interview 2 (AKH).

## 2.6.2. Table on secondary uses and archiving durations

Questions	Legal reference	Detailed description
<i>Are there specific national rules on the archiving durations of EHRs?</i>	Sec. 20 (3) and (4) Health Telematics Act 2012  Sec. 10 (1) no. 3 Hospitals and Sanatoriums Act  Sec. 51 (1) and (3) Physicians Act 1998	ELGA Health Data as well as electronic references to it has to be stored for ten years. After that the data have to be deleted unless they have to be maintained under other provisions (including the following). Medication Data has to be stored in ELGA for one year and then deleted.  <u>The following provisions do not only cover electronic files:</u>  Hospitals are obliged to store clinical files for at least 30 years.  Physicians in private practice are obliged to store information about their patients, the diagnosis, the treatment etc. for at least ten years.
<i>Are there different archiving rules for different providers and institutions?</i>	See above	See above
<i>Is there an obligation to destroy (...) data at the end of the archiving duration or in case of closure of the EHR?</i>	Sec. 20 (3) and (4) Health Telematics Act 2012  Sec. 10 (1) no. 3 Hospitals and Sanatoriums Act Sec. 51 (3) Physicians Act 1998	ELGA Health Data as well as electronic references to it have to be deleted after ten years unless they have to be maintained under other provisions (including the following). Medication Data has to be stored in ELGA for one year and then deleted.  <u>The following provisions do not only cover electronic files:</u>  The Hospitals and Sanatoriums Act as well as the Physicians Act 1998 only lay down a minimum storage time and hence no obligation for deletion. <sup>25</sup>
<i>Are there any other rules about the use of data at the end of the archiving duration or in case of closure of the EHR?</i>		No
<i>Can health data be used for secondary purpose (e.g.</i>	<i>Sec. 46 Data Protection Act</i>	There are no specific provisions allowing the use of health data for secondary purpose; however, they can be used for scientific and statistical

<sup>25</sup> This was confirmed also in the course of the interview with the AKH (Interview 2).

Questions	Legal reference	Detailed description
<i>epidemiological studies, national statistics...)?</i>		purposes under the conditions stipulated in Sec. 46 of the Austrian Data Protection Act. Otherwise the consent of the patient is required. Scientific studies are usually approved by an ethic commission. <sup>26</sup> However, both the Austrian Medical Chamber as well as the ELGA Association deny an intention of allowing the use of ELGA data for scientific purposes.
<i>Are there health data that cannot be used for secondary use?</i>	<i>Sec. 46 Data Protection Act</i>	The provision is not about the data, but about the purpose of the usage. The results may not include personal data and personal data has to be anonymised at the earliest stage possible.
<i>Are there specific rules for the secondary use of health data (e.g. no name mentioned, certain health data that cannot be used)?</i>	<i>Sec. 46 Data Protection Act</i>	The provision is not about the data, but about the purpose of the usage. The results may not include personal data and personal data has to be anonymised at the earliest stage possible.
<i>Does the law say who will be entitled to use and access this data?</i>		No
<i>Is there an opt-in/opt-out system for the secondary uses of eHealth data included in EHRs?</i>		No

<sup>26</sup> Compare *Andreas Valentin, Gerhard Luf, Christian Kopetzki*, Epidemiologische Studien in der Intensivmedizin – Neuland und Graubereich für Ethikkommissionen? In: *Recht der Medizin* 2011/4, 17-23, <http://www.univie.ac.at/medizinrecht/forschung/Praktischer%20Fall.pdf> last accessed 11.04.2014, pp. 17-18.

## **2.7. Requirements on interoperability of EHRs**

### **2.7.1. Main findings**

The Austrian EHR system contains only the minimum requirements: identification of patients and EHR providers, minimum requirements of repositories and restrictions on storage of data. The link to the repositories is not yet defined.

There are no rules on interoperability of national EHRs with other Member States' EHR systems. However, the registration of EHRs from other EU Member States seems to be envisaged and also tested in projects like epSOS. Patients from other EU Member States are already registered if they ask for health services in Austria.

## 2.7.2. Table on interoperability of data requirements

Questions	Legal reference	Detailed description
<i>Are there obligations in the law to develop interoperability of EHRs?</i>	Health Telematics Act 2012	<p>The primary aim of ELGA as a whole is interoperability of EHRs. ELGA is designed as an index providing access to decentralised repositories of health data (e.g. test results, medical images), i.e. EHRs stored at the various healthcare providers.</p> <p>Central components are the index with links to repositories, the identification of patients and health service providers and the access management.</p>
<i>Are there any specific rules/standards on the interoperability of EHR?</i>	<p>Sec. 18 Health Telematics Act (patients)</p> <p>Sec. 9 Health Telematics Act (organization of the Electronic Health-Directory Service (EHDS))</p> <p>Sec. 13 Health Telematics Act (general requirements for EHR)</p> <p>Sec. 14 Health Telematics Act (principles on the usage of data)</p>	<p>The index is the main component of interoperability.</p> <p>Sec. 13 para. 5 reads: „The EHR-System Partners have to provide EHR in a way compliant to the necessary security requirements that allows for a user-friendly integration of EHR for EHR-Participants and EHR-Healthcare Providers, especially with easy to use, effective and for medical criteria optimized search and filter functions.”</p> <p>Details on achieving this objective are not defined yet, in particular the details concerning the links (e.g. purely technical, personal content, some medical content etc.).</p> <p>The identification of patients and health service providers is regulated in great detail (Sec. 18 and Sec. 9 Health Telematics Act).</p> <p>The principles on the usage of data are focused on identity management (Sec. 14 Health Telematics Act).</p>
<i>Does the law consider or refer to interoperability issues with other Member States systems?</i>	Sec. 18 Health Telematics Act	<p>Health service providers can only be those subject to Austrian health law. Patients must be included in the Patient Index (Sec. 18 Health Telematics Act).</p>

## **2.8. Links between EHRs and ePrescriptions**

### **2.8.1. Main findings**

In Austria, an ePrescription system does not exist and is not planned. For the time being, prescriptions are and remain to be paper-based. The following questions were therefore not applicable in relation to Austria.

## 2.8.2. Table on the links between EHRs and ePrescriptions

- *Infrastructure*

Questions	Legal reference	Detailed description
<i>Is the existence of EHR a precondition for the ePrescription system?</i>		No see explanation above
<i>Can an ePrescription be prescribed to a patient who does not have an EHR?</i>		No see explanation above

- *Access*

Questions	Legal reference	Detailed description
<i>Do the doctors, hospital doctors, dentists and pharmacists writing the ePrescription have access to the EHR of the patient?</i>		No see explanation above
<i>Can those health professionals write ePrescriptions without having access to EHRs?</i>		No see explanation above



## 2.9. Other requirements

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

- Health data to be included in EHRs

The legal setting for EHRs in Austria has been established but the implementation is not yet completed and will take several years. Recently the implementation was postponed.<sup>27</sup>

No central database but only a database containing links to the decentralised data stores of health data is foreseen. Patients have to opt-out if they do not wish to participate in the ELGA system.<sup>28</sup>

Efficient use of EHRs is subject to the search functionality. It is the key to an effective operation of EHRs. In practice, however, it is a problem that information in ELGA is structured like paper-based diagnostic findings. According to doctors, often the whole document of findings is not important but only one particular value. In the current structure of ELGA documents, such a value may be hard to find. It can even be difficult to find out that relevant information is available in the first place.

The AKH has a different concept of structuring and presenting findings that resolves these issues.<sup>29</sup>

- Patient consent

The opt-out solution is considered as good practice by ELGA GmbH.<sup>30</sup>

Patient consent allows efficient use of EHRs but the possibility that patients can opt out with regard to single documents could be a problem. It is a high responsibility for a patient to opt-out. Actually patients who do not have any medical qualification may not be able to decide on this properly.<sup>31</sup> Also, the variety of opt-out options makes a comprehensive overview on medical treatments a challenge for the physician.

An opt-in system would have the advantage that both, practitioners and patients, would have reflected on it more intensively. The result could have been a higher degree of compliance, i.e. a higher quality of the EHR, while (partial) opting-out may have an adverse effect on the reliability of the recorded data.<sup>32</sup>

Literature, in particular the former Head of the Data Protection Commission, has taken a different view on the opt-out solution.<sup>33</sup> Ms Souhrada-Kirchmayer criticises that in contrast to the recommendation of WP 131 of the Art. 29 Working Party<sup>34</sup>, the Austrian Health Telematics Act does not foresee a graduated system for consent requirements, depending on the sensibility of the data; but it stipulates a general opt-out system.

Further, she criticises that despite improvements, the Health Telematics Act remains in certain cases

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<sup>27</sup> Interview 2 – AKH.

<sup>28</sup> Interview 1 – ELGA.

<sup>29</sup> Interview 2 – AKH.

<sup>30</sup> Interview 1 – ELGA.

<sup>31</sup> Interview 2 – AKH.

<sup>32</sup> Interview 3 – Austrian Medical Chamber.

<sup>33</sup> *Eva Souhrada-Kirchmayer*, Das elektronische Gesundheitsakte-Gesetz (ELGA-G) aus Datenschutzsicht. In : Jahrbuch 13, Datenschutzrecht und E-Government (NWV Verlag Wien 2013, pp. 79-98 .

<sup>34</sup> Working Document on the processing of personal data relating to health in electronic health records (EHR), WP 131, adopted on 15 February 2007, available at [http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2007/wp131\\_en.pdf](http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2007/wp131_en.pdf).

unclear and laymen cannot understand it. For instance, it requires that information has to be provided especially in cases of HIV infections, mental illness, abortion etc., but it is not specified, who is responsible to provide this information. She also notes, that the Act could be misinterpreted in the way, that health service providers may ask, whether a person exercises their rights/obligation in regard to ELGA. Such questions could put patients under pressure. The doctor may interpret an obvious blinding out of data as mistrust towards her/his person; on the other hand the patient could get under pressure because of the doctor's (expected) reaction. Finally, she criticises that the prohibition on the use of health data has not been stipulated through a constitutional provision.

- Creation, access to and update of EHRs

The creation and update of ELGA links should be a sub function of the used software of the ELGA Health Care Provider so that the duty to record the data can easily be fulfilled.

On a positive note, the Health Telematics Act 2012 restricts the circle of persons who are permitted to access the ELGA system and expressly prohibits its use by occupational physicians, employers, human resource consultants and insurance companies.

- Liability

The obligation for consultation of ELGA files may lead to liability cases of negligence.

A problem could arise through unintended accidental access to data which was not an actual misuse but only a mistake. In particular this could happen in emergency situations when persons are mistaken for someone else because both have the same name and birth date.<sup>35</sup>

The strengthening of the patient's autonomy shapes new framework conditions. It is for instance a problem, whenever the necessary information is there, but there is no time to read it due to an emergency.

- Secondary use and archiving duration

Secondary uses are not allowed. The archiving duration is 10 years for ELGA files.

- Requirements on interoperability of EHRs

The link system does not set high requirements on interoperability. Standards for the exchange of documents between ELGA and Health Care Providers have to be developed.

- Links between EHRs and ePrescriptions

Austria does not use ePrescriptions so far.<sup>36</sup>

- Other requirements

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<sup>35</sup> Interview 2 – AKH.

<sup>36</sup> Interview 1 – ELGA.