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 Italy

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Executive Summary

1. Stage of development of EHRs in Italy

In 2008 the Italian Ministry of Health conducted a study to determine the status of adoption of the EHRs. The study showed that 43% of the local health authorities, 62% of the hospitals and 19% of local clinics use the electronic health records.

As far as health workers using electronic health records, a coverage of 71% was estimated for general practitioners and paediatricians, 67% for other doctors in the National health service while 29% of nurses and 5% of pharmacist adopted it.

The electronic health record is in general adopted to carry out 52% of the specialist hospital services, 33% of the pharmaceutical services and 24% of the emergency care services.

Moreover, 43% of the Italian regions declare to have adopted electronic health records for the management of part of their healthcare data. These data show that in 2008 the EHR was quite well developed in Italy, even without a specific national legal framework.

Hence, in order to promote a national reference model and to support the establishment of a unified regulatory framework, the Ministry of Health in the second half of 2008 set up an inter-institutional working group (hereinafter "EHR working group"), to define specific national guidelines for the creation of an Electronic Health Record system.

The members of the EHR working group are representatives of the Ministry of Health, representatives of the Presidency of the Council of Ministers - Department of Innovation (now the Agency for Digital Italy), regional representatives, a representative of the Italian Data Protection Authority and representatives of Italian Federation of Medical Doctors, Surgeons and Dentists (FNOMCeO).

The national EHR guidelines[1], adopted by the State-Regions Conference on February the 10, 2011, (hereinafter "2011 Ministry of Health Guidelines") are not binding by law but regulate the characteristics of the EHR, of the patient summary, define infrastructural aspects and technological standards, the levels of security and data protection.

Moreover, the EHR working group drafted a national regulation proposal, that has been the basis of the Italian Article 12 of Decree Law 18 October 2012, no. 179, converted into law with amendments by Law 17 December 2012, n. 221, as subsequently amended (hereinafter, D.L. 179/2012), that requires Italian regions and autonomous provinces to establish EHRs by 30 June 2015. The implementation of EHRs will thus take place at the level of regions and autonomous provinces, but in accordance with the common rules set out in Article 12 of D.L. 179/2012.

Article 12 defines electronic health record as "a set of health and socio-health digital data and documents related to present and past clinical events regarding a patient". The same article also provides that "Italian regions and autonomous provinces shall adopt electronic health records by 30 June 2015, in compliance with the current legislation on personal data protection". The adoption of the electronic health records' aims are a) prevention, diagnosis, treatment and rehabilitation, b) study and scientific research in the medical, biomedical and epidemiological field, c) health planning, assessment of the quality of treatment and evaluation of health care.

[1] State-Regions Conference, agreement of February 10, 2011, available, in Italian, at http://www.statoregioni.it/Documenti/DOC_030589_19%20csr.pdf

Article 12 of the Decree Law 18 October 2012, no. 179 is an extremely relevant provision. Beside the definition of electronic health record and of its aims, the article also determines the conditions under which the electronic health records should be created.

The information dealt with in the electronic health records includes prescriptions, services, medical reports, discharge letters, emergencies, diseases and chronic illness. On the contrary, vaccinations and certificates information are less frequently processed with electronic health records.

The adoption of the first implementation decree, according to the provisions of Article 12 (7) of D.L. 179/2012, is forthcoming. It is worth mentioning that the contents are strictly related to the 2011 Ministry of Health Guidelines, and that the EHR working group was involved in the drafting phase.

On March 31, 2014, the Ministry of Health and the Agency for Digital Italy issued the Guidelines for regional project plans presentation on the EHR[2] (hereinafter, "2014 Ministry of Health and Agency for Digital Italy Guidelines"), according to Article 12 (15-bis) of D.L. 179/2012. The majority of regions and autonomous provinces presented their project plans by 30 June 2014, respecting the stated deadline.

According to article 12 (15-quater) of D.L. 179/2012, the Ministry of health and the Agency for Digital Italy are currently evaluating the plans of the regions and autonomous provinces for approval.

In relation to data protection issues, in 2009 Guidelines on the Electronic Health Record and the Health File by the Italian Data Protection Authority (hereinafter, also DPA) adopted the Guidelines on the Electronic Health Record and the Health File [3].

The laws and measures mentioned above represent the most relevant rules regulating electronic health records, but they are not the only ones, as other the Italian legislation – notably the Personal Data Protection Code and the Digital Administration Code – should also be taken into account on the electronic health record is complex and detailed.

2. Summary of legal requirements applying to EHRs

This section provides a summary of the legal requirements relevant to EHRs in Italy. It should be borne in mind that, as the implementing decree has not yet been adopted, not all the rules summarised here are already applicable. Clarifications in this regard are offered in the more detailed sections of this report.

D.L. 179/2012 sets out a definition and the general principles governing EHRs in Italy. Electronic health records can only be created for specific purposes:

- prevention, diagnosis, treatment and rehabilitation functions (pursued by the bodies of the National health service and of the regional socio-health services).
- study and scientific research in the medical, biomedical and epidemiological fields, health planning, verification of quality of care and evaluation of health care (pursued by the Italian Ministry of Labour and the Ministry of Health, the regions and autonomous provinces).

Access to data is only granted to those who are authorised to process it because of their position.
The software and the applications used must ensure full interoperability with the solutions already available in the market.

[2] Guidelines for regional project plans presentation on the EHR, available, in Italian, at http://www.salute.gov.it/imgs/C_17_pubblicazioni_2141_allegato.pdf

[3] Italian Data Protection Authority, Guidelines on the Electronic Health Record and the Health File (as published in Italy's Official Journal no. 178 dated 3 August 2009), available at http://www.garanteprivacy.it, doc. web. No. 1672821.

Furthermore, access to data should be granted only in accordance with the confidentiality principle and measures of protection of the patient's privacy should be enforced. Electronic health records shall always be developed in accordance with the legislation on personal data protection. Therefore, the processing of the data dealt with in the electronic health records can only be carried out with the patient's consent. The lack of such a consent does not affect the patient's right to health. Anyone with access to electronic health records is bound by professional secrecy in accordance with the Italian Law on personal data protection.

Working and having access to electronic health records originates different obligations depending on the role and the activity carried out. Therefore, it is not possible to determine in advance a unique consequence in terms of liability: in facts even for the doctors liability under civil or criminal law might arise. It clarifies that EHRs contain both health data and other data.

The D.L. 179/2012 expressly provides that the free and informed consent of the patient is necessary in order for information to be included in the EHR. Consent does not have to take a specific form. Freedom of consent is preserved by the rule that refusal to give consent can never prejudice the patient's right to health services.

Information is included in the EHR by the persons taking care of the patient within the National Health Service or regional health services. However, there is no clear obligation for relevant operators to feed information into EHRs. The patient may request that information in his possession be included in his EHR, but may not unilaterally modify the EHR, except with regard to a specific section of the EHR – the patient's personal notebook.

The patient's consent is also required for accessing the EHR, save in the case of emergencies. Moreover, consent is not needed where EHRs are accessed for the purposes of research, health planning and evaluation ("secondary uses"), as in these cases identification data may not be utilised.

The D.L. 179/2012 foresees that different persons should have different rights to access or modify EHR data. Neither source explicitly lays down occupational prohibitions (e.g. insurance companies), but such prohibitions result *a contrario* from access being limited to certain categories of persons for specific purposes.

The D.L. 179/2012 requires interoperability of EHRs at regional, national and European levels.

It is worth underlining that the D.L. 179/2012 does not make any distinction between internal and cross-border situations.

Good practices

Under Italian law, the adoption of electronic health records is compulsory. As already mentioned, Decree Law of 18 October 2012, No. 179 requires Italian regions and autonomous provinces to adopt the electronic health records. The deadline for the implementation has been set on 30 June 2015.
The introduction of such a mandatory prevision reveals Italy's aim to push the healthcare digitalisation process. The main purpose of the Italian legislation is indeed to provide more effective means for health protection.

As already underlined, the creation of the electronic health record is subject to the patient's consent. The patient has a central role in the process of creation of the electronic health record, and he or she is protected both as a patient and as the subject of the data processing.

Furthermore, as already mentioned, article 12 of the Decree Law of 18 October 2012, No. 179 requires the electronic health record to be based on software and applications that ensure full interoperability with the technological solutions already existing on the market. Such a requirement will simplify the future transfer of the data contained in the electronic health records among European Countries.

3. Legal barriers

I see no legal barriers to the development and consolidation of electronic health records in Italy. The laws exist, guidelines for the implementation of electronic health records have already been adopted and the requirements to be met for the creation and management of electronic health records have been specified. The patient's right to privacy and the protection of his or her personal data are ensured by the Italian specific privacy legislation.

Therefore, there are no legal limits to the creation of the electronic health record, but a number of cultural difficulties exist. The general awareness of the advantages brought by electronic health records is not well spread and their potential or the risks deriving from their incorrect use are not completely understood. Often concerns on the electronic health records are raised simply because they represent a new instrument. There is a great need to enhance the awareness and general knowledge on the subject. The diffusion of new technological instruments, indeed, often requires a cultural change. For instance, the patient must learn to trust the electronic health record as an instrument. At the same time doctors, pharmacists and anyone else who has access to electronic health records should be aware of their tasks and of the limits and the liability provided for by the law.

Contents

List of abbreviations

EHR(s)	Electronic health record(s)
D.L.	Decree Law
D.Lgs.	Legislative Decree
Italian D.P.A.	Italian Data Protection Authority
LISPA	Lombardia Informatica - Service Company - Lombardia Region
MCB	Bologna Medical Council
RER	Emilia-Romagna Region

1. General context

1.1 EHR systems in place

In 2008, the Ministry of Health conducted a study on the status of electronic health records (EHRs) in Italy. The study showed that 43% of local health authorities, 62% of hospitals and 19% of local clinics used EHRs. As far as health operators using electronic health records are concerned, coverage was estimated at 71% for general practitioners and paediatricians, 67% for other doctors in the National Health Service, 29% for nurses and 5% for pharmacists. EHRs were used in 52% of specialist hospital services, 33% of pharmaceutical services and 24% of emergency care services. Moreover, 43% of Italian regions declare to have adopted electronic health records for the management of part of their healthcare data. Therefore, the structures involved in the use of electronic health records are the local health authorities, hospitals and local clinics. As far as the professionals and operators involved, the use of electronic health records is limited to general medicine doctors and paediatricians, to other doctors in the National Health Service, to nurses and to pharmacists.

In order to promote a national reference model and to support the establishment of a unified regulatory framework, the Ministry of Health in the second half of 2008 set up an inter-institutional working group (hereinafter "EHR working group"), to define specific national guidelines for the creation of an Electronic Health Record system.

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The national EHR guidelines[4], adopted by the State-Regions Conference on February the 10, 2011, (hereinafter "2011 Ministry of Health Guidelines") are not binding by law but regulate the characteristics of the HER, of the patient summary, define infrastructural aspects and technological standards, the levels of security and data protection.

Moreover, the EHR working group drafted a national regulation proposal, that has been the basis of the Italian Article 12 of Decree Law 18 October 2012, no. 179, converted into law with amendments by Law 17 December 2012, n. 221, as subsequently amended (hereinafter, "D.L. 179/2012"), that requires Italian regions and autonomous provinces to establish EHRs by 30 June 2015. The implementation of EHRs will thus take place at the level of regions and autonomous provinces, but in accordance with the common rules set out in Article 12 of D.L. 179/2012.

The article 12 above mentioned established the purposes of EHRs. According to such a provision, EHRs can be used for patient care and therapy purposes as well as for administrative reasons (e.g. the control on the health planning and organization). For such a reason the access to the data will also be extended to administrative operators.

According to article 12 of the D.L. 179/2012, the patient can also upload in the EHRs assessments and opinions.

The use of the EHRs is not limited to specific categories of patients and it can also apply to under age patients. As already said, the creation of EHRs is subject to the consent of the patient. According to Italian legislation, exception made for few specific cases, only people over eighteen years old can express their legitimate consent. When the patient is under age, his or her parents or other legal representatives will give the consent on his behalf.

[4] State-Regions Conference, agreement of February 10, 2011, available, in Italian, at http://www.statoregioni.it/Documenti/DOC_030589_19%20csr.pdf

1.2 Institutional setting

On a national level, the competent authorities are the Italian Ministry of Health and the Agency for Digital Italy. Article 12 (7) of D.L. 179/2012 mandates the Ministry of Health to issue one or more implementing decrees[5] for the full implementation of article 12 of d.l. No. 179 of 18 October 2012.

However, Article 13 (2-quater) of Decree Law 21 June 2013, no. 69, converted into law with amendments by Law 9 August 2013, n. 98, mandates the transformation of implementation decree, from a Ministerial decree to a President of the Council of Ministers decree.

The adoption of the first implementation decree is forthcoming. It is worth mentioning that the contents are strictly related to the 2011 Ministry of Health Guidelines, and that the EHR working group was involved in the drafting phase.

The Decrees will define:

1. The contents of EHRs;
2. The duties and liability limits for persons cooperating in the implementation of EHRs;
3. The data encoding systems;
4. The guarantees and security measures to be applied when processing personal data;
5. The different modalities and levels of access to EHRs by different people;
6. The definition and modalities for the attribution of the patient's unique identification code, which shall not allow the direct identification of the patient;
7. The rules ensuring interoperability of EHRs on the regional, national and European level.

According to article 12 (15-ter) of D.L. 179/2012 the Agency for Digital Italy, on the basis of the requirements defined by the regions and autonomous provinces, will provide, in accordance with the Ministry of health and the regions and autonomous provinces, the national infrastructure that would ensure interoperability between the different existing EHRs systems and those that will be developed by 30 June 2015.

Among the relevant authorities, the Italian Data Protection Authority should also be mentioned.
In 2009, the Authority issued the Guidelines on the Electronic Health Record and the Health File.
Recently, the Italian Data Protection Authority expressed its favourable opinion on the draft of the said implementing decree to be adopted by the President of the Council of Ministers.

The regions and autonomous provinces are in charge of the implementation of EHRs: they shall create and enforce EHRs on their territory in accordance with D.L. 179/2012 and legislation on personal data protection. Regions are also represented in the process of adoption of the implementing decree(s).
According to article 12 (15-bis) of D.L. 179/2012, the Italian regions and autonomous provinces are required to submit, by 30 June 2014, a plan for the implementation of EHRs to the Ministry of Health and to the Agency for Digital Italy. The plan shall be based on the guidelines issued on March 31, 2014, by the Ministry of Health and the Agency for Digital Italy[6]:The majority of regions and autonomous provinces presented their project plans by 30 June 2014, respecting the stated deadline.
According to article 12 (15-quater) of D.L. 179/2012, the Ministry of health and the Agency for Digital Italy are currently evaluating the plans of the regions and autonomous provinces for approval.

1.3 Legal setting and future legal development

[5] The Ministry of Technological Innovation, the Ministry of Economy and Finance and the Agency for Digital Italy are also involved in the preparation of the decree(s).
[6] Guidelines for regional project plans presentation on the HER, available, in Italian, at http://www.salute.gov.it/imgs/C_17_pubblicazioni_2141_allegato.pdf

The most relevant provision on EHRs in Italy is Article 12 of D.L. 179/2012, which obliges Italian regions and autonomous provinces to establish EHRs by 30 June 2015. By 30 June 2014, regions and autonomous provinces are required to prepare projects for the establishment of EHRs.

In order to become fully operational, however, Article 12 still requires implementing measures to be set out by ministerial decree(s). The adoption of the first decree, as previously stated, is forthcoming and it will specify the contents EHRs should have, the tasks of the operators working with the records, the different levels of access to the EHRs and the rules that will ensure interoperability of EHRs on a regional, national and European level.
Apart from Article 12 of D.L. 179/2012, other more general pieces of legislation are relevant. In particular, Legislative Decree 30 June 2003, no. 196 "Personal Data Protection Code", as amended, lays down a number of rules regarding the treatment and holding of personal data, as well as security measures.

Legislative Decree 7 March 2005, no. 82 "Digital Administration Code", as amended, contains provisions governing the Public Connectivity System, in which EHR systems are integrated. The term Public Connectivity System designates the technological infrastructure and the technical rules for the development, sharing and integration of information by the public bodies. Technical and security rules for the functioning of the Public Connectivity System, as set out in the Decree of the President of the Council of Ministers of 1 April 2008 (hereinafter "the 2008 decree"), thus apply also insofar as EHRs are concerned, as do the technical rules on the holding of digital documents set out in the Decree of the President of the Council of Ministers of 3 December 2013[7] (hereinafter "the 2013 decree"). Moreover, the Regulation on the Qualification of Suppliers of the Public Connectivity System[8] (hereinafter, "the Supplier Qualification Regulation") is also relevant.

Relevant non-binding documents include the forementioned 2011 National Guidelines of the Ministry of Health[9] (hereinafter, "the 2011 Ministry of Health Guidelines") and the 2009 Guidelines of the Italian Data Protection Authority[10] (hereinafter, "the 2009 Data Protection Authority Guidelines"). It should be noted that both these sets of guidelines predate the D.L. 179/2012, and are at least in part superseded by the latter. For example, the 2009 Data Protection Authority Guidelines recommend that the objectives of EHRs should relate only to the prevention, care and rehabilitation of the patient, to the exclusion of any other end such as the planning of health care services. The D.L. 179/2012, instead, expressly includes health care planning among the objectives of EHRs.

[7] http://www.gazzettaufficiale.it/eli/id/2014/03/12/14A02098/sg
[8] http://www.progettoicar.it/GetMedia.aspx?id=fab91bc884274b098af6d4228d566ba8&s=0&at=1
[9] State-Regions Conference, agreement of February 10, 2011, available, in Italian, at http://www.statoregioni.it/Documenti/DOC_030589_19%20csr.pdf
[10] http://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/docweb/1634116

2. Legal requirements applying to EHRs in Italy

2.1. Health data to be included in EHRs

2.1.1. Main findings

The table below provides a comprehensive description of the legal requirements applying to EHRs in Italy. The EHRs is regulated by the d.l. of 18 October 2012, No. 179. The Decree of implementation of the D.L. 179/2012 has not been adopted yet.

2.1.2. Table on health data

Questions	Legal reference	Detailed description
Are there specific rules on the content of EHRs? (or regional provisions, agreements, plans?)	D.L. 179/2012 2011 Ministry of Health Guidelines	Article 12(1) of D.L. 179/2012 defines the EHR as "a set of health and socio-health digital data and documents related to present and past clinical events regarding a patient". The d.l. No. 179 of 18 October 2012, does not enumerate the information that should be included in the EHRs. Article 12(7) of D.L. 179/2012 provides that implementing ministerial decree(s) shall establish the content of EHRs. Pending the adoption of the implementing ministerial decree, it may be worth recalling that the 2011 Ministry of Health Guidelines set out recommendations on the content of EHRs, which should include: - patient identification data; - administrative information regarding the patient's history in the National Health Service; - socio-health and health documents (reports, emergency reports, discharge letters); - patient summary (a document created by the general practitioner who collects the clinical history of the patient); - patient's personal notebook (a document created by the patient); - patient's statement on the donation of organs and tissues.
Are these data restricted to purely medical information (e.g. physical or mental health, well-being)?	D.L. 179/2012	Article 12(1) of D.L. 179/2012 states that EHRs contain, in addition to health data, "socio-health" data. However, there is no clear definition of socio-health data in the D.L. 179/2012. Article 12(7) of D.L. 179/2012 provided that implementing ministerial decree(s) shall establish the content of EHRs. The "pharmaceutical dossier" is also part of the EHRs. The patient may also upload the medical data in his possession into the system.

Questions	Legal reference	Detailed description
Is there a definition of EHR or patient's summary provided in the national legislation?	D.L. 179/2012 2011 Ministry of Health Guidelines	Article 12(1) of D.L. 179/2012 defines the EHR as "a set of health and socio-health digital data and documents related to present and past clinical events regarding a patient". The D.L. 179/2012 does not lay down a definition of patient's summary. A definition of "patient's summary" is laid down in section 3.4 of the Guidelines. Article 4 (1) of implementation decree, defines the patient summary.
Are there any requirements on the content of EHRs (e.g. detailed requirements on specific health data or general reference to health data)?	D.L. 179/2012 2011 Ministry of Health Guidelines	Article 12(1) of D.L. 179/2012 states that EHRs contain health data as well as socio-health. Article 12(7) provides that implementing ministerial decree(s) shall establish the content of EHRs. The D.L. 179/2012 does not enumerate the information that should be included in the EHRs. A list of the relevant information will be contained in the Decree of implementation of the d.l. No. 179. A more detailed provision is contained in the National Guidelines on Electronic Health Records of 2011.
Are there any specific rules on the use of a common terminology or coding system to identify diseases, disorders, symptoms and others?	.D.L. 179/2012	Article 12 of D.L. 179/2012 does not contain any provision on common terminology or coding. Article 12(7) provides that implementing ministerial decree(s) shall establish data codification systems.
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)?	D.L. 179/2012	Article 12 of D.L. 179/2012 does not specify whether creating separate categories of data with different levels of confidentiality in EHRs is necessary. However, Article 12(7) provides that implementing ministerial decree(s) shall establish different levels and modalities of access to EHR data, depending on the role of the person exercising the access and the purpose of access.

Questions	Legal reference	Detailed description
		Special safeguards apply in relation to health data and documents regarding HIV-positive persons, women who underwent abortion or decided to give birth anonymously, victims of sexual violence or paedophilia, persons with addictions to drugs or alcohol. Relevant data and documents may only be made visible with an explicit consent of the person concerned.
Are there any specific rules on identification of patients in EHRs?	D.L. 179/2012 Digital Administration Code	Article 12(7) of D.L. 179/2012 states that the patient's unique identification code (to be made operational by the implementing ministerial decree(s)) shall not allow the direct identification of the patient. Identification data in EHRs may not be used for purposes other than prevention, diagnosis, treatment and rehabilitation of patients. Insofar as identification for the purposes of accessing EHRs is concerned, the patient may access his EHR by means of the electronic identity card, national service card, or the public system for the management of the digital identities of citizens and business described in Article 64 of the Digital Administration Code (Articles 10(1) and 24(2)).
Is there is a specific identification number for eHealth purposes?	D.L. 179/2012	Article 12(7) of D.L. 179/2012 provides that implementing ministerial decree(s) shall establish unique identification codes which do not allow the direct identification of the patient, as regards to purposes of studying, scientific researching and health planning.

2.2. Requirements on the institution hosting EHRs data

2.2.1. Main findings

The D.L. 179/2012 does not lay down specific requirements on the institutions hosting EHR data. However, in mandating the adoption of implementing measures, it states that the criteria of the Public Connectivity System established by the Digital Administration Code must be observed.

The Digital Administration Code (and other relevant sources specified in the table) stipulates that the IT services underpinning the Public Connectivity System may only be provided by suppliers who meet certain requirements. Insofar as the EHR system will be integrated into the Public Connectivity System, those safeguards will be relevant for the purposes of this study.

In addition, certain rules set out in the Personal Data Protection Code – notably as regards encryption of health data – are applicable, as are the security measures established by the Digital Administration Code.

Lastly, there are the Guidelines for regional project plans presentation on the Electronic Health Record, issued by Agency for Digital Italy and Ministry of Health.

2.2.2. Table on requirements on the institutions hosting EHRs data

Questions	Legal reference	Detailed description
Are there specific national rules about the hosting and management of data from EHRs?	D.L. 179/2012 Digital Administration Code Personal Data Protection Code	The D.L. 179/2012 does not lay down any specific rule regarding the hosting and management of EHR data. General principles contained in the Digital Administration Code and in the Personal Data Protection Code apply. However, these rules are not specific to EHRs.
Is there a need for a specific authorisation or licence to host and process data from EHRs?	D.L. 179/2012 Digital Administration Code	The D.L. 179/2012 does not require any specific authorisation or licence to host and process EHR data. However, the D.L. 179/2012 makes reference to the fact that EHR systems must comply with the rules of the Public Connectivity System established by the Digital Administration Code (Articles 12(7) and 26(2), respectively). Under that Code, only suppliers meeting certain criteria may provide relevant IT services. Although they would enter into a contract with the public authorities, as opposed to receiving an authorisation or licence, they are still scrutinised in accordance with legal criteria. Also see answer to the next question.
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)?	Digital Administration Code 2008 decree Personal Data Protection Code	The D.L. 179/2012 does not lay down any particular provision regarding the characteristics of the institution hosting or managing EHR data. However, it requires implementing ministerial decrees to define guarantees and security measures and to ensure compliance with the technical rules of the Public Connectivity System. Both the Digital Administration Code, the 2008 decree and the Supplier Qualification Regulation envisage that suppliers of services for the purposes of the Public Connectivity System must have certain characteristics, notably in terms of infrastructure, experience, commercial network and technical assistance, financial soundness.

Questions	Legal reference	Detailed description
		Moreover, general rules on security of personal data (Title V of the Personal Data Protection Code) apply. Personal data must be hosted and protected in such a way as to reduce the risk of destruction, loss, unauthorised access or processing, taking into account technical progress and the nature of the data (Art. 31, Personal Data Protection Code). As a minimum, the rules on the processing and hosting of personal data by electronic means laid down in Article 34 and Annex B to the Personal Data Protection Code must be complied with. These include secure authentication, the use of an authorisation system for access, the keeping of back-up copies of data, as well as data encryption.
In particular, is there any obligation to have the information included in EHRs encrypted?	D.L. 179/2012 Personal Data Protection Code - Annex B	Article 12 of D.L. 179/2012 provides that the implementing ministerial decree(s) must establish guarantees and security measures applicable to the processing of patients' personal data (processing includes the holding of personal data). However, it does not expressly require that data must be encrypted. Nevertheless, a requirement for encryption of personal data concerning health is laid down in Article 34(1)(h) of the Personal Data Protection Code. The Point 24, Annex B, of the Personal Data Protection Code, shall in particular require that "Health care bodies and professionals shall process data disclosing health and sex life as contained in lists, registers or data banks in accordance with the mechanisms referred to in Section 22(6) of the Code also in order to ensure that said data are processed separately from the other personal data allowing data subjects to be identified directly"
Are there any specific auditing requirements for institutions hosting and processing EHRs?	Digital Administration Code 2008 decree Supplier Qualification Regulation	D.L. 179/2012 does not lay down any specific rule regarding auditing of institutions hosting and processing EHRs. However, both the Digital Administration Code, the 2008 decree and the Supplier Qualification Regulation clarify that suppliers of the Public Connectivity System are subject to controls by the Coordinating Commission of the Public Connectivity System and the regions.

Questions	Legal reference	Detailed description
	2011 Ministry of Health Guidelines	A requirement on operators tracking and audit is laid down in section 6 of the Guidelines.

2.3. Patient consent

2.3.1. Main findings

The D.L. 179/2012 expressly provides that the free and informed consent of the patient is necessary in order for information to be included in the EHR. Freedom of consent is preserved by the rule that refusal to give consent can never prejudice the patient's right to health services.

The D.L. 179/2012 does not specify what information must be given to the patient in order for his consent to be considered as "informed".

The D.L. 179/2012 does not lay down any specific requirement of form for the patient's consent. The general rule of the Personal Data Protection Code therefore applies, to the effect that consent may also be given orally. In this case, it is recorded in writing by the health operator.

It is noteworthy that the D.L. 179/2012 does not make any distinction between internal and cross-border situations. The rules summarised above are therefore applicable to both cases.

Finally, there is no provision specific to the sharing of (as opposed to access to) EHR data.

2.3.2. Table on patient consent

Questions	Legal reference	Detailed description
Are there specific national rules on consent from the patient to set-up EHRs?	D.L. 179/2012 Personal Data Protection Code 2011 Ministry of Health Guidelines	Article 12(3-bis) of D.L. 179/2012 states that data may be uploaded into the EHRs only if the patient consents. The patient may also decide which health data shall not be included in the EHR. According to general principles on data protection, consent must be informed. The patient shall receive complete information on the processing of personal data in EHRs. The consent is also required by the Guidelines on the Electronic Health Record and the Health File of the Italian Data Protection Authority. Moreover, according to the Guidelines, the consent must specifically refer to the processing of data in EHRs and it is always possible to withdraw it. Consent must also be free. Therefore, Article 12(5) of D.L. 179/2012 adds that failure to consent access to EHR data does not prejudice the patient's right to health services. The patient can freely refuse or give the consent to the processing as the D.L. 179/2012 provides that the lack of consent does not affect the right to health. On the Guidelines there is a specific section (section 5.1.2) about the consent, wich requires that the consent must be "explicit".
Is a materialised consent needed?	Personal Data Protection Code	Article 12 of D.L. 179/2012 does not lay down any specific requirement of form for consent to the processing of personal data in the EHRs. The general rule of Article 81 of the Personal Data Protection Code therefore applies, according to which consent may also be oral. In such a case, it has to be registered in written form by the health professional.
Are there requirements to inform the patient about the purpose of EHRs and the consequences of the	Personal Data Protection Code	Article 12 of D.L. 179/2012 does not lay down any specific requirement to inform the patient about the purpose of EHRs and the consequence of his consent or refusal to give consent.

Questions	Legal reference	Detailed description
consent or withholding consent to create EHRs?	D.L. 179/2012 Italian Data Protection Authority, Guidelines on the Electronic Health Record and the Health File 2011 Ministry of Health Guidelines	The D.L. 179/2012 states that data can be uploaded on the EHRs only with the patient's consent (Art. 12, par. 3 a). Pending the entry into force of the implementing decree, general rules apply, notably Articles 78, 79 and 80 of the Personal Data Protection Code. These provisions set out simplified requirements under which general practitioners, paediatricians, public and private health centres, and other public bodies have to inform the patient about the processing of personal data in a clear and easily comprehensible manner. Such information must highlight, in particular, the processing of personal data which poses specific risks for fundamental rights and freedoms, or the dignity of the patient (express examples include telemedicine). The patients shall be fully informed on the processing of personal data in EHRs prior to his or her consent. The information must get across to the patient with a clear and simple language. All elements of Art. 13 of d. lgs. No. 196 of 30 June 2003 shall be disclosed. The patient should also be informed that the lack of consent does not affect his or her right to the health. Information shall include the aims and modalities of processing, the consequences of a refusal, the persons or categories of persons to whom data may be communicated or who may access them.
Are there specific national rules on consent from the patient to share data?	D.L. 179/2012 2011 Ministry of Health Guidelines Personal Data Protection Code	Article 12(5) of D.L. 179/2012 provides that the EHR may only be accessed if the patient consents, except for the case of health emergency. However, consent properly regards access to (not sharing of) EHR data. It may also be worth recalling Article 79 of the Personal Data Protection Code, according to which private and public health bodies may seek consent in relation to several health services even if they are provided by different units of the same bodies – whether or not in the same location – provided they are specifically

Questions	Legal reference	Detailed description
		identified.
Are there any opt-in/opt-out rules for patient consent with regard to processing of EHRs?	D.L. 179/2012 Personal Data Protection Code	As explained above, patient consent to the processing of personal data in the EHRs has to be specific and explicit. No opt-out rules are in place.
Are there any opt-in/opt-out rules for patient consent with regard to sharing of EHRs?	D.L. 179/2012 Personal Data Protection Code	As explained above, access to data in EHRs is subject to the patient giving consent. The patient may decide not to allow certain persons to access EHR data. No opt-out rules are in place.
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?	D.L. 179/2012 2011 Ministry of Health Guidelines	General principles apply: the patient must be informed about the persons who will have access to his EHR (Article 7(2)). On the Guidelines there is a specific section (section 5.1.1) with a few requirements.
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)?	D.L. 179/2012	The D.L. 179/2012 does not lay down any specific provision in this regard. Article 12(5) of D.L. 179/2012 requires the patient's consent for accessing EHR data, without making a distinction between internal and cross-border situations. Therefore, patient's consent should be equally required in both internal and cross-border situations.
Are there specific rules on patient consent to share data on a cross-border situation?		See previous answer.

2.4. Creation, access to and update of EHRs

2.4.1. Main findings

The D.L. 179/2012 requires regions and autonomous provinces to establish EHRs by 30 June 2015. It will then be for the persons taking care of the patient within the National Health Service or regional health services to insert information into EHRs, if the patient consents. There is no clear obligation for relevant operators to actually feed information into EHRs, however.

The patient's consent is also required for accessing the EHR, save in the case of emergencies. The exception notably includes situations in which the relevant risk does not regard the patient individually, such as public health emergencies. Moreover, consent is not needed where EHRs are accessed for the purposes of research, health planning and evaluation, as in these cases identification data may not be utilised.

The D.L. 179/2012 foresees that different persons should have different rights to access or modify EHR data.

Article 12 (2) of the D.L. 179/2012 states that the patient must be able to access his EHR, in accordance with general rights derived from the Personal Data Protection Code
In order to facilitate interoperability, including at European level, D.L. 179/2012 requires implementing measures to establish relevant codification and interoperability systems.

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

Questions	Legal reference	Detailed description
Are there any specific national rules regarding who can create and where can EHRs be created?	D.L. 179/2012	Article 12(2) of the D.L. 179/2012 states that regions and autonomous provinces shall establish EHRs by 30 June 2015. This provision refers to the systems necessary to implement EHRs. The subsequent paragraph 3 provides that the persons taking care of the patient within the National Health Service or the regional health services shall feed information into the EHR. The patient may also request that health information in his possession be included in the EHR. Article 12(7) further mandates the adoption of implementing ministerial decree(s) which shall, among other things, define the tasks of persons participating in the implementation of EHRs.
Are there specific national rules on access and update to EHRs?	D.L. 179/2012	Access to EHR data for health care purposes is only allowed if the patient has given is consent, save for emergency situations (Article 12(5), D.L. 179/2012). Access for other purposes (research, health planning and evaluation) does not require the patient's consent because his identification data may not be utilised in these cases (Article 12(6), D.L. 179/2012). Information may only be included in the EHR by persons offering health care treatments to the patient in the framework of the National Health Service or regional health services. Patient's consent is required (Article 12(3)-(3-bis), D.L. 179/2012). Moreover, the patient may request that health information in his possession be included in the EHR (Article 12(3), D.L. 179/2012). It may be worth noting that the revocation of consent for the inclusion of data into the EHR does not prevent the correction of information already included in the EHR.
Are there different categories of access for different health	D.L. 179/2012	Article 12 of D.L. 179/2012 does not specify whether creating separate categories of access for different health professionals is necessary.

Questions	Legal reference	Detailed description
professionals?	2011 Ministry of Health Guidelines	However, Article 12(7) of D.L. 179/2012 provides that implementing ministerial decree(s) shall establish different levels and modalities of access to EHR data, depending on the role of the person exercising the access and the purpose of access. On the Guidelines there is a specific section (section 6.2) about different categories and different access profiles.
Are patients entitled to access their EHRs?	Personal Data Protection Code	Article 12 (2) of D.L. 179/2012 specifies that the patients must be able to access their EHRs. Moreover, the general rule of the Personal Data Protection Code is that persons have the right to access their personal data (Article 7).
Can patient have access to all of EHR content?	Personal Data Protection Code	See previous answer.
Can patient download all or some of EHR content?	Personal Data Protection Code	Article 12 of D.L. 179/2012 does not specify whether patients must be able to download EHR data. However, implementing ministerial decree(s) shall establish different modalities of access to EHR data.
Can patient update their record, modify and erase EHR content?	D.L. 179/2012 Personal Data Protection Code	D.L. 179/2012 only states that the patient may request the inclusion of health data in his possession into their EHR (Article 12(3)). Only in relation to his personal notebook included in the EHR may the patient make autonomous changes (Article 13(2)). According to general provisions on data protection, the patients have the right to supplement, update, and rectify, if necessary, their personal data. It is not possible to change the health information uploaded by doctors.
Do different types of health professionals have the same rights	D.L. 179/2012	Every professional can only process necessary and relevant data to perform his or her duties. This is one of the fundamental principles

Questions	Legal reference	Detailed description
to update EHRs?	Personal Data Protection Code 2011 Ministry of Health Guidelines	applied in the processing of personal data. Pending the entry into force of the draft implementing decree, the rule of differential rights may be derived from the general provision that the processing of personal data (which includes their amendment) must comply with the principle of relevance, completeness and necessity with regard to the purposes for which personal data are collected or processed (Article 11(1) of the Personal Data Protection Code). Article 12 of D.L. 179/2012 does not specify whether different categories of health professionals must have different rights to update EHRs. However, Article 12(7) of D.L. 179/2012 provides that implementing ministerial decree(s) shall establish different levels and modalities of access to EHR data, depending on the role of the person exercising the access and the purpose of access. On the Guidelines there is a specific section (section 6.2) about different access profiles (and consequently about "right to update").
Are there explicit occupational prohibitions? (e.g. insurance companies/occupational physicians…)	D.L. 179/2012 Italian Data Protection Authority Guidelines on the Electronic Health Record and the Health File	Article 12 of D.L. 179/2012 does not lay down any explicit prohibition to access EHR data based on certain specific professions. However, insofar as Article 12(2)-(4) only allow access for certain specific purposes (notably prevention, diagnosis, treatment and rehabilitation) and to certain categories of health professionals (those within the framework of the National Health Service and regional health services), access by other entities and for other purposes should be excluded. On the Guidelines a specific section (section 4), defines the exclusion of "expert witnesses, insurance companies, employers, associations".
Are there exceptions to the access requirements (e.g. in case of emergency)?	D.L. 179/2012	In this case, Art. 82 of d. lgs. No. 196 of 30 June 2003 is applicable. According to this provision, the consent to the processing of personal data may be given after the processing in case of serious, imminent and

Questions	Legal reference	Detailed description
		irreparable risk for the health or bodily integrity and when providing medical care may be negatively affected -in terms of its timeliness or effectiveness- by the need to obtain the data subject's prior consent. Article 12(5) of D.L. 179/2012 explicitly excludes that prior consent is necessary for accessing EHR data in health emergency situations.
Are there any specific rules on identification and authentication for health professionals? *Or are they aggregated?*	D.L. 179/2012 2011 Ministry of Health Guidelines	Article 12 of D.L. 179/2012 does not set out any rule on the identification or authentication of health professionals. However, Article 12(7) of D.L. 179/2012 provides that implementing ministerial decree(s) shall define the modalities of access to EHRs. The Decree of implementation of the d.l. No. 179 of 18 October 2012 will establish different levels of security to access to EHRs. Among the security measures that should be adopted, the Italian D.P.A. Guidelines includes "suitable authentication and authorization systems for the employees depending on the roles and needs of accessing and processing". On the Guidelines there is a specific section (section 6) about "Definition of roles, profiles, and access mode".
Does the patient have the right to know who has accessed to his/her EHRs?	D.L. 179/2012 Data Protection Code	There is no a specific prevision. General principles apply.
Is there an obligation on health professionals to update EHRs?	D.L. 179/2012	As far as the d.l. No. 179 of 18 October 2012, the answer is no. However, an obligation to update the information contained in EHRs might arise from contractual provisions, professional duties and ethical principles. It cannot however be excluded that rules introduced by regions or autonomous provinces, or internal rules to the National Health Service or regional health services may introduce such an obligation.
Are there any provisions for accessing data on 'behalf of' and for	Personal Data Protection Code	Article 12 of D.L. 179/2012 does not provide for the possibility of accessing EHR data on behalf of someone else or for providing a second

Questions	Legal reference	Detailed description
request for second opinion?		opinion. The d.l. No. 179 of 18 October 2012 does not expressly regulated the situation. However, general principles apply.
Is there in place an identification code system for cross-border healthcare purpose?	D.L. 179/2012	Article 12 of D.L. 179/2012 does not contain any provision on code systems for cross-border health care purposes. However, Article 12(7) of D.L. 179/2012 provides that implementing ministerial decree(s) shall establish data codification systems and criteria for interoperability at European level.
Are there any measures that consider access to EHRs from health professionals in another Member State?	D.L. 179/2012	Article 12 of D.L. 179/2012 does not contain any provision on access to EHRs from health professionals in other Member States. However, Article 12(7) of D.L. 179/2012 provides that implementing ministerial decree(s) shall establish data codification systems and criteria for interoperability at European level.

2.5. Liability

2.5.1. Main findings

National legislation does not set out liability rules specific to EHRs. However, a few general rules are relevant and worth mentioning.

First of all, the Personal Data Protection Code provides that whoever causes damage as a consequence of the processing of personal data must restore the damage. "Processing" includes the registration of personal data, as well as their deletion. Both economic and moral damages may be restored. A special rule on burden of proof typical of dangerous activities applies – the person who carried out the processing is presumed to be liable, unless he can prove that the damage occurred despite him having taken all appropriate measures to avoid it.

Secondly, the Personal Data Protection Code and the Criminal Code sanction certain behaviours such as abusive access to IT systems, failure to adopt certain minimum measures to ensure the security of data, etc.

Finally, it is worth mentioning that no obligation is placed on health professionals to access EHRs before treating a patient.

Table on liability

Questions	Legal reference	Detailed description
Does the national legislation set specific medical liability requirements related to the use of EHRs?	D.L. 179/2012	National legislation does not set specific medical liability requirement related to the use of the EHRs.
Can patients be held liable for erasing key medical information in EHRs?	D.L. 179/2012	Article 12 of D.L. 179/2012 does not address this matter.
Can physicians be held liable because of input errors?	Civil code Personal Data Protection Code	National legislation does not set specific medical liability requirements related to the use of the EHRs. Professional liability might arise from the uploading a incorrect information (whether it was negligent, reckless, or intentional). However, a diagnosis cannot be based only on EHR. General rules apply. In particular, Article 15 of the Personal Data Protection Code states that whoever causes a damage as a consequence of the processing of personal data must restore the damage. Both economic and moral damages may be restored. A special rule on burden of proof typical of dangerous activities applies – the person who carried out the processing is presumed to be liable, unless he can prove that the damage occurred despite him having taken all appropriate measures to avoid it. For the purposes of this question, it may be worth recalling that, according to Article 4(1)(a) of the Personal Data Protection Code, "processing" includes the registration of personal data.
Can physicians be held liable because they have erased data from the EHRs?	Personal Data Protection Code Criminal Code	See previous answer. For the purposes of this question, it may be worth recalling that, according to Article 4(1)(a) of the Personal Data Protection Code, "processing" includes the deletion of personal data. If the fact is committed with for the purposes of gaining a profit or harm someone, the criminal penalties of Article 167 of the Personal Date Protection Code may apply.

Questions	Legal reference	Detailed description
		Destruction of EHR data may also integrate several crimes, depending on the circumstances of the case, notably those sanctioned by Articles 615 ter and 635 ter of the Criminal Code.
Are hosting institutions liable in case of defect of their security/software systems?	Personal Data Protection Code Digital Administration Code	The software and the applications used must comply with legislation on the personal data protection. At least the minimum security measures set out in the Personal Data Protection Code and in an Annex thereto shall be adopted. The risks to prevent are: unauthorised access to EHR data, inconsistent processing in relation to the purposes of the EHRs, accidental loss or destruction of EHR data. The processing of personal data in violation of minimum technical rules is punished with an administrative sanction from €10.000 to €120.000 (Article 162(2-bis) of the Personal Data Protection Code), without prejudice to other applicable sanctions or liability for damages. Failure to take minimum technical measures can also result in up to two years of arrest (Article 169(1) of the Personal Data Protection Code). The public administrations have to provide data availability and business continuity, as described in Article 50 and 50 bis of the Digital Administration Code.
Are there measures in place to limit the liability risks for health professionals (e.g guidelines, awareness-raising)?		Doctors and health workers who have access to the EHRs should be in charge for the processing. According to Art. 30 of d. lgs. No. 196 of 30 June 2003, people in charge must dictate specific instructions for the data processing. Suitable authentication, authorization, traceability, login and transactions systems, as well as audit log to control access should be adopted.
Are there liability rules related to breach of access to EHRs (e.g. privacy breach)?	Civil Code Criminal Code	Both civil and criminal liability may arise in case of violation of any provision on security measures of the d. lgs. No. 196 of 30 June 2003. According to par. 1 of the Art. 169 of the d. lgs., whoever fails to adopt the minimum measures referred to in Section 33 shall be punished by detention for up to two years. There is no liability rule specifically laid down for unauthorised access to EHRs. General rules apply.

Questions	Legal reference	Detailed description
	Personal Data Protection Code	The Civil Code provides for the restoration of damages, be them economic (Article 2043) or not (Article 2059). The Criminal Code sanctions abusive access to protected IT systems (Article 615 ter). Moreover, the criminal penalties set out in the Personal Data Protection Code may apply in certain circumstances (Article 167).
Is there an obligation on health professionals to access EHRs prior to take a decision involving the patient?		There is not such an express requirement. General principles apply.
Are there liability rules related to the misuse of secondary use of health data?	Personal Data Protection Code	Although there is no specific liability rule regarding secondary uses of health data, general rules apply. In particular, Article 15 of the Personal Data Protection Code states that whoever causes a damage as a consequence of the processing of personal data must restore the damage. Both economic and moral damages may be restored. A special rule on burden of proof typical of dangerous activities applies – the person who carried out the processing is presumed to be liable, unless he can prove that the damage occurred despite him having taken all appropriate measures to avoid it.

2.6. Secondary uses and archiving durations

2.6.1. Main findings

The D.L. 179/2012 permits "secondary uses" of EHR data (i.e. use for the purposes of research, health service planning and evaluation) by the Ministries of Employment and Health, the regions and autonomous provinces within the limits of their respective competences. The patient's consent is not required in relation to secondary uses, as direct identification information may not be utilised in these cases.

The D.L. 179/2012 does not lay down any specific provision on archiving EHR data.

2.6.2. Table on secondary uses and archiving durations

Questions	Legal reference	Detailed description
Are there specific national rules on the archiving durations of EHRs?	Circular No. 19 Italian Ministry of Health of 19 December 1986	There is no specific provision in this regard. In relation to the paper health records, the Circular No. 19 of the Italian Ministry of Health of 19 December 1986 provides that "health records, and the related reports should be kept indefinitely, as they represent an official act necessary to ensure legal certainty. It also represents a valuable document for historical health research". Finally, the legislation on the personal data protection provides that data cannot be stored for a longer period than the one necessary to achieve the processing purpose.
Are there different archiving rules for different providers and institutions?		There is no specific provision in this regard. General principles apply.
Is there an obligation to destroy (…) data at the end of the archiving duration or in case of closure of the EHR?		There is no obligation to destroy data at the end of the archiving period or in case of closure of the EHR. General principles apply.
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?		There is no specific rule about the use of data at the end of the archiving duration or in case of closure of the EHR. General principles apply.
Can health data be used for secondary purpose (e.g. epidemiological studies, national statistics...)?	D.L. 179/2012 Personal Data Protection Code	Article 12(2) of D.L. 179/2012 states that EHRs are established, inter alia, for the purposes of medical and epidemiological research, as well as health service planning and evaluation. Where EHR data is used for such purposes, patient identification data may not be utilised (Article 12(6)). Article 12(7) of D.L. 179/2012 provides that the implementing ministerial decree(s) shall establish, inter alia, the modalities and access levels for the purposes referred to above.
Are there health data that cannot be used for secondary use?	D.L. 179/2012	See answer to previous question.

Questions	Legal reference	Detailed description
Are there specific rules for the secondary use of health data (e.g. no name mentioned, certain health data that cannot be used)?	D.L. 179/2012	See answers to the previous two questions.
Does the law say who will be entitled to use and access this data?	D.L. 179/ 2012	Article 12(6) of D.L. 179/2012 entitles regions and autonomous provinces, as well as the Ministry of Employment and the Ministry of Health, within the limits of their respective competences, to use EHR data for secondary purposes. Article 12(7) of D.L. 179/2012 provides that the implementing ministerial decree(s) shall establish, inter alia, the modalities and access levels for the purposes referred to above.
Is there an opt-in/opt-out system for the secondary uses of eHealth data included in EHRs?	D.L. 179/2012	There is no opt-in/opt-out system regarding secondary uses of EHR data. It may also be worth clarifying that the requirement of consent only applies for the purposes of prevention, diagnosis, health treatment and rehabilitation, but not for secondary purposes (Article 12(5)-(6) of D.L. 179/2012. This can be explained in light of the fact that identification data may not be utilised in the context of secondary uses of EHR data.

2.7. Requirements on interoperability of EHRs

2.7.1. Main findings

The D.L. 179/2012 requires implementing measures to ensure the interoperability of EHR systems at regional, national and European level (Article 12(7)). However, implementing measures are not yet into force.

2.7.2. Table on interoperability of data requirements

Questions	Legal reference	Detailed description
Are there obligations in the law to develop interoperability of EHRs?	D.L. 179/2012	Article 12(7) of D.L. 179/2012 provides that the implementing ministerial decree(s) shall establish criteria for the interoperability of EHRs at regional, national and European level.
Are there any specific rules/standards on the interoperability of EHR?	D.L. 179/2012 2014 Ministry of Health and Agency for Digital Italy Guidelines	No specific rules/standards on the interoperability of EHR systems are currently in force. A few preliminary indications of technical nature are defined in paragraph 6 of Guidelines for regional project plans presentation on the Electronic Health Record.
Does the law consider or refer to interoperability issues with other Member States systems?	D.L. 179/2012	See answer to the first question in this table.

2.8. Links between EHRs and ePrescriptions

2.8.1. Main findings

The e-Prescription system predates, and it is not dependent on, the EHR system. Legal sources relevant to e-Prescription include:

- The Decree of the President of the Council of Minister of 26 March 2008 on the modalities for the transmission of prescriptions by IT means by the doctors of the National Health Service;
- The Ministerial Decrees of 14 July 2010, 21 February 2011, 21 July 2011 and 2 July 2012 promoting e-prescriptions;
- The Ministerial Decree of 2 November 2011, replacing traditional prescription with on e-prescription
- Article 13 of D.L. 179/2012. validity of e-prescription on the whole national territory.

The D.L. 179/2012 provides that persons operating within the National Health Service or the regional health services who provide health services to the patient may access his EHR, but it does not add further detail.

The table below describes the Italian legal framework on ePrescriptions. The transition paper to electronic prescriptions is one of the specific goals of the Italian Ministry of Health.

D.p.c.m. of 26 March 2008 regulates the electronic transmission of the data contained in the prescriptions made by the doctors in the National health service.

Art. 13 of d.l. No. 179 of 18 October 2012 regulates the gradual replacement of paper prescriptions with ePrescriptions in the regions and autonomous provinces.

The regions and autonomous provinces shall gradually replace the paper prescriptions with the electronic ones. According to par. 2 of Art. 13 of D.L. 179/2012, the pharmaceutical electronic prescriptions will have full legal value on the national territory starting from 1 January 2014.

2.8.2. Table on the links between EHRs and ePrescriptions

- ***Infrastructure***

Questions	Legal reference	Detailed description
Is the existence of EHR a precondition for the ePrescription system?		The e-Prescription system predates, and it is not dependent on, the EHR system. According to the implementation decree, the prescription (hence the e-prescription as well) is a part of EHR. Legal sources relevant to e-Prescription include: - The Decree of the President of the Council of Minister of 26 March 2008 on the modalities for the transmission of prescriptions by IT means by the doctors of the National Health Service; - The Ministerial Decrees of 14 July 2010, 21 February 2011, 21 July 2011 and 2 July 2012 promoting e-prescriptions; - The Ministerial Decree of 2 November 2011, replacing traditional prescription with on e-prescription - Article 13 of D.L. 179/2012. validity of e-prescription on the whole national territory..
Can an ePrescription be prescribed to a patient who does not have an EHR?		The e-Prescription system predates, and it is not dependent on, the EHR system

- ***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?	D.L. 179/2012	Article 12(4) of D.L. 179/2012 only provides that persons operating within the National Health Service or the regional health services who provide health services to the patient may access his EHR. However, Article 12(7) states that implementing ministerial decree(s) shall establish the modalities and levels of access to EHR data for different persons. In any case, consent from the patient is necessary to access the EHR.
Can those health professionals write ePrescriptions without having access to		The e-Prescription system predates, and it is not dependent on, the EHR system.

Questions	Legal reference	Detailed description
EHRs?		

2.9. Other requirements

Restrictions deriving from the regulations on the personal data protection may require a few more considerations. The Guidelines on the Electronic Health Record and the Health File adopted by the Italian D.P.A. for the protection of personal data state that "the EHR is a logical set of health care information and records that aims at documenting a person's clinical history and can be shared by several data controllers; accordingly, the highest transparency should be featured both in terms of its structure and in terms of its operation. Hence, the processing of personal data performed via an EHR should be notified to the Italian D.P.A. with an *ad-hoc* communication".

Great attention is also paid to the security requirements. Given the importance of the personal data processed via EHRs, specific technical arrangements should be adopted in order to ensure the appropriate security level (art. 31 of the Italian Data Protection Code) - without prejudice to the minimum measures that data controllers are required to take according to the Data Protection Code. In particular, in order to protect data against unauthorised accesses, theft and/or loss, in whole or in part, the following measures should be taken:

- suitable authentication and authorisation systems should apply to those in charge for the processing as a function of the respective access/processing requirements (e.g. as for browsing, changing and adding records);
- procedures to regularly check quality and consistency of the authentication credentials and authorisation profiles should be implemented and should apply to the people in charge for the processing;
- criteria to encrypt and/or keep separate those data that are suitable for disclosing health and sex life from any other personal data should be outlined;
- accesses and operations should be logged;
- audit logging to control database accesses and detect abnormalities should be implemented.

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

- **Good practices for the development of EHRs in Italy**

In Italy the development and diffusion of the EHRs is still in progress and is being led by a specific regulatory framework[11].

EHRs are defined by D.L. 179/2012. Article 12 defines the EHR as "a set of health and socio-health digital documents and data generated by present and past clinical events regarding a patient".

The purposes of EHRs are: a) prevention, diagnosis, treatment and rehabilitation, b) study and scientific research in the medical, biomedical and epidemiological field, c) health planning, assessment of the quality of the treatment and evaluation of the health care.

The D.L. 179/2012also provides that the EHRs must be implemented by the regions and autonomous provinces by 30 June 2015.

The State-Regions Conference on February the 10, 2011, adopted the national EHR guidelines[12], In 2009 the Italian Data Protection Authority issued the Guidelines on the Electronic Health Record and the Health File.

The first Decree for the implementation of D.L. 179/2012 is forthcoming. The Decree will define:

1. the contents of EHRs;
2. the kind of liability for the parties working with and using the EHRs, as well as their duties;
3. the data encoding systems;
4. the security measures to be adopted in personal data processing;
5. the different access levels to the EHRs;
6. the creation of the patient's identification code;
7. the rules ensuring interoperability of EHRs on a regional, national and European level.

It is possible to imagine that the Decree will try to ensure the patient's fundamental rights. The EHR is indeed designed to be under the control of the patient[13].The processing of the data in EHRs can only be carried out with the patient's consent. The patient has the right to choose freely if and which data to include in his or her EHR. The consent must be free, specific and explicit[14]. No opt-out rules are provided. The lack of consent does not affect the patient's right to health. The consent must also be informed: the patients shall be fully informed on the processing of personal data in EHRs prior to providing his or her consent. According the Guidelines adopted by the Italian D.P.A. the consent must specifically relate to the processing of data in EHRs and withdrawal is always possible.
The patient has the right to add information, update and rectify his or her personal data if necessary.
The patient may decide not to allow certain persons to consult the records and has the right to know the categories of people having access to his or her personal data[15].

Legal barriers for the development of EHRs in Italy

The process of adoption of the Decree of implementation of D.L. 179/2012 is slow and complex[16].

[11] Interview with the RER on 7 February 2014 and interview with Italian D.P.A., 26 February 2014.
[12] State-Regions Conference, agreement of February 10, 2011, available, in Italian, at http://www.statoregioni.it/Documenti/DOC_030589_19%20csr.pdf
[13] Interview with the MCB on 4 February 2014 and interview with RER on 7 February 2014 and interview with Italian D.P.A., 26 February 2014.
[14] Interview with Italian D.P.A. on 26 February 2014.
[15] Interview with Italian D.P.A. on 26 February 2014.

As observed by the Italian D.P.A., the drafting of the Decree of implementation, still in progress, has been a very challenging work. The EHR working group has discussed a number of issues and provisions to be adopted and all the parties involved could bring their perspective to the discussion. The debate carried on will presumably result in a great collaborative work[17]. [18]

In the current situation, the content of the EHR is potentially unlimited. This might lead to uncertainty in the use of the EHR[19]. Yet the law provides for the adoption of a Decree of implementation that will detail which health data should be included. Nevertheless, at present, legal obstacles could arise in case of lack of harmonisation of the content of the EHR.

As health professionals pointed out, the development of EHR in Italy depends on how the legal framework will be implemented. According to their opinion, the implementation on the basis of a specific program is needed[20].

The patient has the right to obscure at any time the data in EHR. This right is sometime perceived as an obstacle, but it is necessary to ensure the patient's right to the protection of his or her personal data[21]. Another legal obstacle might be found in the lack of specific determination of the data retention period.

Furthermore, national legislation does not specify which rules on medical liability are applicable in case of use of the EHR. Consequently, general rules on medical liability apply. These rules have been described by stakeholders as rules that enhance health professionals' reluctance to using and developing the EHR system.

Regarding liability's issues, a problem may also arise when critical results are uploaded on the personal EHR. Is uploading the critical or negative result a suitable technique to avoid psychological stress to the patient?[22]

In addition, cultural obstacles exist. The awareness and knowledge about EHRs it is not uniform.

Doctors not always understand the benefits that can derive from using the EHRs. They more often perceive the unpaid overload of work[23]. This has led to great distrust in the system by health professionals and to a consequent lack of promotion of the use of the EHRs.

[16] Interview with the RER, on 7 February 2014 and interview with LISPA on 17 February 2014.
[17] The favourable opinion of the DPA on the EHR implementation decree allows the overcoming of the last step on the way of the final adoption of the decree (See documentation available, in Italian at http://www.garanteprivacy.it/garante/doc.jsp?ID=3230826).
[18] Interview with Italian D.P.A. on 26 February 2014
[19] Interview with LISPA on 17 February 2014.
[20] Interview with the MCB on 4 February 2014 and interview with LISPA on 17 February 2014.
[21] Interview with Italian D.P.A. on 26 February 2014.
[22] Interview with the RER on 7 February 2014.
[23] Interview with the MCB on 4 February 2014.