

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 Norway



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Executive Summary

1. Stage of development of EHRs in Norway

Norway has been an early user of information and communications technology (ICT) in the health and care sector. However, patient medical records tend to be spread in the different health care institutions, clinics and other locations from where a patient obtains medical help. Moreover, the contents of patients' medical records are today only to a very little extent stored as structured text. It has been – and still is – a political aim in Norway that relevant and necessary patient data follow the patient and are available for health care personnel who provide primary health care, irrespective of where the patient may have previously obtained health care and irrespective of how the health sector is organised. Another aim is that new digital applications may be directly accessible to patients via the Internet. These aims were put forward in the White Paper *Én innbygger – én journal* (One inhabitant – one patient record – Meld. St. 9 (2012-2013)) and in the White Paper on a Digital Agenda for Norway (Meld. St. 23 (2012-2013)).

The Norwegian Ministry of Health and Care Services (*Helse- og omsorgsdepartementet*) formulates and implements the national health policy with the help of several subordinate institutions. The Norwegian Directorate of Health (*Helsedirektoratet*) is the executive agency and competent authority subordinate to this ministry, whereas the Norwegian Board of Health Supervision (*Helsetilsynet*) is an independent authority responsible for the general supervision of the health services of Norway.

There are various laws and regulations regulating patient medical records, personal health data filing systems used for therapeutic purposes as well as those used for secondary purposes.

2. Summary of legal requirements applying to EHRs

The term 'electronic patient medical record' (*elektronisk pasientjournal*) is not explicitly defined in the law.¹ Section 6, first paragraph, first sentence, of the Personal Health Data Filing System Act states that personal health data filing systems established for therapeutic purposes *may* be kept by automatic means. Moreover, section 6, fourth paragraph, provides a legal basis for regulations to be established requiring that data in personal health data filing systems established for therapeutic purposes *shall* be processed electronically. In fact, in June 2013, a Consultation Paper proposing draft regulations on ICT-standards in the health and care sector (*Høringsnotat - Forslag til forskrift om IKT-standarder i helse- og omsorgssektoren*) was published. These draft regulations are proposing that all personal health data filing systems used for therapeutic purposes (*behandlingsrettede helseregistre*) shall be kept electronically.² However, these draft regulations are still pending.

There are different types and categories of health data and personal health data filing systems in Norway as well as different types of records and registers such as patient medical records (*pasientjournaler*), local, regional or central personal health data filing systems (*locale, regionale, sentrale helseregistre*),³ and data processed in medical and health research.⁴

The Regulations on Patient Records has a long list of information that shall be included in a patient record 'provided they are relevant and necessary'. This list is not exhaustive as section 8, third paragraph, states that other data than that specified shall be recorded in the patient record to the extent

¹ See the *travaux préparatoires* to the Personal Health Data Filing System Act (Ot.prp. nr. 5 (1999-2000), paragraph 7.2.4.3.

² See proposed regulations, section 3, first paragraph, <<http://www.regjeringen.no/nb/dep/hod/dok/hoeringer/hoeringsdok/2013/horing-av-forslag-til-forskrift-om-ikt-.html?id=731556>>.

³ See section 1.1.2.

⁴ See section 1.2.

that they are ‘relevant and necessary’. The patient record, according to the Health Personnel Act (section 40), shall be kept in accordance with good professional conduct and shall contain relevant and necessary information about the patient and the health care, as well as the information that is required in order to comply with the notification requirements or the duty of disclosure laid down in or pursuant to the law.

With regards to identification rules, one should distinguish between data held for primary use (see Regulations on Patient Records, section 8(a) which requires identification provided it is ‘relevant and necessary’), and data held for secondary use (see the Personal Health Data Filing System Act and its provisions inter alia on de-identification, anonymization and pseudonymization of data).

The main rule with regards to regional, local and central personal health data filing systems is that the name, personal identity number or other characteristics that directly identify a natural person may only be processed with the consent of the data subject. The Personal Health Data Filing System Act regulates when and how central, regional and local personal health data filing systems may be created (see section 2.2.1).

All the institutions which provide health care are obliged to have a proper medical record system (see section 5-10 of the Municipal Health Care Act; section 3-2 of the Specialist Health Services Act; and section 4 of the Regulations on Patient Records). It is, however, the particular health personnel member who provides health care who has a duty to enter and record information in terms of the Health Personnel Act (sections 39 and 40). With regards to some health records, the patient has a right to opt out of the processing of his/her personal data – this is the case, for example, with the patient medical record (*pasientjournal*) and the patient’s core medical record (*kjernejournal*).

According to the Personal Health Data Filing System Act, when the personal health data is collected from the data subject directly (section 23), the data subject must be inter alia informed of the purpose of the processing of the personal health data, and of any other circumstance that will enable the data subject to exercise his rights pursuant to this Act in the best possible way. There are also opt-in/opt-out rules for patient consent with regard to sharing of health data (Health Personnel Act, sections 25 and 45). One should note especially the requirement in sections 25 and 45 ‘to provide health care in a responsible manner’. Access to personal health data in personal health data filing systems established for therapeutic purposes across institutions may only be given following express consent from the data subject.

According to the Health Personnel Act, there is a duty to provide the patient access to his/her medical records. The Act also provides for the circumstances where there may be correction of patient records or deletion of information in patient records (sections 42-44). Other than this, in the case of medical records pursuant to the Regulations on Patient Record (section 13), once a journal entry has been signed, it can only be changed according to the rules on correction or deletion in terms of sections 42, 43 and 44 of the Health Personnel Act.

In the case of personal health data filing systems, the data controller has a duty to ensure the quality of personal health data (section 17 (Internal control), Personal Health Data Filing System Act). Documentation in a patient’s medical records is to be processed in accordance with the rules of the Personal Data Act (section 10, Regulations on Patient Records).

Online access by a patient to some (limited) of his/her patient information is possible via the national internet portal (‘Min Helse’ on helsenorge.no) by means of a secure electronic ID. The patient may view the information but not update his/her medical record, modify or erase the online content. However, indirect access is possible and, indeed, it is a patient's right (section 5-1, first paragraph, Patients’ Rights Act) to have access to his or her medical records with enclosures and upon special request to be entitled to a copy. The patient also has a right to access the logs of health data filing systems established for therapeutic purposes as to who has had access to health information on him or her (Personal Health Data Filing Systems Act, section 13).

Health care personnel are liable for breach of:

- their duty, as per section 4, first paragraph, of the Health Personnel Act, to conduct their work in accordance with the requirements to professional responsibility and diligent care that can be expected based on their qualifications, the nature of their work and the situation in general;
- their duty of confidentiality in section 21 Health Personnel Act.

The general rules of Norwegian law of torts would apply. However, there could also be serious consequences for the health care personnel in terms of the Health Personnel Act (e.g. warning, revocation of licence to practice, etc.) and the Criminal Code.

The Personal Data Act, the Personal Health Data Filing System Act and the Health Research Act respectively contain rules on liability (by the data controller in the case of the Personal Data Act and the Personal Health Data Filing System Act, or by the person or body responsible for medical and health research in terms of the Health Research Act) for damage suffered as a result of the fact that personal health data was processed contrary to provisions laid down in the respective law.

Norway has specific and detailed rules on the archiving of patient medical records (primary use) as well as personal health data stored for secondary use. The rules specify the length of time that records may be kept as well as the extent to which there is an obligation to transfer elsewhere or destroy the data, in case of cessation of operation of the particular institution holding the data.

One of Norway's central personal health data filing systems is the National Database for Electronic Prescriptions (*Nasjonal database for elektroniske resepter*) set up in terms of section 8, third paragraph, no. 9 of the Personal Health Data Filing System Act. In terms of the Regulations on the ePrescriptions Register (*Reseptregisteret*), issued pursuant to section 8 paragraph 4 of the aforementioned Act, the collection, storage and processing of information in the ePrescriptions Database shall take place electronically (section 1-1, second paragraph). The ePrescription system is thus based on the existence of the National Database for ePrescriptions.

3. Good practices

The Data Protection Authority has issued a report, in Norwegian, *Strategi for godt personvern i helsesektoren* (Strategy for good data protection in the health sector) of June 2011, which is still pertinent and relevant.⁵ In this report, the Data Protection Authority states that it gives high priority to the health sector as this is a large user of sensitive personal data. In particular, new solutions and the new legal framework in the sector shall safeguard privacy in a better manner, especially in light of the type/form of the medical health register and the individual's right to self-determination. In addition, the health sector shall positively contribute to a strengthening of access control and logging of data. Finally, the individual needs to keep oversight and control of information about himself. With regards to central personal health data filing systems (*sentrale helseregistre*), the report states that, where new health registers of this type are created, it is important that data protection is embedded in the design of such registers from the start. A good data protection principle is that such health registers distinguish between the patient's identity and the medical health data, and that these are stored in different locations. Moreover, the report recommends that privacy-enhancing technologies should be used as much as possible. In fact, Annex III of the report lists the 7 Foundational Principles for Privacy by Design developed by Dr. Ann Cavoukian. With regards to medical and health research, the report states that data protection and information security implications should be assessed and attended to early in the application process by the project manager and the REC. Hereto the following principles are applied to the central health register:

- It is important to find a good balance between how knowledge needs and patients' privacy

⁵ See https://www.datatilsynet.no/Global/04_planer_rapporter/helsesstrategi_NOV2011.pdf

- must be maintained;
- The patient should not be identified to a greater extent than is necessary to fulfil the purpose of the register;
- Health information and identity information should be kept separate. The best policy is to store identity information externally;
- The most radical and sensitive health records should be based on the consent of the patient; and
- Citizens must generally be allowed to opt out of registration in health records.

A prerequisite for effective and secure electronic communication between health care personnel is that information is kept electronically in the respective institution. Although several of these institutions have electronic patient medical record systems as well as administrative systems, much of the communication between the actors is still carried out through the use of paper-based and diverse electronic solutions. To facilitate that the use of ICT-standards promotes secure electronic interaction and exchange inside and between institutions, the Consultation Paper proposing draft regulations on ICT-standards in the health and care sector was published in June 2013 and is currently pending. The draft regulations, inter alia, are proposing that there should be a duty on institutions to use standardised message exchange.⁶

A number of potential legal barriers and challenges to development of EHRs in Norway have been raised and are sought to be addressed in the various White Papers, discussion and consultation papers and documents proposing new laws and regulations in the health sector such as the proposal for a new Patient Medical Record Act and a new Personal Health Filing System Act, etc.

4. Legal barriers

Among the main challenges existing today is the fact that the legal framework for patient medical records, personal health data filing systems used for therapeutic purposes and those used for secondary purposes, is intricate and spread in and across various statutes and regulations. The current Personal Health Data Filing System Act, for example, regulates both personal health data filing systems used for therapeutic purposes and those used for secondary purposes. One of the aims of the proposed draft bill for a new Patient Medical Records Act and for a draft bill on a new Personal Health Data Filing System Act is to have a clearer scope for each of these draft statutes: the proposed Patient Medical Records Act will regulate patient medical records and personal health data filing systems used for therapeutic purposes – i.e. primary use – whereas the proposed bill for a new Personal Health Data Filing System Act will regulate secondary use of personal health data.

Amongst the potential legal barriers are the following:

- when legal requirements are considered too technical to be implemented: The Regulations on health information security (helseinformasjonssikkerhetsforskriften) are not yet in force because the legal requirements in such regulations are considered to be too technical by the health service providers (see section 3);
- the current strict legal rules and limitations on the sharing of personal health data between health personnel (see section 3).

⁶ See further, section 2.7.1 of this report.

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List of abbreviations

EHRs	Electronic Health Records
REC	Regional committee for medical and health research ethics

List of primary legislation

Archives Act	Archives Act of 4 December 1992 No. 126, in Norwegian 'Lov om arkiv' abbreviated as 'arkivloven'
Health Personnel Act	Act of 2 July 1999 No. 64 on health care personnel, etc. in Norwegian 'Lov om helsepersonell m.v.' abbreviated as 'helsepersonelloven'
Health Research Act	Act of 20 June 2008 No. 44 on medical and health research, in Norwegian, 'Lov om medisinsk og helsefaglig forskning', abbreviated as 'helseforskningsloven'
Patient Injury Act	Act of 15 June 2001 No. 53 on compensation for patient injury etc, in Norwegian 'Lov om erstatning ved pasientskader mv' abbreviated as 'pasientskadeloven'
Patients' Rights Act	Act of 2 July 1999 No. 63 relating to Patients' Rights, in Norwegian, 'Lov om pasient- og brukerrettigheter' abbreviated as 'pasient- og brukerrettighetsloven'
Personal Data Act	Act of 14 April 2000 No. 31 relating to the processing of personal data, in Norwegian 'Lov om behandling av personopplysninger' abbreviated as 'personopplysningsloven'
Personal Data Regulations	Regulations on the processing of personal data, laid down by Royal Decree of 15 December 2000 pursuant to the Personal Data Act, in Norwegian 'Forskrift om behandling av personopplysninger' abbreviated as 'personopplysningsforskriften'
Personal Health Data Filing System Act	Act of 18 May 2001 No. 24 on Personal Health Data Filing Systems and the Processing of Personal Health Data, in Norwegian 'Lov om helseregistre og behandling av helseopplysninger' abbreviated as 'helseregisterloven'
Municipal Health Care Act	Act of 24 June 2011 No. 30 on municipal health and care services etc., in Norwegian, 'Lov om kommunale helse- og omsorgstjenester m.m.' abbreviated as 'helse- og omsorgstjenesteloven'

Specialist Health Services Act	Act of 2 July 1999 No. 61 on specialist health services etc, in Norwegian, ‘Lov om spesialisthelsetjenesten m.m.’ abbreviated as ‘spesialisthelsetjenesteloven’
List of secondary legislation	
Cancer Registry Regulations	Regulations of 21 December 2001 No. 1477 on the collection and processing of personal health data in the Cancer Registry, in Norwegian, ‘Kreftregisterforskriften’
Regulations on Health Information Security	Regulations of 24 June 2011 no. 628 on information security upon electronic access to health information in health data filing systems established for therapeutic purposes, in Norwegian ‘Forskrift om informasjonssikkerhet ved elektronisk tilgang til helseopplysninger i behandlingsrettede helseregistre’ abbreviated as ‘Helseinformasjonssikkerhetsforskriften’; <i>not yet in force.</i>
Regulations on the <i>Kjernejournal</i>	Regulations of 31 May 2013 no.563 on the national core register, in Norwegian, ‘Forskrift om nasjonal kjernejournal’ abbreviated as ‘kjernejournalforskriften’.
Regulations on the Organization of Medical and Health Research	Regulations of 1 July 2009 no. 955 on the organization of medical and health research, in Norwegian, ‘Forskrift om organisering av medisinsk og helsefaglig forskning’
Regulations on the ePrescriptions Database	Regulations of 21 December 2007 no. 1610 on the processing of medical data in the national database for electronic prescriptions, in Norwegian, ‘Forskrift om behandling av helseopplysninger i nasjonal database for elektroniske resepter’ abbreviated as ‘Reseptformidlerforskriften’
Regulations on the Prescriptions Database	Regulations of 17 October 2003 no. 1246 on the collection and processing of health data in the Norwegian Prescription Database, in Norwegian ‘Forskrift om innsamling og behandling av helseopplysninger i Reseptbasert legemiddelregisteret’ abbreviated as ‘Reseptregisteret’.
Regulations on Patient Records	Regulations of 21 December 2000 No. 1385 on patient records pursuant to the Health Personnel Act, in Norwegian, ‘Forskrift om pasientjournal’
Regulations of 31 October 2008 No. 1166	Regulations of 31 October 2008 No. 1166 issued

pursuant to the Patient Injury Act, in Norwegian,
'Forskrift om pasientskadelovens virkeområde og
om tilskuddsplikt for den som yter helsehjelp
utenfor den offentlige helse- og omsorgstjenesten'

1. General context

1.1. EHR systems in place

1.1.1 Development of IT in health and care and main policies⁷

The use of information technology (IT) in the Norwegian health and care sector had its modest beginnings in the 1960s when computers – at that time very costly – were taken into use primarily by large hospitals. They were first and foremost used as a purely administrative tool.

In the 1970s, increasingly more hospitals used IT for patient administration, eventually also for lab requisitions. These were the precursors of the electronic patient medical record system (*pasientjournal*) which are in use in hospitals today. In the middle of the 1970s, family doctors started getting interested in IT and in 1980 there was what today could be considered to be the first complete electronic patient medical record system used by a group of doctors in Balsfjord municipality.

In the 1980s several new ICT systems came on the market, both general electronic patient medical record systems and more specialised systems such as those intended for a specific specialist environment in a hospital. Such systems were first and foremost meant for documentation and storage of clinical notes, and some types of integration with other internal systems like radiology and laboratory results.

Interaction between institutions to support patient progress across the whole health and care service achieved high priority from mid-2000, and has in later years been a central theme in white papers (*stortingsmeldinger*) such as St. meld. 18 (2008-2009) *Ei forvaltning for demokrati og felleskap*,⁸ St. meld. 47 (2008-2009) *Samhandlingsreformen*,⁹ Meld. St. 16 (2010-2011) *Nasjonal helse- og omsorgsplan*,¹⁰ and in the national strategies for ICT in the health and care sector.

Norway has had several national strategies and action plans on electronic integration and ICT in the health and care sector. From the early 1997 national action plan *Mer helse for hver bIT*¹¹ issued by the then Social and Health Department with the aim of reducing paper-based message exchange into electronic ones, to the more recent *Samspill 2.0* on electronic integration issued in 2011 by the Health and Care Department.¹² In 2009, the pre-project to the national health register project (*helseregisterprosjekt*) was established to coordinate and modernise the national clinical quality registers (*kvalitetsregistre*) and the central registers. The main *helseregisterprosjekt* commenced in 2011 to follow up the strategy plan *Bedre helseregistre – bedre helse 2010-2020*¹³. Another important White Paper is Meld. St. 9 (2012-2013) *Én innbygger – én journal*¹⁴ which proposes the establishment of one patient medical record system which will include all the health and care sector, and which will also examine alternative solutions before a final decision is taken.¹⁵ The White Paper on a Digital Agenda for Norway (Meld. St. 23 (2012–2013)) inter alia lists the following goals for government:¹⁶

⁷ This section is loosely based on and translated from the White Paper Meld. St. 9 (2012-2013) *Én innbygger – én journal* (One inhabitant – one patient record) p. 14-15.

⁸ Loosely translated as ‘An administration for democracy and community’.

⁹ Loosely translated as ‘Interaction reform’.

¹⁰ Loosely translated as ‘Plan for national health and care’.

¹¹ Loosely translated as ‘More health for every bIT’.

¹² The document is available in Norwegian at <<http://www.helsedirektoratet.no/publikasjoner/samspill-20-nasjonal-strategi-for-elektronisk-samhandling-i-helse-og-omsorgssektoren-2008-2013/Sider/default.aspx>>.

¹³ Loosely translated as ‘Better health registers – better health 2010-2020’.

¹⁴ See footnote 7.

¹⁵ See *Høring: Forslag til ny pasientjournallov og ny helseregisterlov* (“Consultation Paper proposing a new Medical Records Act and new Personal Health Data Filing Systems Act”), 28 June 2013, in Norwegian http://www.regjeringen.no/pages/38380934/Hoeringsnotat_helseregisterlov.pdf, p. 16.

¹⁶ See the White Paper, also in English, at <<http://www.regjeringen.no/nb/dep/kmd/Dokument/proposisjonar-og-meldingar/stortingsmeldingar/2012-2013/meld-st-23-20122013-2/6.html?id=729047>>.

- ICT should help citizens gain more control of their own health and offer better opportunities to live safely at home with a high quality of life.
- ICT should be used to achieve high-quality and efficient health and care services.
- ICT should enable the elderly and others to live safely and independently at home, despite impaired health.

Figures from HELFO¹⁷ cited in the June 2013 Consultation Paper proposing draft regulations on ICT-standards in the health and care sector¹⁸ show that circa 98% of family doctors (*fastleger*) in Norway use electronic patient medical record systems (*elektroniske pasientjournalssystem*). The remainder are mostly older doctors and doctors in small practices. It also states that all the health enterprises (*helseforetak*) use electronic patient medical record systems, though probably parts of the patient medical records in some places are recorded on paper (such as, for example, in mental health care where the health enterprises rent institutional space from private enterprises).¹⁹ It appears that few health care personnel that fall within the Health Personnel Act keep patient medical records solely on paper (an example of the latter group cited in the aforementioned Consultation Paper are pedicurists (*fotterapeuter*)).²⁰

1.1.2 Categories and types of different registers

The key terminology used in Norwegian law regarding health records is:

- *pasientjournal*, translated as ‘patient record’ (or ‘patient medical record’): the main law is the Health Personnel Act and the Regulations on Patient Record issued pursuant to it. The Regulations on Patient Record define ‘*pasientjournal/journal*’ as ‘a collection or group of written/registered information on a patient in connection with health care’ (section 2(7)) which may be kept electronically. In turn, ‘health care’ is defined in the Health Personnel Act (section 3, third paragraph) as ‘any act that has a preventive, diagnostic, therapeutic, health-preserving or rehabilitative objective and that is performed by health personnel’.
- *behandlingsrettet helseregistre*, translated as ‘health data filing system established for therapeutic purposes’ and defined in section 2(7) of the Personal Health Data Filing System Act as ‘a system of patient records and information or other personal health data filing system for the purpose of providing a basis for acts that have preventive, diagnostic, therapeutic, health-preserving or rehabilitative objective in relation to the individual patient and that are performed by health personnel, and the administration of such acts’.
- *helseregister*, translated as ‘personal health data filing system’: The term ‘personal health data filing system’ is defined in section 2 (6) of the Personal Health Data Filing System Act as a ‘personal health data filing system: filing systems, records, etc. where personal health data are systematically stored so that information concerning a natural person may be retrieved’. The term ‘personal health data filing system’ is a logical term and not computer science definition.²¹ A health register may thus consist of several data files and can be physically recorded in several locations.²²

The term ‘health data filing system established for therapeutic purposes’ (*behandlingsrettet helseregister*) is more comprehensive than the term ‘patient record’ (or ‘patient medical record’) in

¹⁷ HELFO (*Helseøkonomiforvaltningen*), the Norwegian Health Economics Administration (HELFO), is a sub-ordinate institution directly linked to the Norwegian Directorate of Health. See further <<http://www.helfo.no/omhelfo/Sider/about-helfo.aspx>>.

¹⁸ See, in Norwegian, *Høringsnotat Forslag til forskrift om IKT-standarder i helse- og omsorgssektoren*, June 2013, <http://www.regjeringen.no/nb/dep/hod/dok/hoeringer/hoeringsdok/2013/horing-av-forslag-til-forskrift-om-ikt-.html?id=731556>, p. 16-17.

¹⁹ Ibid p 16.

²⁰ There are also some non-profit institutions (*ideelle institusjoner*) which do not have electronic patient medical records. See further, ibid p. 16-17.

²¹ See further *Høring: Forslag til ny pasientjournallov og ny helseregisterlov*, n 15, p. 79.

²² Ibid.

sections 39 and 40 of the Health Personnel Act.²³ Whereas a patient medical data in electronic form contains a lot of sensitive data about a patient, patient administrative systems often have sensitive data about many patients.²⁴

The term ‘electronic patient medical record’ (*elektronisk pasientjournal*) is not as yet explicitly defined in the law.²⁵ According to the *travaux préparatoires* to the Personal Health Data Filing System Act, the content of the term ‘electronic patient medical records’ should be derived from the provisions in the Health Personnel Act on the duty of health personnel to keep patient medical records (section 39) and the requirements as to the contents of such records (section 40).²⁶ The term ‘electronic patient medical record’ (*elektronisk pasientjournal*) is included in the definition of ‘health data filing system established for therapeutic purposes’ (*behandlingsrettet helseregister*).²⁷ Section 6, first paragraph, first sentence, of the Personal Health Data Filing System Act states that personal health data filing systems established for therapeutic purposes *may* be kept by automatic means. Section 6, fourth paragraph, provides that regulations may be issued which lay down that data in personal health data filing systems established for therapeutic purposes shall be processed electronically. In fact, in June 2013, a Consultation Paper was published proposing draft regulations on ICT-standards in the health and care sector (*Høringsnotat - Forslag til forskrift om IKT-standarder i helse- og omsorgssektoren*)²⁸. These draft regulations are proposing that all personal health data filing systems used for therapeutic purposes (*behandlingsrettede helseregistre*) shall be kept electronically.²⁹ These draft regulations are still pending.

The Personal Health Data Filing System Act applies to (section 3):

1. the processing of personal health data in the public health and care administration and the health and care service, which occurs partially or wholly by electronic means to achieve the purposes set out in section 1, i.e. ‘to contribute towards providing public health services and the public health administration with information and knowledge without violating the right to privacy, so as to ensure that medical assistance may be provided in an adequate, effective manner. Through research and statistics, the Act shall contribute towards information on and knowledge of the state of public health, causes of impaired health and illness trends for administration, quality assurance, planning and management purposes. The Act shall ensure that personal health data are processed in accordance with fundamental respect for the right to privacy, including the need to protect personal integrity and respect for private life and ensure that personal health data are of adequate quality’.
2. other processing of personal health data in the public health administration and health and care services for such purposes, when the personal health data are part of or are intended to be part of a personal health data filing system, and
3. the health archives register in the Norwegian Health Archives.

Personal health data filing systems may be established for two types of uses:

- i. those used for therapeutic purposes for individual patients (*behandlingsrettede helseregistre*), as per the Personal Health Data Filing System Act (section 2(7) and sections 6 and 6a – 6d (section 2 (7))), and electronic patient medical records (see sections 39 and 40 of the Health Personnel Act³⁰ and the Regulations on Patient Records issued pursuant to the

²³ Ibid, 79.

²⁴ See the *travaux préparatoires* to the Personal Health Data Filing System Act (Ot.prp. nr. 5 (1999-2000), paragraph 7.2.4.3.

²⁵ Ibid 7.2.4.3.

²⁶ Ibid 7.2.4.3.

²⁷ See *Høring: Forslag til ny pasientjournallov og ny helseregisterlov*, n 15, p. 33.

²⁸ See, in Norwegian, *Høringsnotat Forslag til forskrift om IKT-standarder i helse- og omsorgssektoren*, June 2013, <<http://www.regjeringen.no/nb/dep/hod/dok/hoeringer/hoeringsdok/2013/horing-av-forslag-til-forskrift-om-ikt-.html?id=731556>>.

²⁹ See proposed regulations n 28, section 3, first paragraph.

³⁰ Note what was stated above that the term ‘electronic patient medical record’ (*elektronisk pasientjournal*) is not explicitly defined in the law - see n 26.

- Health Personnel Act);
- ii. other use (secondary use) which is not therapeutic, i.e. health registers which are not used for direct treatment of patients but which are used as a basis for research, health supervision, quality improvement, statistics, planning, management or other purpose as per the Personal Health Data Filing System Act.³¹

Electronic health records are addressed specifically by the Personal Health Data Filing System Act. The Personal Data Act applies as complementary law, unless otherwise stated in the Personal Health Data Filing System Act. Similarly, with regards to patient medical records, documentation is to be processed in accordance with the rules of the Personal Data Act (section 10, Regulations on Patient Records).

There are many different types of personal health data filing systems (*helseregistre*) in Norway. Common for all registers is that they are meant to contribute to better health and that they are legally based on a provision in a law, regulation or established through a license from the Data Protection Authority.³² The Personal Health Data Filing System Act distinguishes between the following categories:

- (1) Local and regional health registers, see the Personal Health Data Filing System Act section 7;
- (2) Central health registers, see the Personal Health Data Filing System Act section 8.

Local health registers are primarily registers which are set up under the direction of a municipal or health enterprise. They may contain data about persons who have a link with the region or municipality, but also about persons without such a link. Regional health registers are mainly established by regional health enterprises (*regionale helseforetak*). A determining factor is the level at which the register was initiated and who the data controller is for the register. Regional health registers comprise both registers about disease, registers on health services, clinical quality registers and other registers which do not have the treatment of individual patients as their primary purpose.³³ The exact number of local and regional health registers in Norway is not known. However, during the pre-project to the national health register project, around 200 clinical quality registers in specialist health services were documented, such as the Norwegian Diabetes Register of adults and the Cerebral Palsy Register.³⁴ National clinical quality registers are registers where one can continuously document results for a limited group of patients based on individual course of treatment, often limited to a particular disease or type of treatment. The process of treatment and the results of treatment are used in local quality improvement efforts and as a basis for research, quality assurance and improvement of the health services for the population.³⁵ By 2013, 45 clinical quality registers had the status of a national register, following approval by the Health and Care Department.³⁶ National status of such registers also implies that the regional health enterprise which has responsibility as data controller, assumes responsibility for follow-up, development and management of the register.³⁷ With regards to local and regional personal health data filing systems, the processing of characteristics that directly identify a natural person may only be processed with the consent of the data subject (section 7, second and third paragraphs, second sentence). The data subject's consent is not necessary if the regulations provide that the personal health data may only be processed in pseudonymized or de-identified form (section 7, second and third paragraphs, third sentence).

Central health registers are nationwide in scope and set up in terms of section 8 of the Personal Health Data Filing System Act. The purpose and use of each register is regulated through a separate and specific regulation (subsidiary legislation). There are currently around 17 central health registers in

³¹ See further *Høring: Forslag til ny pasientjournallov og ny helseregisterlov*, n 15, p. 34.

³² *Ibid* 54, 131.

³³ *Ibid* 54.

³⁴ *Ibid* 54-55.

³⁵ *Ibid* 55.

³⁶ *Ibid*.

³⁷ *Ibid*.

Norway, with the *Kjernejournal*, once fully set up, being the eighteenth.³⁸ The following ten registers contain directly identifiable personal data (name, personal identity number and other characteristics that directly identify a natural person) and may be processed without the consent of the data subject insofar as this is necessary to achieve the purpose of the register:

1. Causes of Death Registry
2. Cancer Registry
3. Medical Birth Registry
4. System of notification of infectious diseases
5. The Central Tuberculosis Register
6. System for Vaccination Control (SYSVAK)
7. Defence Forces Health Records
8. Norwegian Register of Patient Records
9. National Database for Electronic Prescriptions
10. National Register of Cardiovascular Disease.

All the above ten central health registers are set up under section 8, third paragraph of the Personal Health Data Filing System Act. Another register with directly identifiable personal data which is not based on the consent of the data subject is the health archives register in the National Health Archives (section 8, ninth paragraph). Each of the above registers has been discussed and approved by Stortinget (the Norwegian Parliament) and no other register of this type may be set up without it having been discussed in and approved by Stortinget.

The Register on the genetic screening of newborns set up *inter alia* in terms of section 8, paragraph 2 of the Personal Health Data Filing System Act, has directly identifiable personal data which are based on the consent of the data subjects.

The other five central registers contain de-identified or pseudonymous data. Each of these central registers has been established pursuant to regulations adopted in terms of section 8, second paragraph of the Personal Health Data Filing System Act without first having to be discussed in and approved by the Stortinget.³⁹ The *Nasjonal Kjernejournal*, currently being set up in Norway, though still a pilot project, is another central register set up specifically in terms of section 6d of the aforementioned Act (see below section 1.3).

Note that the National Database for Electronic Prescriptions is established as one of the central health registers set up under section 8, third paragraph of the Personal Health Data Filing System Act and contains directly identifiable personal data which is not based on the consent of the data subject.

1.2. Institutional setting

The Norwegian Ministry of Health and Care Services (*Helse- og omsorgsdepartementet*) formulates and implements the national health policy with the help of several subordinate institutions.

The Norwegian Directorate of Health (*Helsedirektoratet*) is an executive agency and competent authority subordinate to the Norwegian Ministry of Health and Care Services. The political frameworks to which the Directorate is subject are the political platform of the government in office at any time and resolutions of the government and of Parliament.⁴⁰ As such, it is responsible for the compilation of various draft bills and regulations, national guidelines and campaigns. It also advises the ministries concerned on health policy and legislation.⁴¹

³⁸ See in Norwegian, < <http://www.fhi.no/helseregistre/om-helseregistre/sentrale-helseregistre> >. See also <<http://www.helseregistre.no/>>.

³⁹ See, in Norwegian, < <http://www.fhi.no/helseregistre/om-helseregistre/sentrale-helseregistre> >.

⁴⁰ See website of the Norwegian Directorate of Health < <http://helsedirektoratet.no/english/Sider/default.aspx>>.

⁴¹ See *Norway and Health: An Introduction*, Norwegian Directorate of Health, 04/2009, Ref No IS-1730 E, p. 14 at < <http://helsedirektoratet.no/english/publications/norway-and-health--an-introduction/Publikasjoner/norway-and-health-an->

The Norwegian Board of Health Supervision (*Helsetilsynet*) is an independent authority responsible for the general supervision of the health services of Norway. It directs the supervision authorities at the county level: the offices of the county governors, which have responsibility for supervision of social services, health services and health care personnel, and child welfare services. The supervisory authorities are concerned with quality, legal aspects, complaints and the task of ensuring adequate and equitable health services.⁴²

Norway is divided into 19 regional authority areas or counties (*fylker*), which in turn are divided into around 428 local authority areas or municipalities (*kommuner*).

The municipalities are responsible for providing reasonable, high-quality health care and social services to everyone in need of them, regardless of age or diagnosis. The state is responsible for ensuring equal framework conditions through legislation and financial frameworks. In addition, the state carries the responsibility of exercising supervision and control. Some of the spheres included under municipal health and care services are:⁴³

- Regular General Practitioner Scheme
- Care of the elderly
- Work with addiction and psychiatric health
- Municipal social services
- Dental care services
- Alternative treatment
- Public physiotherapy services
- Allocation of municipal services and the right to appeal

Moreover, there are four regional health enterprises (*regionale helseforetak*) which administer the so-called specialist health care services (which include all the hospitals) within each region, with appointed boards responsible for governance and results. These are:⁴⁴

- Helse Vest RHF (western region)
- Helse Midt-Norge RHF (central Norway)
- Helse Nord RHF (northern region)
- Helse Sør-Øst RHF (south-east region)

The public health service and public health administration are required to obtain a licence or to notify the processing of personal data to the Data Protection Authority (*datatilsynet*) in terms of the Personal Data Act and its regulations, as well as the Personal Health Data Filing System Act. The same obligation is given to self-employed (i.e. not public) health professionals. The Norwegian Data Protection Authority (*datatilsynet*) is set up and regulated in terms of Chapter VIII of the Personal Data Act as an independent administrative body subordinate to the King and the Ministry.⁴⁵ However, the King and the Ministry may not issue instructions regarding or reverse the Data Protection Authority's exercise of authority in individual cases pursuant to statute (section 42, first paragraph, Personal Data Act).

introduction.pdf>.

⁴² See further <<http://helsetilsynet.no/no/Norwegian-Board-of-Health-Supervision/Organization/>>.

⁴³ See <<http://www.regjeringen.no/en/dep/hod/Subjects/municipal-health-and-care-services-.html?id=10903>>.

⁴⁴ See <<http://www.regjeringen.no/en/dep/hod/Subjects/hospitals/oversikt-over-landets-helseforetak.html?id=485362>>.

⁴⁵ The Data Protection Authority shall: keep a systematic, public record of all processing that is reported or for which a licence has been granted; deal with applications for licences, receive notifications and assess whether orders shall be made in cases where this is authorized by law; keep itself informed of and provide information on general national and international developments in the processing of personal data and on the problems related to such processing; identify risks to protection of privacy, and provide advice on ways of avoiding or limiting such risks; provide advice and guidance in matters relating to protection of privacy and the protection of personal data to persons who are planning to process personal data or develop systems for such processing, including assistance in drawing up codes of conduct for various sectors; on request or on its own initiative give its opinion on matters relating to the processing of personal data; and submit an annual report on its activities to the King. See section 42, third paragraph, Personal Data Act.

In the case of medical health research, the Health Research Act has made the process for application for approval more efficient, due to the main principle in the Act that such an application only needs to be directed to one body, viz. to the Regional Committee for Medical and Health Research Ethics (REC) in the applicant's geographical area. There are four such regional committees:⁴⁶

- REC West
- REC Central
- REC North
- REC South East

The Health Research Act (section 2) applies to all medical and health research on human beings, human biological material or personal health data. Such research also includes pilot studies and experimental treatments. Upon the entry into force of the Health Research Act, the RECs took over the tasks that earlier lay with the Data Protection Authority (i.e. licensing for the processing of health data) and the Directorate of Health (exemption from the duty of confidentiality and approval of the setting up of research biobanks).⁴⁷

1.3. Legal setting and future legal development

The Norwegian national identity number (*fødselsnummer*) is a unique identifier for all Norwegian citizens. Moreover, a foreigner who intends to reside in Norway for a period longer than 6 months will be allocated a national ID.⁴⁸

As described above, it has been and is a political objective in Norway to achieve ever higher levels of electronic interaction within the health and care sector (the so-called '*samhandlingsreformen*').⁴⁹ In this context, there are a number of bills and proposals for regulations pending, the more salient of which are highlighted below:

- On 28 June 2013, the Norwegian Ministry of Health and Care Services issued a "Consultation Paper proposing a new Medical Records Act and new Personal Health Data Filing Systems Act".⁵⁰
- There is a Consultation paper with a proposal for regulations on ICT-standards in the health and care sector currently pending.⁵¹
- Also pending is a Consultation paper with a proposal for regulations on the Norwegian Health Archives, which is open for comments till 1 April 2014.⁵²

An important new health data filing system established for therapeutic purposes in terms of section 6d of the Personal Health Data Filing System Act is the *Nasjonal Kjernejournal*, a central and inter-institutional health data filing system which shall contain a limited set of relevant personal health data which are necessary to provide proper medical help.⁵³ The *Kjernejournal* is still in pilot stage, and is currently being introduced and tested in a few counties in Norway, with the aim that it will gradually

⁴⁶ See further https://helseforskning.etikkom.no/ikbViewer/page/komiteerogmoter/alle?p_dim=34677&_ikbLanguageCode=us.

⁴⁷ See further, in Norwegian, *Høring: Forslag til ny pasientjournallov og ny helseregisterlov*, n 15, p. 43.

⁴⁸ See further <http://www.skatteetaten.no/en/International-pages/Felles-innhold-benytted-i-flere-malgrupper/Articles/Norwegian-national-ID-numbers/>.

⁴⁹ See website of Ministry of Health Care and Services, in Norwegian, <http://www.regjeringen.no/en/dep/hod/Subjects/samhandlingsreformen.html?id=680424>.

⁵⁰ *Høring: Forslag til ny pasientjournallov og ny helseregisterlov* ("Consultation Paper proposing a new Medical Records Act and new Personal Health Data Filing Systems Act"), 28 June 2013, in Norwegian http://www.regjeringen.no/pages/38380934/Hoeringsnotat_helseregisterlov.pdf.

⁵¹ See *Høringsnotat Forslag til forskrift om IKT-standarder i helse- og omsorgssektoren*, June 2013, <http://www.regjeringen.no/nb/dep/hod/dok/hoeringer/hoeringsdok/2013/horing-av-forslag-til-forskrift-om-ikt-.html?id=731556>.

⁵² See *Høringsnotat Forslag til forskrift om Norsk helsearkiv og Helsearkivregisteret (helsearkivforskriften)* <<http://www.regjeringen.no/nb/dep/hod/dok/hoeringer/hoeringsdok/2013/horing-av-forslag-til-forskrift-om-norsk/horningsnotat.html?id=747688>>.

⁵³ Section 6d, third paragraph.

be introduced in the whole country.⁵⁴ The details and contents of this data filing system are further specified in the Regulations on the *Kjernejournal*.

The main laws (Acts and regulations) relevant for this study are listed in ‘List of Abbreviations’ in this report.

General Note: References in this Report to provisions in the various Acts and Regulations are based on a free translation into English of the original Norwegian texts. Such translations are thus not official.

This report is current up to 28 February 2014.

⁵⁴ For more on its introduction, see, in Norwegian, < <http://www.helsedirektoratet.no/it-helse/kjernejournal/utproving-av-kjernejournal/Sider/default.aspx> >.

2. Legal requirements applying to EHRs in Norway

2.1. Health data to be included in EHRs

2.1.1. Main findings

The term ‘electronic patient medical record’ (*elektronisk pasientjournal*) is not explicitly defined in the law.⁵⁵ According to the *travaux préparatoires* to the Personal Health Data Filing System Act, the contents of the term ‘electronic patient medical records’ should be derived from the provisions in the Health Personnel Act on the duty of health personnel to keep patient medical records (section 39) and the requirements as to the contents of such records (section 40).⁵⁶ The term ‘electronic patient medical record’ (*elektronisk pasientjournal*) is included in the definition of ‘health data filing system established for therapeutic purposes’ (*behandlingsrettet helseregister*).⁵⁷ Section 6, first paragraph, first sentence, of the Personal Health Data Filing System Act states that personal health data filing systems established for therapeutic purposes *may* be kept by automatic means. Section 6, fourth paragraph, provides that regulations may be issued which lay down that data in personal health data filing systems established for therapeutic purposes *shall* be processed electronically. In fact, in June 2013, a Consultation Paper was published proposing draft regulations on ICT-standards in the health and care sector (*Høringsnotat - Forslag til forskrift om IKT-standarder i helse- og omsorgssektoren*)⁵⁸. These draft regulations are proposing that all personal health data filing systems used for therapeutic purposes (*behandlingsrettede helseregistre*) shall be kept electronically.⁵⁹ However, these draft regulations are still pending.

There are different types and categories of health data and personal health data filing systems in Norway as well as different types of registers (see section 1.1.2).

The Regulations on Patient Records has a long list of information that shall be included in a patient record ‘provided they are relevant and necessary’. This list is not exhaustive as section 8, third paragraph states that other data than that specified shall be recorded in the patient record to the extent that they are ‘relevant and necessary’. The patient record, according to the Health Personnel Act (section 40), shall be kept in accordance with good professional conduct and shall contain relevant and necessary information about the patient and the health care, as well as the information that is required in order to comply with the notification requirements or the duty of disclosure laid down in or pursuant to the law.

With regards to identification rules, one should distinguish between data held for primary use (see Regulations on Patient Records, s. 8(a) which requires identification provided it is ‘relevant and necessary’), and data held for secondary use (see the Personal Health Data Filing System Act and its provisions inter alia on de-identification, anonymization and pseudonymization of data).

⁵⁵ See the *travaux préparatoires* to the Personal Health Data Filing System Act (Ot.prp. nr. 5 (1999-2000)), paragraph 7.2.4.3.

⁵⁶ Ibid 7.2.4.3.

⁵⁷ See *Høring: Forslag til ny pasientjournallov og ny helseregisterlov*, n 15, p. 33.

⁵⁸ See proposed regulations n 28.

⁵⁹ See proposed regulations n 28, section 3, first paragraph.

2.1.2. Table on health data

Questions	Legal reference	Detailed description
<p><i>Are there specific rules on the content of EHRs? (or regional provisions, agreements, plans?)</i></p>	<p>- Health Personnel Act; - Regulations on Patient Records.</p> <p>- Personal Health Data Filing System Act and the various pieces of subsidiary legislation issued pursuant to this Act.</p> <p>The above cross-refer to: - Personal Data Act; - Personal Data Regulations, in particular sections 7-25, 7-26 and 7-27.</p>	<p>Section 8, first paragraph of the Regulations on Patient Records has a long list (sub-paragraphs (a) to (u)) of information that shall be included in a patient record 'provided they are relevant and necessary'. This list is not exhaustive as section 8, third paragraph states that other data than that specified in the first and second paragraphs shall be recorded in the patient record to the extent that they are 'relevant and necessary'.</p> <p>See, for e.g. section 4 of the Regulations on the <i>Kjernejournal</i>, etc.</p>
<p><i>Are these data restricted to purely medical information (e.g. physical or mental health, well-being)?</i></p>	<p>section 8, Regulations on Patient Records</p> <p>section 40, Health Personnel Act</p>	<p>Section 8, first paragraph of the Regulations on Patient Records has a long list of information that shall be included in a patient record 'provided they are relevant and necessary'. It includes, inter alia, (q) 'whether information is given to the police, the child welfare service, health and health care services, social services etc. ... The information that was given should be specified.'</p> <p>Section 8, third paragraph states that information other than that mentioned in the first and third paragraphs shall be included in the record to the extent that it is 'relevant and necessary'.</p> <p>Section 40 provides that the patient record shall be kept in accordance with good professional conduct and shall contain relevant and necessary information about the patient and the health care, as well as the information that is required in order to comply with the notification requirements or the duty of disclosure laid down in or pursuant to the law. The record shall be easy to comprehend by other qualified health personnel.</p>

Questions	Legal reference	Detailed description
	section 2 (1), Personal Health Data Filing System Act	<p>Note section 2(1) of the Personal Health Data Filing System Act which defines 'personal health data' (<i>helseopplysninger</i>) as follows: 'personal health data: any information subject to the duty of confidentiality pursuant to the Health Personnel Act section 21 and other information and assessments regarding health matters or that are significant for health matters, that may be linked to a natural person'. Note: section 21 Health Personnel Act: 'Health care personnel shall prevent that others get access or knowledge to information on people's bodily or health condition or other personal circumstances that they get knowledge of in their capacity as health care personnel.'</p>
<p><i>Is there a definition of EHR or patient's summary provided in the national legislation?</i></p>	<p>Health Personnel Act, sections 39-40;</p>	<p>The term 'electronic patient medical record' (<i>elektronisk pasientjournal</i>) is not explicitly defined in the law.⁶⁰ According to the <i>travaux preparatoires</i> to the Personal Health Data Filing System Act, the contents of the term 'electronic patient medical records' should be derived from the provisions in the Health Personnel Act on the duty of health personnel to keep patient medical records (section 39) and the requirements as to the contents of such records (section 40).⁶¹ The term 'electronic patient medical record' (<i>elektronisk pasientjournal</i>) is included in the definition of 'health data filing system established for therapeutic purposes' (<i>behandlingsrettet helseregister</i>).⁶² Section 6, first paragraph, first sentence, of the Personal Health Data Filing System Act states that personal health data filing systems established for therapeutic purposes <i>may</i> be kept by automatic means. Section 6, fourth paragraph, provides that regulations may be issued which lay down that data in personal health data filing systems established for therapeutic purposes <i>shall</i> be processed electronically. In fact, in June 2013, a Consultation Document was published proposing draft regulations on ICT-standards in the health and care sector (<i>Høringsnotat - Forslag til forskrift om IKT-standarder i helse- og omsorgssektoren</i>)⁶³. These draft regulations are proposing that all</p>

⁶⁰ See the *travaux preparatoires* to the Personal Health Data Filing System Act (Ot.prp. nr. 5 (1999-2000), paragraph 7.2.4.3.

⁶¹ Ibid 7.2.4.3.

⁶² See *Høring: Forslag til ny pasientjournallov og ny helseregisterlov*, n 15, p. 33.

⁶³ See proposed regulations n 28.

Questions	Legal reference	Detailed description
	<p>Personal Health Data Filing System Act, section 2(7), section 2(6); section 6</p> <p>Section 2 (6)(7), Personal Health Data Filing System Act</p> <p>Section 3 (a), Regulations on patient records; section 46 Health Personnel Act</p>	<p>personal health data filing systems used for therapeutic purposes (<i>behandlingsrettede helseregistre</i>) shall be kept electronically.⁶⁴ However, these draft regulations are still pending.</p> <p>Section 2(7): 'health data filing system established for therapeutic purposes: a system of patient records and information or other personal health data filing system for the purpose of providing a basis for acts that have preventive, diagnostic, therapeutic, health-preserving or rehabilitative objective in relation to the individual patient and that are performed by health personnel, and the administration of such acts'.</p> <p>Section 2(6): 'personal health data filing systems: filing systems, records, etc. where personal health data are systematically stored so that information concerning a natural person may be retrieved'</p> <p>Note the scope of the Personal Health Data Filing System Act in section 3 thereof, is inter alia:</p> <ol style="list-style-type: none"> 1. the processing of personal health data in the public health and care administration and the health and care service, which occurs partially or wholly by electronic means to achieve the purposes set out in section 1; 2. other processing of personal health data in the public health administration and health and care services for such purposes, when the personal health data are part of or are intended to be part of a personal health data filing system, and 3. the health archives register in the Norwegian Health Archives. <p>Section 3 (a) 'patient record/record: a collection or group of written/registered information on a patient in connection with medical help'.</p> <p>Note that section 46, Health Personnel Act states that a patient record can be kept electronically.</p>
<p><i>Are there any requirements on the content of EHRs (e.g. detailed requirements on</i></p>	<p>section 8, Regulations on Patient Records</p>	<p>Section 8 contains a detailed list of what should be contained in a patient record (see above).</p>

⁶⁴ See proposed regulations n 28, section 3, first paragraph.

Questions	Legal reference	Detailed description
<p><i>specific health data or general reference to health data)?</i></p>	<p>See relevant provisions on content of each respective register, in the various regulations issued pursuant to the Personal Health Data Filing System Act</p>	<p>The various Regulations issued pursuant to the Personal Health Data Filing System Act normally contain detailed requirements on the type and extent of the specific health data that is processed. For example, Section 1-2 of the Cancer Registry Regulations provides:</p> <p>"The Cancer Registry shall contain personal health data relating to all persons in Norway who have or have had cancer. The Cancer Registry shall contain personal health data on precancerous conditions and benign tumours in the central nervous system.</p> <p>The Cancer Registry may also contain personal health data relating to affected relatives of persons in Norway shown by documentary evidence to be predisposed to or to have hereditary cancer that may be made the object of unsolicited contact and disclosure, if the relative concerned, after having received information about the way such data is processed in the Cancer Registry, does not object thereto.</p> <p>The Cancer Registry may furthermore contain personal health data relating to persons who have participated in screening programmes for early diagnosis and control of cancer. For negative findings; data that directly identify a natural person may only be recorded permanently by consent. Data that directly identify a natural person may, however, be stored temporarily so that the quality of the data may be assured.'</p> <p>See also above, for e.g. the contents of the <i>Kjernejournal</i>.</p>
<p><i>Are there any specific rules on the use of a common terminology or coding system to identify diseases, disorders, symptoms and others?</i></p>	<p>Guidelines to medical codes 2014</p>	<p>There are several coding systems used. These include:</p> <ul style="list-style-type: none"> - ICD-10: International Classification of Diseases and related health problems - ICPC: International Classification of Primary Health Care - NCSP and NCMP: this code is used for surgical and medical procedures - ICF: the International Classification of Functioning, Disability and Health - NCRP 2014: Norwegian Classification of Radiological Procedures - <i>Laboratoriekodeverk</i>: Norwegian laboratory code - ATC: Anatomical Therapeutic Chemical Classification System for the classification of drugs

Questions	Legal reference	Detailed description
		<ul style="list-style-type: none"> - Multiaxial classification in psychic health care for children and the young (BUP-Klass)⁶⁵ - ICD-DA-3: classification system for use within dental health care - The Norwegian SNOMED - Special codes (særkoder) – a list for 2014 may be viewed at <http://helsedirektoratet.no/kvalitet-planlegging/helsefaglige-kodeverk/kodeveiledning/Sider/default.aspx>. <p>The above list is based on the codes listed on the website of the Norwegian Directorate of Health (in Norwegian) – see further http://helsedirektoratet.no/kvalitet-planlegging/helsefaglige-kodeverk/sokeverktoy/Sider/default.aspx</p> <p>Guidelines (in Norwegian) to some of the medical codes is available at <http://helsedirektoratet.no/kvalitet-planlegging/helsefaglige-kodeverk/kodeveiledning/Sider/default.aspx> - The guidelines are known as <i>Kodeveiledning 2014</i> (Guidelines to medical codes 2014).</p>
<p><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></p>	<p>Section 2(1)(2)(3)(4), Personal Health Data Filing System Act</p>	<p>There is no general distinction between types of health data. The main distinction in the Personal Health Data Filing System Act is in the <i>degree</i> to which the person to whom the data relates can be identified or not and thus, in the <i>form</i> that the health data is processed. The Act distinguishes between personal health data (§2(1)), de-identified personal health data (section 2(2)), anonymous data (2(3)) and pseudonymous health data (section 2(4)), namely:</p> <p>Section 2(1): personal health data: any information subject to the duty of confidentiality pursuant to the Health Personnel Act section 21 and other information and assessments regarding health matters or that are significant for health matters, that may be linked to a natural person,</p> <p>Section 2(2): de-identified personal health data: personal health data from which the name, personal identity number and other characteristics serving to identify a person have been removed, so that the data can no longer be linked to a natural person, and where the identity can only be traced through alignment with the same data that were previously removed,</p>

⁶⁵ Informal translation from the Norwegian *Multiaksial klassifikasjon i psykisk helsevern for barn og unge (BUP-klass)*

Questions	Legal reference	Detailed description
		<p>Section 2(3): anonymous data: data from which the name, personal identity number and other characteristics serving to identify a person have been removed, so that the data can no longer be linked to a natural person,</p> <p>Section 2(4): pseudonymous health data: personal health data in which the identity has been encrypted or otherwise concealed, but nonetheless individualized so that it is possible to follow each person through the health system without his identity being revealed.</p>
<p><i>Are there any specific rules on identification of patients in EHRs?</i></p>	<p>Section 8, Regulations on Patient Records</p> <p>Sections 7 and 8 Personal Health Data Filing System Act</p>	<p>Section 8 on the content requirements of patient records provides that the patient record shall contain the following information, provided it is relevant and necessary: (a) sufficient information to be able to identify and contact the patient, including the patient's name, address, municipality of residence, personal number, telephone number, civil status and profession.</p> <p>Section 7 dealing with regional and local personal health data filing systems provides inter alia:</p> <p>'... The name, personal identity number or other characteristics that directly identify a natural person may only be processed with the consent of the data subject. The latter's consent is not necessary if the regulations provide that the personal health data may only be processed in pseudonymized or de-identified form. The regulations shall state the purpose of the processing of the personal health data, which data may be processed, and, if appropriate, prescribe further rules as to who shall effect the pseudonymization and principles for how this shall be done. ...'</p> <p>Section 8 dealing with central personal health data filing systems, provides inter alia, in its second and third paragraphs:</p> <p>'... The name, personal identity number or other characteristics that directly identify a natural person may only be processed with the consent of the Data Subject. The latter's consent is not necessary if the regulations provide that the personal health data may only be processed in pseudonymized or de-identified form. If appropriate, the regulations shall prescribe further rules regarding who shall effect the pseudonymization and principles for how this shall be done.</p> <p>In the following registers, the name, personal identity number and other characteristics that directly identify a natural person may be processed without the</p>

Questions	Legal reference	Detailed description
		<p>consent of the Data Subject insofar as this is necessary to achieve the purpose of the register:</p> <ol style="list-style-type: none"> 1. Causes of Death Registry 2. Cancer Registry 3. Medical Birth Registry 4. System of notification of infectious diseases 5. The Central Tuberculosis Register 6. System for Vaccination Control (SYSVAK) 7. Defence Forces Health Records 8. Norwegian Register of Patient Records 9. National Database for Electronic Prescriptions 10. National Register of Cardiovascular Disease
<p><i>Is there is a specific identification number for eHealth purposes?</i></p>	<p>Personal Data Act, section 12</p> <p>Sections 7 and 8 Personal Health Data Filing System Act; Section 8 Regulations on Patient Records</p>	<p>With regards to the use of national identity numbers (<i>fødselsnummer</i>), etc. section 12 of the Personal Data Act provides that:</p> <p>'National identity numbers and other clear means of identification may only be used in the processing when there is an objective need for certain identification and the method is necessary to achieve such identification.</p> <p>The Data Protection Authority may require a controller to use such means of identification as are mentioned in the first paragraph to ensure that the personal data are of adequate quality.</p> <p>The King may by regulations prescribe further rules regarding the use of national identity numbers and other clear means of identification.'</p> <p>Where the patient or data subject is identified, there is no other specific ID number used except for the personal identity number (<i>fødselsnummer</i>). (See the answer to the previous question.)⁶⁶</p>

⁶⁶ This is also the view of the interviewees from the Norwegian Medical Association.

2.2. Requirements on the institution hosting EHRs data

2.2.1. Main findings

All the institutions which provide health care are obliged to have a proper medical record system (see section 5-10 of the Municipal Health Care Act; section 3-2 of the Specialist Health Services Act; and section 4 of the Regulations on Patient Records).

The general rule in section 33 of the Personal Data Act is that a licence from the Data Protection Authority is required for the processing of sensitive personal data. However, certain processing actions do not need a licence under this section 33. Indeed, Chapter 7 of the Personal Data Regulations provides rules as to when certain processing methods, also related to health data, are not subject to licensing but to notification (see examples in table 2.2.2 below). The general rule in the Personal Data Act is that all processing of identifiable personal data is subject to a duty to notify such processing to the Data Protection Authority unless the processing is (a) subject to an obligation to obtain a licence from the Data Protection Authority or (b) it is exempted from the obligation to obtain a licence or to notify pursuant to Chapter 7 of the Data Protection Regulations.

In the case of personal health data filing systems (*helseregistre*), reference should be made to sections 5 to 8. Section 8 of the Personal Health Data Filing System Act regulates central personal health data filing systems (*sentral helseregister*) whereas section 7 regulates local and regional personal health data filing systems.

In the case of central personal health data filing systems (*sentral helseregister*) where identifiable personal data (*personidentifiserbare helseregistre*) is to be processed without the consent of the data subject, no such register may be created unless *Stortinget* has permitted the creation of such a data filing system by means of statute and insofar as this is necessary to achieve the purpose of the data filing system. Note that a law (or amendment to an existing law – typically a new insertion in section 8, third paragraph) is required. It is not sufficient to merely issue regulations (i.e. omitting the requirement for a law) where identifiable personal data are to be processed without consent. Once a new personal health data filing system has been created by law, the processing of data in such filing system is then regulated in further detail in specific regulations established for such purpose (section 8, second paragraph).

The consent of the data subject is not necessary, provided that regulations provide that the personal data is to be processed only in pseudonymous or de-identified form (section 8, second paragraph, third sentence). Central personal health data filing systems with pseudonymous or de-identified personal data are created, and the processing of personal data regulated, through specific regulations established for such purposes.

In the case of regional and local personal health data filing systems (section 7, Personal Health Data Filing System Act), the name, personal identity number or other characteristics that directly identify a natural person may only be processed with the consent of the data subject (section 7, second paragraph, second sentence). According to section 7 (second paragraph, third sentence and third paragraph, third sentence), the consent of the data subject is not necessary provided that regulations provide that the personal data is to be processed only in pseudonymous or de-identified form.

In the case where the proposed data filing system shall process identifiable personal data with the consent of the data subject, a difference of interpretation has arisen between the Data Protection Authority and the Ministry of Justice's legal section in connection with applications for a licence to set up clinical quality registers with a national coverage.⁶⁷ Health registers about disease or clinical

⁶⁷ See Consultation Paper Consultation Paper proposing a new Medical Records Act and new Personal Health Data Filing

quality registers (*kvalitetsregistre*) which contain several diagnosis and very sensitive data on the whole population ought to be regulated in regulations, according to the Data Protection Authority.⁶⁸ However, the Ministry of Justice's legal department holds that such personal health data filing systems may be set up through a licence from the Data Protection Authority. This difference of interpretation is highlighted in, inter alia, the Consultation Paper proposing a new Medical Records Act and new Personal Health Data Filing Systems Act.⁶⁹

Indeed, the Data Protection Authority has stated that the *travaux préparatoires* to the (current) Personal Health Data Filing System Act lay down criteria linked to the extent of information, coverage, population and duration to determine when personal health data filing systems are to be created through a licence from the Data Protection Authority or when they are to be created through regulations. According to such *travaux préparatoires*, 'personal health data filing systems with few and not especially sensitive personal health data may be created by a licence from the Data Protection Authority. The same applies to personal health data filing systems which are not intended to exist for a long period. A prerequisite for the collection of personal health data for use in personal health data filing systems established for a limited time is that the data subject has consented, unless there is or shall be made provision for an exception to the duty of confidentiality in accordance with the Health Personnel Act section 29.'⁷⁰

Note that, according to section 29, the data controller for the respective personal health data filing system shall notify the Data Protection Authority before processing personal health data by automatic means and before establishing a manual personal health data filing system.

In the case of medical health research, the Health Research Act has made the process for application for approval more efficient, due to the main principle in the Act that such an application need only be directed to one body, viz. to the Regional Committee for Medical and Health Research Ethics (REC) in the applicant's geographical area.

There are strict rules on access to personal health data in the data controller's institution as well as obligations on internal control, and on ensuring satisfactory data security with regard to confidentiality, integrity, quality and accessibility in connection with the processing of personal health data. Thus, for example, according to section 13a, Personal Health Data Filing System Act, '[i]t is forbidden to read, search or in another manner acquire, use or possess personal health data that is processed pursuant to this Act except when justified for reasons of providing health assistance to the patient, administration of such health assistance, or as specifically authorized in statute or regulation.' There is a similar provision in section 21a of the Health Personnel Act. Moreover, according to section 45, first paragraph, third sentence, of the Health Personnel Act, '[i]t shall be evident from the patient medical record that other health personnel have been given access to the patient records.' Moreover, among the data that should be recorded in the patient's medical record (*pasientjournal*), provided it is relevant and necessary, is information whether the medical record (*pasientjournal*) has been exchanged with other health care personnel, e.g. referrals, epicrisis, etc. (Regulations on Patient Records (section 8(1)).

Systems Act, n 15, p. 131-132.

⁶⁸ See the Data Protection Authority's comments, in Norwegian, to the Proposed Bill for a new Patient Medical Records Act and a bill for a new Personal Health Data Filing Systems Act, p. 23, at <<http://www.regjeringen.no/pages/38380933/datatilsynet.pdf>>.

⁶⁹ See n 15, p. 131-132.

⁷⁰ Unofficial translation from the *travaux préparatoires*, the Ot. prp. nr. 5 for 1999-2000, p. 92.

2.2.2. Table on requirements on the institutions hosting EHRs data

Questions	Legal reference	Detailed description
<p>Are there specific national rules about the hosting and management of data from EHRs?</p>	Section 4, Regulations on Patient Records;	According to section 4, institutions which provide medical health are obliged to set up a medical record system which must be organized in such a way as to satisfy the requirements laid down in or in accordance with the law, including rules on access to the patient medical record, etc.
	Municipal Health Care Act, section 5-10	Section 5-10, Municipal Health Care Act states that the municipality and institution who are contractually bound to the municipality to provide health and care services, shall ensure that the patient medical record and information systems in the institution are proper (<i>forsvarlige</i>). They shall take into consideration the need for effective electronic collaboration when procuring and further developing their patient medical records and information systems.
	Specialist Health Services Act, section 3-2	A similar obligation to that in section 5-10, Municipal Health Care Act, is laid down in section 3-2, Specialist Health Services Act, with regards to those health institutions providing health care under the latter Act.
	Health Personnel Act, especially section 39	Section 39: Health care providers are obliged to enter or record information in a patient record. Section 39, first and second paragraphs provide: The health care provider shall enter or record information as mentioned in section 40 in a patient record for the individual patient. The duty to keep patient records does not apply to co-operating personnel providing care in accordance with instructions or guidance from other health personnel. Health institutions shall designate one person with superior responsibility for the individual patient record including making decisions relating to what information is to be entered into the patient record.
	Health Personnel Act; Regulations on Patient Records	Medical records may be held either electronically or otherwise - see section 46 Health Personnel Act; see section 3(a) Regulations on Patient Records definition of 'patient records'.
	See also Personal Health Data Filing Systems Act	The Personal Health Data Filing Systems Act has extensive rules on local and regional health data filing systems, central health data filing systems and health

Questions	Legal reference	Detailed description
		<p>data filing systems established for therapeutic purposes. Central health data filing systems as well as large, national and long-term personal health data filing systems are also regulated through regulations (subsidiary legislation) pursuant to the Personal Health Data Filing Systems Act.</p>
<p><i>Is there a need for a specific authorisation or licence to host and process data from EHRs?</i></p>	<p>Section 33, Personal Data Act</p> <p>Personal Data Regulations, Chapter 7 Part IV 'Processing that is exempt from the obligation to obtain a licence, but subject to the obligation to give notification'.</p>	<p>Section 33, Personal Data Act, lays down the general rule that a licence from the Data Protection Authority is required for the processing of sensitive personal data. However, regulations may be prescribed to the effect that certain processing methods are not subject to such licensing.</p> <p>NOTE: Section 7-22 provides that processing covered by inter alia sections 7-25 to 7-27 shall be exempt from the obligation to obtain a licence pursuant to section 33, first paragraph, of the Personal Data Act. However, notification of the processing shall be given pursuant to section 31, first paragraph, Personal Data Act. Exemption from the licensing obligation shall only apply if the personal data are processed in keeping with the purpose that follows from the individual provision. The provisions of the Personal Data Act regarding personal data processing in chapters I to V and VII to IX shall be complied with even if no licence is required.</p> <p>Section 7-25: The processing of patient data by health or social welfare professionals who are not subject to official authorisation shall be exempt from the obligation to obtain a licence pursuant to §33, first paragraph, of the Personal Data Act. Exemption from the licensing obligation shall only apply if the personal data are processed in connection with:</p> <ul style="list-style-type: none"> a) treatment and follow-up of individual patients, or b) preparation of statistics. <p>Section 7-26: The processing of patient data by officially authorized health professional and health professionals who have been granted a licence to practice shall be exempt from the obligation to obtain a licence pursuant to §33, first paragraph, of the Personal Data Act. Exemption from the licensing obligation shall only apply if the personal data are processed in connection with:</p> <ul style="list-style-type: none"> a) treatment and follow-up of individual patients, b) work as an appointed expert, or c) preparation of statistics.

Questions	Legal reference	Detailed description
	<p data-bbox="707 735 1066 831">Health Research Act, chapter 3, in particular, sections 9 and 10</p> <p data-bbox="707 906 1066 970">Section 5, Personal Health Data Filing Systems Act</p>	<p data-bbox="1088 233 1469 256">Section 7-27: Research projects</p> <p data-bbox="1088 264 2051 459">“Processing of personal data in connection with a research project is exempt from the obligation to obtain a licence pursuant to section 33, first paragraph, of the Personal Data Act as long as the project is recommended by a data protection officer (<i>personvernombud</i>). If the project concerns a medical and health research project, it must also be recommended [i.e. prior approval] by a regional committee for medical and health research ethics (REC).</p> <p data-bbox="1088 467 2051 699">Research projects which have a wide scope and long duration, as well as research on a large data set which is not pseudonymised or de-identified in another secure manner, are not exempt. The exemption covers so-called "absentee analyses" provided these are based on consent. Absentee analyses means analyses of the distribution of education, income and benefits and so on, among people attending and people not attending, to calculate the importance of the non-attendance.”</p> <p data-bbox="1088 738 2051 866">In the case of medical health research, the Health Research Act requires that an application should be directed to the Regional Committee for Medical and Health Research Ethics (REC) in the applicant’s geographical area. (See also section Error! Reference source not found.).</p> <p data-bbox="1088 906 2051 1106">Section 5, first paragraph: General rule that personal health data may only be processed by automatic means when this is permitted pursuant to the Personal Data Act sections 9 and 33, the Health Research Act, or it is so provided by statute and is not prohibited on other special legal grounds. The same applies to other processing of personal health data, if the data are part of, or are intended to be part of, a health data filing system.</p> <p data-bbox="1088 1114 2051 1273">Section 5, second paragraph inter alia provides that the obligation to obtain a licence pursuant to section 33 of the Personal Data Act shall not apply to the processing of personal health data that takes place pursuant to regulations laid down pursuant to sections 6 to 8. Note that these sections deal with the following matters:</p> <ul data-bbox="1088 1281 2051 1375" style="list-style-type: none"> - section 6: personal health data filing system established for therapeutic purposes - section 6a: inter-institutional personal health data filing systems established for therapeutic purposes

Questions	Legal reference	Detailed description
	<p>Personal Health Data Filing System Act, section 29</p> <p>Health Research Act</p>	<ul style="list-style-type: none"> - section 6b: inter-institutional personal health data filing systems established for therapeutic purposes – health care personnel in a formal collaboration - section 6c: Personal health data filing systems for administration and case review - section 6d: National 'Kjernejournal' - section 7: Regional and local personal health data filing systems - section 8: Central personal health data filing systems <p>See also section 2.2.1 above.</p> <p>According to section 29, the data controller for the respective personal health data filing system shall notify the Data Protection Authority before processing personal health data by automatic means and before establishing a manual personal health data filing system.</p> <p>In the case of medical health research, the Health Research Act requires that an application should be directed to the Regional Committee for Medical and Health Research Ethics (REC) in the applicant’s geographical area.</p>
<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>Personal Health Data Filing System Act, in particular sections 13, 16 -17;</p> <p>See also the regulations issued pursuant to this Act.</p>	<p>Section 13: Access to personal health data in the data controller's and the data processor's institution: This provides inter alia in paragraph 1:</p> <p>Only the data controller, the data processors and persons working under the instructions of the controller or the processor may be granted access to personal health data. Access may only be granted insofar as this is necessary for the work of the person concerned and in accordance with the rules that apply regarding the duty of confidentiality.</p> <p>Section 16: Ensuring confidentiality, integrity, quality and accessibility:</p> <p>‘The data controller and the data processor shall by means of planned, systematic measures, ensure satisfactory data security with regard to confidentiality, integrity, quality and accessibility in connection with the processing of personal health data.</p> <p>In the registers named in section 8 third paragraph, directly person-identifying characteristics shall be stored encrypted. The requirement that characteristics that directly identify a person shall be stored encrypted does not apply for the</p>

Questions	Legal reference	Detailed description
		<p>National database for electronic prescriptions.</p> <p>To achieve satisfactory data security, the controller and the processor shall document the data system and the security measures. Such documentation shall be accessible to the employees of the controller and of the processor. The documentation shall also be accessible to the supervisory authorities.</p> <p>Any controller who allows other persons to have access to personal health data, e.g. a data processor or other persons performing tasks in connection with the data system, shall ensure that the said persons fulfil the requirements set out in the first and second paragraphs.</p> <p>The King may prescribe regulations regarding data security in connection with the processing of personal health data pursuant to this Act. The King may for instance set further requirements as regards electronic signatures, communication and long-term storage, the authorization of software and the use of standards, classification systems and coding systems, and which national or international system of standards shall be followed.’</p> <p>Note especially paragraph 4 of section 16 above.</p> <p>Section 17: Internal control provides that:</p> <p>‘The data controller shall establish and maintain such planned and systematic measures as are necessary to fulfil the requirements laid down in or pursuant to this Act, including measures to ensure the quality of personal health data.</p> <p>The controller shall document the measures. The documentation shall be accessible to the employees of the controller and of the processor. The documentation shall also be accessible to the supervisory authorities.</p> <p>The King may by regulations prescribe further rules regarding internal control.’</p> <p>See also the regulations issued pursuant to this Act, such as the Regulations on Health Information Security.</p> <p>NOTE: The Regulations on health information security (<i>helseinformasjonssikkerhetsforskriften</i>) are not yet in force (see chapter 3 below).</p> <p>To the extent that two or more data controllers use the same IT-solution hosted</p>

Questions	Legal reference	Detailed description
	<p>Personal Health Data Filing System Act, in particular section 13a; Health Personnel Act, section 21a</p> <p>Health Personnel Act, section 45, first paragraph</p> <p>Section 8(1), Regulations on Patient Records</p>	<p>by a common data processor, the data will have to be stored in separate databases, or stored encrypted for each data controller respectively.</p> <p>According to section 13a, Personal Health Data Filing System Act: 'It is forbidden to read, search or in another manner acquire, use or possess personal health data that is processed pursuant to this Act except when justified for reasons of providing health assistance to the patient, administration of such health assistance, or as specifically authorized in statute or regulation.' There is a similar provision in section 21a of the Health Personnel Act.</p> <p>According to section 45, first paragraph, third sentence, of the Health Personnel Act, '[i]t shall be evident from the patient medical record that other health personnel have been given access to the patient records.'</p> <p>Moreover, among the data that should be recorded in the patient's medical record (<i>pasientjournal</i>), provided it is relevant and necessary, is information whether the medical record (<i>pasientjournal</i>) has been exchanged with other health care personnel, e.g. referrals, epicrisis, etc. (Regulations on Patient Records (section 8(1)).</p>
<p><i>In particular, is there any obligation to have the information included in EHRs encrypted?</i></p>	<p>Personal Health Data Filing System Act, in particular section 16</p>	<p>Section 16, second paragraph provides that: 'In the registers named in section 8 third paragraph (see above list), directly person-identifying characteristics shall be stored encrypted. The requirement that characteristics that directly identify a person shall be stored encrypted does not apply for the National database for electronic prescriptions.'</p> <p>See also the rules on information security in section 16 and internal control in</p>

Questions	Legal reference	Detailed description
		section 17. To the extent that two or more data controllers use the same IT-solution hosted by a common data processor, the data will have to be stored in separate databases, or stored encrypted for each data controller respectively.
<i>Are there any specific auditing requirements for institutions hosting and processing EHRs?</i>	Personal Health Data Filing System Act, in particular section 17	See rules re internal control above-mentioned. Note the power of the King to, by regulations, prescribe further rules regarding internal control. One finds, for example, such rules scattered in the various regulations on the central personal health registers (pursuant to section 8), for e.g. section 2-4 on quality control of health information in the Regulations on the Norwegian Register of Patient Records.

2.3. Patient consent

2.3.1. Main findings

In Norway, there is actually a duty on health care providers to enter or record data in a patient record (*journal* or *pasientjournal*) (Health Personnel Act). The patient has a right to opt out of the processing of his/her personal data in both the *pasientjournal* and the patient's *kjernejournal*.

The requirement for consent is interpreted more restrictively in the Personal Data Act than it is in the Patients' Rights Act with respect to consent to receive primary health care. Thus, section 2(7) of the Personal Data Act defines the term 'consent' as 'any freely given, specific and informed declaration by the data subject to the effect that he or she agrees to the processing of personal data relating to him or her'.⁷¹ However, section 4-2 of the Patients' Rights Act states that '[c]onsent may be given explicitly or tacitly. Tacit consent is considered to have been given if it is probable, based on the patient's conduct and all other circumstances, that he or she accepts the health care.' Moreover, section 7, first paragraph, of the Health Personnel Act, provides that '[h]ealth personnel shall immediately provide the health care they are capable of when it must be assumed that the health care is of vital importance. Pursuant to the limitations laid down by the Patients Rights Act section 4-9,⁷² necessary health care shall be given, even if the patient is incapable of granting his consent thereto, and even if the patient objects to the treatment.' Any such consent or objection to the treatment, as well as the patient's consent or decision to opt-out with regards to the processing of personal data, should be recorded in the patient's medical record (*pasientjournal*) in terms of the Regulations on Patient Records, section 8(j).

The main rule with regards to regional, local and central personal health data filing systems is that the name, personal identity number or other characteristics that directly identify a natural person may only be processed with the consent of the data subject. With regards to the *creation* of central, regional and local personal health data filing systems, the rules are intricate (see the discussion in section 2.2.1).

According to the Personal Health Data Filing System Act, when the personal health data is collected from the data subject directly (section 23), the data subject must be inter alia informed of the purpose of the processing of the personal health data, and of any other circumstance that will enable the data subject to exercise his rights pursuant to this Act in the best possible way.

There are also opt-in/opt-out rules for patient consent with regard to sharing of health data (Health Personnel Act, sections 25 and 45). One should note especially the requirement in sections 25 and 45 'to provide health care in a responsible manner'.

Access to personal health data in personal health data filing systems established for therapeutic purposes across institutions may only be given following express consent from the data subject.

⁷¹ There is an identical definition of 'consent' in the Personal Health Data Filing System Act, section 2 no. 11.

⁷² Section 4-9, Patients' Rights Act, regulates the patient's right to refuse health care in special situations.

2.3.2. Table on patient consent

Questions	Legal reference	Detailed description
<p>Are there specific national rules on consent from the patient to set-up EHRs?</p>	<p>Health Personnel Act, in particular chapter 8 on the duty relating to documentation</p> <p>Section 8, Regulations on Patient Records</p> <p>Sections 7 and 8 Personal Health Data Filing System Act</p>	<p>In Norway, according to section 39 of the Health Personnel Act, there is actually a <u>duty</u> on health care providers to enter or record data as mentioned in section 40 in a patient record (<i>journal</i> or <i>pasientjournal</i>). Note that the term ‘health care’ (helsehjelp) in the Health Personnel Act is defined in section 2 as “shall mean any act that has a preventive, diagnostic, therapeutic, health-preserving or rehabilitative objective and that is performed by health personnel.’</p> <p>If the patient has opted out of the processing of his/her personal data, this opt-out is included in the patient’s record, provided it is relevant and necessary – see section 8(j), Regulations on Patient Records. This also applies to the patient’s consent regarding the processing of information as well as the patient’s other reservations, demands or conditions.</p> <p>The main rule with regards to regional, local and central personal health data filing systems is that the name, personal identity number or other characteristics that directly identify a natural person may only be processed with the consent of the data subject. The latter’s consent is not necessary if the regulations provide that the personal health data may only be processed in pseudonymized or de-identified form.</p> <p>However, section 8 specifies that with regards to the following central registers, the name, personal identity number and other characteristics that directly identify a natural person may be processed without the consent of the data subject insofar as this is necessary to achieve the purpose of the register:</p> <ol style="list-style-type: none"> 1. Causes of Death Registry 2. Cancer Registry 3. Medical Birth Registry 4. System of notification of infectious diseases 5. The Central Tuberculosis Register 6. System for Vaccination Control (SYSVAK)

	<p>Section 6d, Personal Health Data Filing System Act;</p> <p>Regulations on the <i>Kjernejournal</i></p> <p>Personal Data Act, section 2(7);</p> <p>Section 8(j), Regulations on Patient Records</p> <p>Section 9, Personal Data Act</p>	<p>7. Defence Forces Health Records 8. Norwegian Register of Patient Records 9. National Database for Electronic Prescriptions 10. National Register of Cardiovascular Disease</p> <p>Moreover, section 6d on the setting up of the <i>Kjernejournal</i> provides that information may be registered and in any other way processed in this health data filing system without the consent of the data subject. However, the latter has the right to opt-out of the processing of his/her personal health data in the register, in which case only the information specified in the Regulations on the <i>Kjernejournal</i> may be registered (see especially section 4, Regulations on the <i>Kjernejournal</i>). This register is an inter-institutional personal health data filing system established for therapeutic purposes.</p> <p>The Personal Data Act defines ‘consent’ in the following way (section 2(7)): ‘any freely given, specific/explicit and informed declaration by the data subject to the effect that he or she agrees to the processing of personal data relating to him or her’.⁷³ The patient's consent or decision to opt-out with regards to the processing of personal data should be recorded in the patient's medical record (<i>pasientjournal</i>) in terms of the Regulations on Patient Records, section 8(j).</p> <p>Section 9, Personal Data Act contains the general rules on the processing of sensitive personal data; section 9(a) allows processing when the data subject consents to the processing, if the processing satisfies one of the conditions for the processing of personal data in section 8.</p>
<i>Is a materialised consent needed?</i>		No
<i>Are there requirements to inform the patient about the purpose of EHRs and the consequences of the consent or withholding consent to create</i>	Section 23-25, Personal Health Data Filing System Act	According to the Personal Health Data Filing System Act, when the personal health data is collected from the data subject directly (section 23), the data subject must be inter alia informed of: - the purpose of the processing of the personal health data;

⁷³ There is an identical definition of ‘consent’ in the Personal Health Data Filing System Act, section 2 no. 11.

<p><i>EHRs?</i></p>	<p>Sections 19, 20 and 23, Personal Data Act</p>	<p>- whether the giving of the personal health data is voluntary or not; - any other circumstance that will enable the data subject to exercise his rights pursuant to this Act in the best possible way. With regard to information to the patient of the consequences of giving or withholding, this is likely to be implicit in the requirement in section 23, para 1 (5), regarding the obligation to provide information when data is collected from the data subject, about ‘any other circumstance that will enable the data subject to exercise his rights pursuant to this Act in the best possible way ...’⁷⁴.</p> <p>When the data is collected from other sources than the data subject (section 24), the above-mentioned information as per section 23 must also be given to the data subject. However, the data subject is not entitled to notification if the collection or communication of data is expressly authorized by statute. The above echo the provisions in the Personal Data Act in sections 19 and 20.</p> <p>Section 25 of the Personal Health Data Filing System Act lays down a series of exceptions to the right to information and access. These, to a certain extent, echo and overlap section 23 of the Personal Data Act.</p>
<p><i>Are there specific national rules on consent from the patient to share data?</i></p>	<p>Personal Health Data Filing System Act, section 13</p>	<p>Section 13 of the Personal Health Data Filing System Act provides that only the data controller, the data processors and persons working under the instructions of the controller or the processor may be granted access to personal health data. Access may only be granted insofar as this is necessary for the work of the person concerned and in accordance with the rules that apply regarding the duty of confidentiality. For purposes of access to personal health data in personal health data filing systems established for therapeutic purposes the regulations may exempt from s.13, first paragraph, first sentence aforementioned. Access to personal health data in personal health data filing systems established for therapeutic purposes across institutions may only be</p>

⁷⁴ This is also the view of the Data Protection Authority.

	<p>Section 6d, Personal Health Data Filing System Act</p> <p>Personal Health Data Filing System Act, section 14</p>	<p>given following express consent from the data subject.</p> <p>Section 13, paragraph 5 states that a request for personal health data and access to personal health data from another enterprise may only include one patient at a time. The data subject shall have the right to view the log of the personal health data filing system established for therapeutic purposes that indicates who has had access to the personal health data regarding his/her person.</p> <p>There are also the Regulations on Health Information Security enacted pursuant to section 13, though these are not yet in force.</p> <p>Note that the draft bill for a new Personal Health Data Filing System suggests the removal of the difference between access internally within an organization and access given to other institutions. According to the proposed draft, it would be the data controller who would then determine to what extent access should be provided.⁷⁵</p> <p>Note also the requirements of section 6d (regarding the national core register or <i>kjernejournal</i>), Personal Health Data Filing System Act mentioned earlier.</p> <p>Although there is an obligation to provide the data subject, at the time of data collection, with information of, inter alia, whether the data will be disclosed and if so, the identity of the recipient (sections 23-24 Personal Health Data Filing System Act, echoing similar provisions in the Personal Data Act (sections 19-20), section 14 of the Personal Health Data Filing System Act permits the disclosure of personal health data. Section 14 provides that personal health data in personal health data filing systems established for therapeutic purposes may be disclosed or transferred for alignment with data relating to the same patient in another personal health data filing system established for therapeutic purposes, provided that this is authorized pursuant to section 12. Aligned personal health data may, after the name and personal identity number have been removed, be disclosed or transferred to an enterprise as decided by the</p>
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⁷⁵ See section 3 below. See Consultation Paper *Høring: Forslag til ny pasientjournallov og ny helseregisterlov* n 15, p. 69-70.

		Ministry, when the purpose is to de-identify or anonymize the data. Personal health data may, moreover, be disclosed or transferred when disclosure or transfer is authorized by or pursuant to statute, and the recipient of the data is authorized to process them pursuant to the Personal Data Act.
<i>Are there any opt-in/opt-out rules for patient consent with regard to processing of EHRs?</i>	<p>Section 8, Regulations on Patient Records; Health Personnel Act, in particular chapter 8 on the duty relating to documentation;</p> <p>Section 6d, Personal Health Data Filing System Act; Regulations on the <i>Kjernejournal</i></p>	<p>With regards to the patient record (<i>journal</i> or <i>pasientjournal</i>), the patient has a right to opt-out (<i>reservasjonsrett</i>) from the processing of information. Any consent or opt-out decision by the patient is entered in the patient record ‘provided it is relevant and necessary’. Note, however that the health care personnel is obliged by law to create and maintain such record. See answers to question 1 of this table above.</p> <p>With regards to the processing of information in the <i>Kjernejournal</i>, the patient has a right to opt-out of the processing of personal health data, in which case only the information specified in the Regulations on the <i>Kjernejournal</i> may be registered (see especially section 4, Regulations on the <i>Kjernejournal</i> – see above).</p>
<i>Are there any opt-in/opt-out rules for patient consent with regard to sharing of EHRs?</i>	<p>Section 6d, Personal Health Data Filing System Act;</p> <p>Regulations on the <i>Kjernejournal</i></p> <p>Section 25, Health Personnel Act</p>	<p>Section 6d, fifth paragraph provides that health care personnel with a need to know in the context of providing their professional services when providing health care can, with the consent of the data subject, be given access to necessary and relevant personal health data from the national <i>Kjernejournal</i>. This is, however, subject to the Regulations on the <i>Kjernejournal</i>, in particular section 8 on withdrawal by the data subject of consent given pursuant to section 6d aforementioned. Section 25, Health Personnel Act, specifies that:</p> <ul style="list-style-type: none"> - unless the patient objects thereto, confidential information may be given to co-operating medical personnel when this is necessary in order to provide responsible health care. - The duty of confidentiality pursuant to section 21 is furthermore not to prevent personnel who are providing assistance with electronic processing of such information, or who is providing servicing or maintenance of equipment, from gaining access to

	Section 45, Health Personnel Act	<p>such information, when such assistance is necessary in order to comply with statutory requirements for documentation.</p> <ul style="list-style-type: none"> - Unless the patient objects thereto, confidential information may be given to co-operating medical personnel when this is necessary to protect the needs of the patient's children. - Personnel as mentioned in the first, second and third paragraphs are subject to the same duty of confidentiality as health personnel. <p>Section 45, Health Personnel Act inter alia provides that unless the patient objects thereto, health personnel as mentioned in section 39 may give the patient record or information therein to others who provide health care pursuant to this Act when this is necessary in order to provide health care in a responsible manner. With regards to electronic access to health data across institutions, section 13 third and fourth paragraphs shall apply. It shall be evident from the patient record that other health personnel have been given access to the patient records pursuant to the first sentence.</p> <p>Note especially the requirement in sections 25 and 45 'to provide health care in a responsible manner'.</p>
<i>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?</i>	Section 23, first paragraph, point 5, Personal Health Data Filing System Act	<p>In the case of information about the purpose of electronic health registers, see above.</p> <p>With regards whether there are any requirements to inform the patient of the consequences of giving or withholding consent on the sharing of data, this is likely to be implicit in the requirement in section 23, para 1 (5), regarding the obligation to provide information when data is collected from the data subject, about 'any other circumstance that will enable the data subject to exercise his rights pursuant to this Act in the best possible way ...'.⁷⁶</p> <p>See also above.</p>

⁷⁶ This is also the view of the Data Protection Authority.

<p><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></p>	<p>Sections 4 and 13, Personal Health Data Filing System Act;</p> <p>Personal Data Act, chapter V;</p> <p>Health Personnel Act, sections 21 and 21a</p>	<p>Not regarding access; but transfer yes. The Personal Health Data Filing System Act is a national initiative – see also section 4, Personal Health Data Filing System Act, on the law’s geographic application. So is the Health Personnel Act.</p> <p>With regards to <i>direct access</i>, note also the limitations in section 13, first paragraph of the Personal Health Data Filing System Act re who may have direct access to the data (see above), as well as the responsibilities of the data controller in terms of section 16.⁷⁷</p> <p>With regards to <i>transfer of data</i>, this is possible provided all the basic rules on the transfer of personal data to other countries in Chapter V of the Personal Data Act are fulfilled.</p> <p>Note also the general rule of confidentiality (section 21) owed by health personnel relating to information relating to people’s health or medical condition or other personal information that they get to know in their capacity of health personnel.</p> <p>Section 21a prohibits the unlawful acquisition of confidential information; there is a general prohibition of access to such information unless this is justified in the provision of ‘health care’ as defined in the Act to the patient, the administration of such help or is otherwise justified in the law or regulations. There is a similar prohibition in section 13a of the Personal Health Data Filing System Act.</p> <p>See also section 3 on ‘<i>Limitations on the sharing of health data between health personnel</i>’ below.</p>

⁷⁷ The view of the interviewees from the Norwegian Medical Association is that the patient may consent that data be disclosed/transferred, provided that the requirements of the pertinent Norwegian laws are fulfilled; however, the Norwegian Medical Association holds that the patient’s consent that direct access be provided is rather futile in view of the strict requirements, limitations and duties on the data controller in sections 13 and 16 of the Personal Health Data Filing System Act.

<p><i>Are there specific rules on patient consent to share data on a cross-border situation?</i></p>	<p>Personal Data Act, chapter V</p>	<p>In the case of transfer of personal data, there are the general rules in the Personal Data Act, chapter V. In effect, section 29, first paragraph of the Personal Data Act provides that '[p]ersonal data may only be transferred to countries which ensure an adequate level of protection of the data. Countries which have implemented Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data meet the requirement as regards an adequate level of protection.'</p>
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2.4. Creation, access to and update of EHRs

2.4.1. Main findings

In Norway, according to section 39 of the Health Personnel Act, there is actually a duty on health care providers to enter or record information – whether electronically or manually - as mentioned in section 40 in a patient medical record (*journal* or *pasientjournal*). The term ‘electronic patient medical record’ (*elektronisk pasientjournal*) is not explicitly defined in the law.⁷⁸ Section 6, first paragraph, first sentence, of the Personal Health Data Filing System Act states that personal health data filing systems established for therapeutic purposes *may* be kept by automatic means. Moreover, section 6, fourth paragraph, provides a legal basis for regulations to be established requiring that data in personal health data filing systems established for therapeutic purposes *shall* be processed electronically. In fact, in June 2013, a Consultation Paper proposing draft regulations on ICT-standards in the health and care sector (*Høringsnotat - Forslag til forskrift om IKT-standarder i helse- og omsorgssektoren*) was published. These draft regulations are proposing that all personal health data filing systems used for therapeutic purposes (*behandlingsrettede helseregistre*) shall be kept electronically.⁷⁹ However, these draft regulations are still pending.

Regional, local and central health registers may only be established pursuant to the Personal Health Data Filing System Act or other specific law. See further on this the discussion in section 2.2.1 above. Section 6 regulates health data filing systems created for therapeutic purposes.

According to the Health Personnel Act, there is a duty to provide the patient access to his/her medical records. The Act also provides for the circumstances where there may be correction of patient records or deletion of information in patient records (sections 42-44). Other than this, in the case of medical records pursuant to the Regulations on Patient Record (section 13), once a journal entry has been signed, it can only be changed according to the rules on correction or deletion in terms of sections 42, 43 and 44 of the Health Personnel Act.

In the case of personal health data filing systems, the data controller has a duty to ensure the quality of personal health data (section 17 (Internal control), Personal Health Data Filing System Act).

There is a general rule of confidentiality (section 21, Health Personnel Act) owed by health personnel with regards to information relating to people’s health or medical condition or other personal information that they get to know in their capacity as health personnel. However, there are certain exceptional circumstances where access to the data may be given to different health professionals (see Health Personnel Act). In the case of information in the *Kjernejournal*, the requirement for consent does not apply in emergency situations where there is serious danger for the patient’s life, when there is no time to obtain the patient’s consent or where the patient, because of his/her physical or psychological state, is not in a position to consent. Moreover, when it is necessary to provide justifiable health care to the patient, his/her family doctor (*fastlege*), health care personnel who are responsible to provide medication in a hospital and in a community nursing centre, doctor or nurse in a specialist health service (*spesialisthelsetjenesten*) and those in the chain of emergency medicine may be given access to health information in the national *Kjernejournal* without the consent of the patient in terms of section 6d of the Personal Health Data Filing System Act.

Documentation in a patient’s medical records is to be processed in accordance with the rules of the

⁷⁸ See the *travaux préparatoires* to the Personal Health Data Filing System Act (Ot.prp. nr. 5 (1999-2000), paragraph 7.2.4.3.

⁷⁹ See proposed regulations, section 3, first paragraph, <<http://www.regjeringen.no/nb/dep/hod/dok/hoeringer/hoeringsdok/2013/horing-av-forslag-til-forskrift-om-ikt-.html?id=731556>>.

Personal Data Act (section 10, Regulations on Patient Records).

Online access (direct access) by a patient to some of his/her patient information is possible via the national internet portal ('Min Helse' on helsenorge.no) by means of a secure electronic ID. At present, only some limited information from the various electronic health registers is accessible online. The patient may not update his/her medical record, modify and erase the online content. Non-electronic or indirect access is also possible for the patient. Indeed, it is the patient's right (section 5-1, first paragraph, Patients' Rights Act) to have access to his or her medical records with enclosures and upon special request to be entitled to a copy.

The patient also has a right to access the logs of health data filing systems established for therapeutic purposes as to who has had access to health information on him or her (Personal Health Data Filing Systems Act, section 13).

According to section 22 of the Health Personnel Act, the duty of confidentiality according to section 21 does not prevent information from being made known to the person that the information directly relates to, or to others, to the extent to which the person who is entitled to confidentiality gives his consent thereto. Nevertheless, an insurance company cannot get access or knowledge of data in those cases where the person that the information directly relates to, can be denied access according to section 5-1, second paragraph, of the Patient's Rights Act.

In the case of the national *Kjernejournal*, it is forbidden to disclose information on the data subject to the employer, insurance company or the public prosecutor even if the data subject consents.

Those who are given electronic access to health information in the national *Kjernejournal* shall be authenticated at a high security level.

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

Questions	Legal reference	Detailed description
<p><i>Are there any specific national rules regarding who can create and where can EHRs be created?</i></p>	<p>Health Personnel Act, in particular chapter 8 on the duty relating to documentation; section 3</p> <p>Personal Health Data Filing System Act, in particular sections 6-8</p>	<p>In Norway, according to section 39 of the Health Personnel Act, there is actually a duty on health care providers to enter or record information as mentioned in section 40 in a patient medical record (<i>journal</i> or <i>pasientjournal</i>).</p> <p>Note that the term ‘health care’ (helsehjelp) in the Health Personnel Act is defined in section 2 as “shall mean any act that has a preventive, diagnostic, therapeutic, health-preserving or rehabilitative objective and that is performed by health personnel”.</p> <p>Note that section 3 of the Health Personnel Act defines health professionals (i.e. health care personnel or health care provider) as:</p> <ul style="list-style-type: none"> - Personnel with an authorisation pursuant to section 48 or a licence pursuant to section 49, - Personnel in the health care services or in pharmacies who provide health care as mentioned in the third paragraph, - Pupils and students who in training as health personnel provide health care as mentioned in the third paragraph. <p>Regional, local and central health registers may only be established pursuant to the Personal Health Data Filing System Act or other specific law. See, further on this, the discussion in section 2.2.1 above. See section 6 re health data filing systems created for therapeutic purposes (see above).</p>
<p><i>Are there specific national rules on access and update to EHRs?</i></p>	<p>Health Personnel Act, chapter 8</p> <p>Personal Health Data Filing System Act, in particular sections 13, 13a, 16, 19, as well as chapter 4 (sections 20-25)</p>	<p>See especially: section 41 which lays down a duty to provide patient access to records; section 42 on the correction of patient records; section 43 on deletion of information in patient records</p> <p>Section 13 deals with access to personal health data in the data controller’s and the data processor’s institution; section 13a prohibits unlawful access to personal health data. Section 16 lays down a duty to ensure confidentiality, integrity, quality and accessibility of the</p>

	and chapter 5 of the Act (sections 26-28).	data. Section 19 lays down a time limit for replying to inquiries regarding access. Chapter 4 of the Act deals with the data controller's duty to provide information and the data subject's right to access. Chapter 5 contains special rules regarding rectification and erasure of personal health data. (More on sections 13 and 16 in Table 2.2.2 above.)
<i>Are there different categories of access for different health professionals?</i>	Health Personnel Act, in particular: sections 21, 21a, 25, 26, 27, 28, 29, 29b, 29c and section 45; Section 21a; Personal Health Data Filing System Act, section 13a Health Personnel Act, section 45 Personal Health Data Filing System Act, section 13, last paragraph	There is a general rule of confidentiality (section 21) owed by health personnel relating to information relating to people's health or medical condition or other personal information that they get to know in their capacity of health personnel. Section 21a prohibits the unlawful acquisition of confidential information; there is a general prohibition of access to such information unless this is justified in the provision of 'health care' as defined in the Act to the patient, the administration of such help or is otherwise justified in the law or regulations. There is a similar prohibition in section 13a of the Personal Health Data Filing System Act. According to section 45, first paragraph, of the Health Personnel Act: 'Unless the patient objects thereto, health personnel as mentioned in section 39 may give the patient record or information therein to others who provide health care pursuant to the Act when this is necessary in order to provide health care in a responsible manner. With regard to electronic access to health data across institutions, section 13, third and fourth paragraphs, of the Personal Health Data Filing System Act applies. It shall be evident from the patient medical record that other health personnel have been given access to the patient records.' (For more detail on section 45, see Table 2.3.2 above). According to section 13, last paragraph of the Personal Health Data Filing System Act, the patient 'shall have the right to view the log of the personal health data filing system established for therapeutic purposes that indicates who has had access to the personal health data

		contains provisions on access control. This Code of Conduct, and its legal (contractual) basis, is discussed below in section 2.7.1 and Table 2.7.2.
<i>Are patients entitled to access their EHRs?</i>	<p>Patients' Rights Act, section 5-1;</p> <p>Health Personnel Act, section 41</p> <p>Personal Health Data Filing System Act, section 22</p>	<p>The patient can access information via the national internet portal ('Min helse'⁸¹ on helsenorge.no) by means of a secure electronic ID. (See types of acceptable secure electronic IDs on helsenorge.no).</p> <p>Indirect access (i.e. not directly by the patient but via health personnel) is also possible. Section 5-1, first paragraph, of the Patients' Rights Act, provides that the patient is entitled to have access to his or her medical records with enclosures and upon special request. Upon request, the patient is entitled to a brief and simple explanation of medical terms, etc.</p> <p>See also the patients' right of access in the Health Personnel Act, especially: section 41 which lays down a duty on the health care provider to provide access to the patient records to anyone entitled thereto pursuant to the provisions of the Patients Rights Act section 5-1. In health institutions the person with superior responsibility for patient records pursuant to section 39 shall make sure that access is provided pursuant to the first paragraph.</p> <p>Section 22: 'Any person who so requests has a right of access to personal health data filing systems established for therapeutic purposes insofar as this is authorized by section 5-1 of the Patients' Rights Act and section 41 of the Health Personnel Act.</p> <p>When personal health data are processed pursuant to sections 5, 6a, 6c, 6d, 7 and 8, the Data Subject has the right, upon inquiry, in addition to the information specified in section 21, first paragraph, to be informed of:</p> <ol style="list-style-type: none"> 1. the personal health data concerning the Data Subject that are being processed, and

⁸¹ This stands for 'my health'.

		<p>2. the security measures implemented in connection with the processing of personal health data insofar as this knowledge does not prejudice security.</p> <p>The data subject may also demand that the data controller elaborates on the information in section 21, first paragraph, to the extent that this is necessary to enable the data subject to protect his or her own interests.</p> <p>Information pursuant to the first and second paragraphs may be demanded in writing from the controller or from his processor as mentioned in section 18. The person who is requested to grant access may demand that the data subject submit a written, signed request.</p> <p>Regulations may provide further provisions on the right to access to the processing of personal health data pursuant to the second and third paragraphs. Where special grounds make it necessary, the King may issue regulations specifying that the data subject must pay a charge to the data controller. The charge cannot exceed the actual costs to comply with the demand.'</p>
<p><i>Can patient have access to all of EHR content?</i></p>	<p>See above;</p> <p>Note especially Patients' Rights Act, section 5-1, second paragraph</p>	<p>No, not electronically. With regards to indirect access (i.e. not directly/online by the patient), see above.</p> <p>There are only few exceptions to the right of indirect access to one's own patient medical record. Thus, section 5-1, second paragraph, of the Patients' Rights Act provides that the patient may be denied access to information in his or her medical records if this is absolutely necessary in order to avoid endangering the patient's life or serious damage to the patient's health, or if access is clearly inadvisable out of consideration for persons close to the patient.</p> <p>However, with regards to direct access by the patient to his or her own electronic health records, currently only some (limited) information in the various electronic health records or personal health data filing systems is accessible online. A patient may access:</p> <ul style="list-style-type: none"> - his/her own ePrescriptions; - the ePrescriptions of the patient's children who are under the age of

		<p>16 and who live at the same registered address as the patient, provided that children between the age of 12 and 16 may ask their doctor to mark their ePrescriptions such that their parents or guardians will not be able to find out that such ePrescriptions exist;⁸²</p> <ul style="list-style-type: none"> - his/her own vaccination record; - the ePrescriptions for those who have given the patient authorization (for a limited time, given in writing by filling in a specific form) to access such information; - the vaccination record of his/her children who are under the age of 16 years and who live at the same registered address as the patient; - in those municipalities where there is already such access, access to the patient's <i>Kjernejournal</i>. One of the aims of the <i>Kjernejournal</i> project, which is currently still in the pilot stage, is that it will be eventually extended to cover all of Norway.
<i>Can patient download all or some of EHR content?</i>		<p>No. However, the vaccination details (see above) may be printed by the patient.</p> <p>One of the aims of the <i>Kjernejournal</i> project, which is still in the pilot stage, is that eventually the patient may be able to download a pdf-file of his or her <i>Kjernejournal</i>. This is not yet possible.⁸³</p>
<i>Can patient update their record, modify and erase EHR content?</i>		<p>No, not directly. Note, however, that section 5-2 of the Patients' Rights Act provides that the patient or the person to whom the information concerns, may demand that the information in the medical records be corrected or erased pursuant to the provisions of sections 42 to 44 of the Health Personnel Act.</p>
<i>Do different types of health professionals have the same rights to update EHRs?</i>	Health Personnel Act, sections 39, 42-44	<p>No</p> <p>See section 39, first and second paragraphs (see Table 2.2.2).</p> <p>Section 42 lays down a duty on the health care provider as specified</p>

⁸² See, in Norwegian, < <https://helsenorge.no/Selvbetjening/Sider/om-e-resept/Reseptane-til-barnet-ditt.aspx> >.

⁸³ See discussions with interviewees from the Directorate of Health.

	<p>Regulations on Patient Record, section 13</p> <p>Personal Health Data Filing System Act, section 17.</p>	<p>in section 39 (see above) to correct patient records. Section 43 deals with when information in patient records may be deleted by health personnel. Section 44 regulates the situation where information is recorded on the wrong person.</p> <p>With regards to medical records pursuant to the Regulations on Patient Record (section 13), once a journal entry has been signed, it can only be changed according to the rules on correction or deletion in terms of sections 42, 43 and 44 of the Health Personnel Act.</p> <p>According to section 17 (Internal control), Personal Health Data Filing System Act, the data controller has a <u>duty</u> to ensure the quality of personal health data.</p> <p>One of the aims of the <i>Kjernejournal</i> project is that the patient's family doctor and the medical care personnel who treats the patient, should be able to update (i.e. not change – see above) their patient's <i>Kjernejournal</i>.⁸⁴</p>
<p><i>Are there explicit occupational prohibitions? (e.g. insurance companies/occupational physicians...)</i></p>	<p>Health Personnel Act, section 22</p>	<p>According to section 22 of the Health Personnel Act, the duty of confidentiality according to section 21 does not prevent information from being made known to the person that the information directly relates to, or to others, to the extent to which the person who is entitled to confidentiality gives his consent thereto. Nevertheless, an insurance company cannot get access or knowledge of data in those cases where the person that the information directly relates to, can be denied access according to section 5-1, second paragraph, of the Patient's Rights Act.</p> <p>(Section 5-1, second paragraph, of the Patients' Rights Act provides that the patient may be denied access to information in his or her medical records if this is absolutely necessary in order to avoid endangering the patient's life or serious damage to the patient's health, or if access is clearly inadvisable out of consideration for</p>

⁸⁴ See discussions with interviewees from the Directorate of Health.

	Regulations on the <i>Kjernejournal</i> , section 11	persons close to the patient.) In the case of the national <i>Kjernejournal</i> , it is forbidden to disclose information on the data subject to the employer, insurance company or the public prosecutor even if the data subject consents.
<i>Are there exceptions to the access requirements (e.g. in case of emergency)?</i>	Regulations on the <i>Kjernejournal</i> , section 7 Personal Health Data Filing System Act, section 6d	With regards to information in the <i>Kjernejournal</i> , the requirement for consent does not apply in emergency situations where there is serious danger for the patient's life, when there is no time to obtain the patient's consent or where the patient, because of his/her physical or psychological state, is not in a position to consent. A record shall be entered in the <i>kjernejournal</i> why consent was not obtained. When it is necessary to provide justifiable health care to the patient, his family doctor (<i>fastlege</i>), health care personnel who are responsible to provide medication in a hospital and in a community nursing centre, doctor or nurse in a specialist health service (<i>spesialisthelsetjenesten</i>) and those in the chain of emergency medicine may be given access to health information in the national <i>Kjernejournal</i> without the consent of the patient in terms of section 6d of the Personal Health Data Filing System Act.
<i>Are there any specific rules on identification and authentication for health professionals? Or are they aggregated?</i>	Regulations on the <i>Kjernejournal</i> , section 9 Health Personnel Act, sections 25 and 45; Personal Health Data Filing System Act, sections 13 and 16	See section 9 on access control. Note in particular the second paragraph of section 9 which states that those who are given electronic access to health information in the national <i>kjernejournal</i> shall be authenticated at a high security level. See also the rules on confidentiality in sections 25 and 45 of the Health Personnel Act and sections 13 and 16 of the Personal Health Data Filing System Act (above). NOTE: The "Code of Conduct for information security in the healthcare, care, and social services sector" (Code of Conduct) ⁸⁵ also

⁸⁵ See n 80.

		contains provisions on access control. This Code of Conduct, and its legal (contractual) basis, is discussed below in section 2.7.1 and Table 2.7.2.
<i>Does the patient have the right to know who has accessed to his/her EHRs?</i>	Personal Health Data Filing System Act, section 13, sixth paragraph	The patient has a right to access the logs of health data filing systems established for therapeutic purposes as to who has had access to health information on him or her.
<i>Is there an obligation on health professionals to update EHRs?</i>	Personal Health Data Filing System Act, sections 16 and 17 Health Personnel Act, sections 42-44 Patient Record Regulations (section 13)	Section 16 lays down a duty on the data controller and data processor to ensure satisfactory data security with regard to confidentiality, integrity, quality and accessibility of the data. Section 17 lays down provisions on internal control. (See above). Section 42 lays down a duty on the health care provider as specified in section 39 (see above) to correct patient records. Section 43 deals with when information in patient records may be deleted by health personnel. Section 44 regulates the situation where information is recorded on the wrong person. With regards to medical records pursuant to the Patient Record Regulations (section 13), once a journal entry has been signed, it can only be changed according to the rules on correction or deletion in terms of sections 42, 43 and 44 of the Health Personnel Act.
<i>Are there any provisions for accessing data on 'behalf of' and for request for second opinion?</i>	Patients' Rights Act, sections 5-1, 3-3, 3-4; section 2-3	Section 5-1 deals with access rights to medical records. In particular, section 5-1, third paragraph, deals with the case that a representative of the patient has the right of access to information when this has been denied to the patient. In addition, the provisions of section 3-3 and 3-4 apply with regard to another person's right of access to information. More particularly, section 3-3 regulates when information may be given to the patient's next of kin; section 3-4 regulates access to information when the patient is a minor. Section 2-3: Right to re-evaluation: Upon referral from a general practitioner, the patient is entitled to have his or her health

	Health Personnel Act, sections 25 and 45	<p>condition re-evaluated by the specialist health service. This right applies only once for the same condition.</p> <p>With regards to health care personnel providing other health care personnel with access to patient data, the rules in sections 25 and 45 of the Health Personnel Act apply (see above).</p>
<i>Is there in place an identification code system for cross-border healthcare purpose?</i>		<p>No. Norway does, however, participate in the European Health Insurance Card system. See http://www.helfo.no/privatperson/europeisk-helsetrygdkort/Sider/default.en-GB.aspx.</p> <p>None of the interviewees from the Data Protection Authority, Directorate of Health or the Medical Association is aware of any specific ID code.</p> <p>As mentioned earlier (Table 2.1.2), in Norway, where the patient or data subject is identified, there is no other specific ID number used except for the personal identity number (<i>fødselsnummer</i>). (See the answer to the previous question.)</p>
<i>Are there any measures that consider access to EHRs from health professionals in another Member State?</i>		<p>No such specific measures are known. None of the interviewees from the Data Protection Authority, Directorate of Health or the Medical Association are aware of any such measures.</p>

2.5. Liability

2.5.1. Main findings

Health care personnel are liable for breach of:

- their duty, as per section 4, first paragraph, of the Health Personnel Act, to conduct their work in accordance with the requirements to professional responsibility and diligent care that can be expected based on their qualifications, the nature of their work and the situation in general.
- their duty of confidentiality in section 21 Health Personnel Act: 'Health care personnel shall prevent that others get access or knowledge to information on people's bodily or health condition or other personal circumstances that they get knowledge of in their capacity as health care personnel.'

The general rules of Norwegian law of torts would apply. However, there could also be serious consequences for the health care personnel in terms of the Health Personnel Act (chapter 11).

Breach of the duty of confidentiality will also become punishable in accordance with section 209 of the 2005 Criminal Code, once this Act enters into effect.

According to section 144 of the 1902 Criminal Code, inter alia, doctors, psychologists, chemists (*apotekere*), midwives and nurses as well as their attending staff or helpers, who unlawfully reveal secrets which have been confided to them or to their superiors by virtue of their office, are punishable with a fine or up to 6 months' imprisonment.

Moreover, according to section 35, first paragraph, of the Personal Health Data Filing System Act, the data controller shall compensate damage suffered as a result of the fact that personal health data have been processed contrary to provisions laid down in or pursuant to this Act, unless it is established that the damage is not due to error or neglect on the part of the controller. The same principle applies pursuant to section 49 of the Personal Data Act.

The Norwegian System of Patient Injury Compensation (*Norsk Pasientskadeerstatning*) is a public agency under the Norwegian Ministry of Health and Care Services. *Norsk Pasientskadeerstatning* handles compensation claims free of charge for patients who have sustained an injury while in the care of the health service.⁸⁶ It is set up under the Patient Injury Act and contribution thereto is required of both public and private health and care services.

According to section 2 of the Patient Injury Act, patients and others who have suffered loss due to patient injury have a right to compensation when the injury is inter alia due to:

- (a) Failure in the provision of health care, even if no one is to blame;
- (b) Technical failure of apparatus, instrument or other equipment which is used in the provision of health care; ...
- (e) Circumstances which lead to liability for the health and care service or health care personnel according to general rules on liability.

Though there is no specific obligation on health professionals to access EHRs prior to take a decision involving the patient, the general rule in section 4, first paragraph, of the Health Personnel Act states that health personnel shall conduct their work in accordance with the requirements for professional responsibility and diligent care that can be expected based on their qualifications, the nature of their work and the situation in general. According to the interviewees from the Health Directorate, this is likely to imply that, where the patient's *Kjernejournal* is available, the doctor should consult it.

⁸⁶ See < <http://www.regjeringen.no/en/dep/hod/About-the-Ministry/Subordinate-institutions/the-norwegian-system-of-compensation-to-.html?id=279763> >.

The Personal Data Act, the Personal Health Data Filing System Act and the Health Research Act respectively contain rules on liability (by the data controller in the case of the Personal Data Act and the Personal Health Data Filing System Act, or by the person or body responsible for medical and health research in terms of the Health Research Act) for damage suffered as a result of the fact that personal health data was processed contrary to provisions laid down in the respective law.

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>		Yes. See below.
<i>Can patients be held liable for erasing key medical information in EHRs?</i>		Not applicable. See Table 2.4.2.
<i>Can physicians be held liable because of input errors?</i>	Health Personnel Act, sections 4 and 21; 2005 Criminal Code, section 209; 1902 Criminal Code, section 121	This could be seen as a breach of: <ul style="list-style-type: none"> - the duty of health personnel, as per section 4, first paragraph, of the Health Personnel Act, to conduct their work in accordance with the requirements for professional responsibility and diligent care that can be expected based on their qualifications, the nature of their work and the situation in general. - The duty of confidentiality in section 21 Health Personnel Act: 'Health care personnel shall prevent that others get access or knowledge to information on people's bodily or health condition or other personal circumstances that they get knowledge of in their capacity as health care personnel.' <p>The general rules of Norwegian law of torts would apply.</p> <p>Breach of the duty of confidentiality will also become punishable in accordance with section 209 of the 2005 Criminal Code, once this provision in the 2005 Criminal Code is brought into force. The punishment will be a fine or imprisonment for up to one year. Note that this section, like most of the 2005 Criminal Code, has not yet come into effect. Breach of such provision may also give rise to liability for compensation.</p> <p>According to section 121, first paragraph, of the 1902 Criminal Code, whoever wilfully (<i>forsettlig</i>) or with gross negligence (<i>grovt uaktsomt</i>)</p>

	<p>1902 Criminal Code, section 144</p> <p>Personal Health Data Filing System Act, section 35</p>	<p>breaches a duty of confidentiality which, in terms of a provision of the law or a valid order given in his or her line of service or work for a state or municipal organ, is punishable with a fine or imprisonment of up to 6 months.</p> <p>According to section 144 of the 1902 Criminal Code, inter alia, doctors, psychologists, chemists (<i>apotekere</i>), midwives and nurses as well as their attending staff or helpers, who unlawfully reveal secrets which have been confided to them or to their superiors by virtue of their office, are punishable with a fine or up to 6 months' imprisonment.</p> <p><u>Note:</u> The provisions in the 1902 Criminal Code will eventually no longer apply once the 2005 Criminal Code fully comes into effect.</p> <p>Note also the consequences for the health care personnel in terms of the Health Personnel Act. Chapter 11 deals with the consequences for the breach of the Act which include: warning; revocation of authorisation or license or specialist authorisation; limitation of authorisation; order of examination by experts, etc.</p> <p>Moreover, according to section 35, first paragraph, of the Personal Health Data Filing System Act, the data controller shall compensate damage suffered as a result of the fact that personal health data have been processed contrary to provisions laid down in or pursuant to this Act, unless it is established that the damage is not due to error or neglect on the part of the controller.</p>
<i>Can physicians be held liable because they have erased data from the EHRs?</i>		Yes. See answer to the above question.
<i>Are hosting institutions liable in case of defect of their security/software systems?</i>	Patient Injury Act, section 2	<p>Section 2, Patient Injury Act, inter alia provides that patients and others who have suffered loss due to patient injury have a right to compensation when the injury is due to:</p> <ul style="list-style-type: none"> (a) Failure in the provision of health care, even if no one is to blame; (b) Technical failure of apparatus, instrument or other equipment which is used in the provision of health care;...

		(e) Circumstances which lead to liability for the health and care service or health care personnel according to general rules on liability.
<i>Are there measures in place to limit the liability risks for health professionals (e.g. guidelines, awareness-raising)?</i>	<p>Personal Health Data Filing System Act, section 35</p> <p>Patient Injury Act</p>	<p>In the case of breach of the Personal Health Data Filing System Act, according to section 35, second paragraph thereof, the compensation shall be equivalent to the financial loss incurred by the injured party as a result of the unlawful processing of the personal health data. The controller may also be ordered to pay such compensation for damage of a non-economic nature (compensation for non-pecuniary damage) as seems reasonable.</p> <p>The Norwegian System of Patient Injury Compensation (<i>Norsk Pasientskadeerstatning</i>) is a public agency under the Norwegian Ministry of Health and Care Services. <i>Norsk Pasientskadeerstatning</i> handles compensation claims free of charge for patients who have sustained an injury while in the care of the health service.⁸⁷ It is set up under the Patient Injury Act.</p> <p>The state, regional health enterprises, counties and municipalities shall, according to section 7, Patient Injury, Act, pay a contribution to <i>Norsk Pasientskadeerstatning</i> to cover compensation for patient injuries suffered in the public health and care services, as well as for its administration, in accordance with the Regulations issued under the Act (viz. Regulations of 31 October 2008 No. 1166).</p> <p>Those who provide health care outside the public health and care services shall, according to section 8, Patient Injury Act, notify and pay a contribution to <i>Norsk Pasientskadeerstatning</i> to cover compensation for patient injury caused outside the public health and care services as well as for its administration. This is also further regulated in the Regulations of 31 October 2008 No. 1166.</p>
<i>Are there liability rules related to</i>	Personal Data Act,	Section 49, first and third paragraphs provide that:

⁸⁷ Ibid.

	<p>Personal Data Act, sections 47 and 48</p> <p>Personal Health Data Filing System Act, section 35</p> <p>Health Research Act, chapter 10</p>	<p>the data offence fine order. If a data offence fine order is tested in court, all aspects of the case may be tried.</p> <p>The Data Protection Authority may order that processing of personal data in violation of the provisions in, or in pursuance of, this Act shall cease, or impose conditions which must be met in order that the processing comes into compliance with the Act.'</p> <p>Note that the fine as per section 46, first paragraph, can be rather substantial. It can be up to a maximum of ten times the National Insurance Basic Amount. The National Insurance Basic Amount (<i>grunnbeløpet</i>) as per 1. May 2013 is kr. 85245 (Norwegian <i>kroner</i>).⁸⁸</p> <p>Coercive fines may be issued in terms of section 47 (<i>tvangsmulkt</i>) if such orders have not been complied with in the time limit set for compliance. Penalties (fines or imprisonment) are payable according to section 48.</p> <p>Section 35, Personal Health Data Filing System Act, deals with compensation – se below.</p> <p>See also below Health Research Act, chapter 10 provisions relating to data protection.</p>
<p><i>Is there an obligation on health professionals to access EHRs prior to take a decision involving the patient?</i></p>	<p>Health Personnel Act, section 4</p>	<p>Not specific but general obligation. Note, however, the general rule in section 4, first paragraph, of the Health Personnel Act which states that health personnel shall conduct their work in accordance with the requirements for professional responsibility and diligent care that can be expected based on their qualifications, the nature of their work and the situation in general. In practice, this implies that health care personnel treating a patient ought to look up any relevant data in all the patient's medical records which are available to that health care personnel.</p>

⁸⁸ See <See [https://www.nav.no/Om+NAV/Satsar+og+utbetalingsdatoar/Grunnbel%C3%B8pet+\(G\)>](https://www.nav.no/Om+NAV/Satsar+og+utbetalingsdatoar/Grunnbel%C3%B8pet+(G)>).

		<p>Moreover, according to the interviewees from the Health Directorate, this is likely to imply that, where the patient's <i>Kjernejournal</i> is available, the doctor should consult it.</p>
<p><i>Are there liability rules related to the misuse of secondary use of health data?</i></p>	<p>Health Research Act, section, chapter 10 (sections 50-54)</p>	<p>Section 50 provides as follows:</p> <p>The rules in the Patient Injury Act apply accordingly to injuries that arise under medical trials.</p> <p>The person or body responsible for the research must compensate injuries that arise as a result of human biological material or personal health data being processed in a manner that contravenes provisions in or pursuant to this Act, unless it can be proven that the injury was not due to errors or negligence on the part of the person or body responsible for the research.</p> <p>The compensation must correspond to the financial loss that the injured person has incurred as a result of the unlawful processing of their human biological material or personal health data. The person in charge of data processing may also be ordered to pay reasonable compensation for injuries of a non-financial nature (compensation for non-pecuniary loss).</p> <p>Private persons or bodies responsible for the research must provide security through insurance for the financial liability that may arise pursuant to the second and third paragraphs above.</p> <p>The Norwegian Board of Health Supervision (<i>Helsetilsynet</i>) has the right to issue orders requiring rectification or discontinuation of medical health research in terms of section 51 of the Health Research Act. The Data Protection Authority also has a right to issue orders for rectification or discontinuation of health research according to the provisions of section 52. Both the Norwegian Board of Health Supervision and the Data Protection Authority have the right to issue coercive fines if the time limit given for rectification has not been complied with, in terms of section 53 of the Act. Section 54 provides that anyone who willfully or through gross negligence violates or is complicit in violation of provisions laid down in the Health Research Act or provisions laid down pursuant to this Act shall be liable to fines or imprisonment not</p>

	<p>Personal Health Data Filing System Act, section 35</p> <p>Personal Health Data Filing System Act, sections 32-34</p>	<p>exceeding one year or both. If there are particularly aggravating circumstances, a sentence of imprisonment of up to three years may be imposed.</p> <p>Section 35, Personal Health Data Filing System Act, deals with compensation: The data controller shall compensate damage suffered as a result of the fact that personal health data have been processed contrary to provisions laid down in or pursuant to this Act, unless it is established that the damage is not due to error or neglect on the part of the controller. The compensation shall be equivalent to the financial loss incurred by the injured party as a result of the unlawful processing of the personal health data. The controller may also be ordered to pay such compensation for damage of a non-economic nature (compensation for non-pecuniary damage) as seems reasonable.</p> <p>According to section 32, Personal Health Data Filing System Act, the Data Protection Authority may issue orders for cessation or rectification of processing in contravention of the Act. Coercive fines may be issued (section 33) and also imprisonment in cases falling within section 34.</p>
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2.6. Secondary uses and archiving durations

2.6.1. Main findings

Norway has specific and detailed rules on the archiving of patient medical records (primary use) as well as personal health data stored for secondary use. The rules specify the length of time that records may be kept as well as the extent to which there is an obligation to transfer or destroy the data, in case of cessation of operation of the particular institution holding the data.

The Health Research Act *inter alia* lays down requirements for the organization and execution of medical and health research (chapter 2), and also requires application for prior approval and a duty to notify the regional committee for medical and health research ethics (chapter 3).

Section 8a on the health archives register (*helsearkivregisteret*) is a new section that was introduced in the Personal Health Data Filing System Act on and with effect from 22 June 2012. On that same date, the Archives Act was also amended to include the Norwegian Health Archives (*Norsk helsearkiv*) as part of The National Archives of Norway. The health archives register is a central personal health data filing system with identifiable personal documentation which will be handed over to the Norwegian Health Archives. There is currently a proposal for draft Regulations on the Norwegian Health Archives and the health archive register (*helsearkivforskriften*) which is open for consultation until 1 April 2014. It should be noted that, according to the aforementioned draft Regulations,⁸⁹ the Norwegian Health Archives will only comprise material from the specialist health services (*spesialisthelsetjenester*) in terms of the Specialist Health Services Act.

⁸⁹ See Consultation Document, in Norwegian, *Høringsnotat Forslag til forskrift om Norsk helsearkiv og Helsearkivregisteret (helsearkivforskriften)*, n 52, p. 15.

2.6.2. Table on secondary uses and archiving durations

Questions	Legal reference	Detailed description
<p><i>Are there specific national rules on the archiving durations of EHRs?</i></p>	<p>Regulations on Patient Records, section 14</p> <p>Personal Data Act, section 28</p> <p>Regulations on the <i>Kjernejournal</i>, section 10</p> <p>Personal Health Data Filing System Act, section</p>	<p>Section 14, second paragraph, provides that the patient medical records shall be kept until, according to the nature of the health care provided, there is no longer considered to be need for their use. Unless the patient medical record is to be kept in accordance with the Archives Act or other law, all personal information shall be deleted (see Personal Data Act, section 28). However, personal data may still be stored for historical, statistical or scientific purposes, if the public interest in that stored information clearly outweighs the disadvantages that it may bring to the individual.</p> <p>Delivery or deposit as aforesaid shall not take place according to the second and third paragraph of section 14 unless at least 10 years have passed since the last journal entry.</p> <p>Section 14, third paragraph, provides that patient medical records in public institutions fall within the provisions on public archives within and in accordance with the Archives Act, including provisions on conservation, scrapping and delivery to state, county or municipal archives.</p> <p>Section 14, fourth paragraph provides that patient medical records in private institutions may be delivered to a public archive depot or deposited in another storage institution.</p> <p>Section 10, Regulations on the <i>Kjernejournal</i>, provides that data in the <i>Kjernejournal</i> shall be deleted when it is no longer necessary for the purpose of processing of the data in accordance with section 27, Health Personnel Act. The second paragraph of section 10 then provides certain periods after which certain specific data in the <i>Kjernejournal</i> shall be deleted.</p> <p>Section 8a on the health archives register (<i>helsearkivregisteret</i>) is a new section that was introduced in the Personal Health Data Filing System</p>

	8a, section 27	<p>Act on and with effect from 22 June 2012. On that same date, the Archives Act was also amended to include the Norwegian Health Archives (<i>Norsk helsearkiv</i>) as part of The National Archives of Norway.</p> <p>Section 8a states that the health archives register is a central personal health data filing system with identifiable personal documentation handed over to the Norwegian Health Archives. The data in the health archives register may be processed without the consent of the data subject. The Director General of The National Archives (<i>Riksarkivaren</i>) is the data controller for the data in the health archives register. Pursuant to section 8a, regulations may be passed to regulate further the establishment of the health archives register, the processing of health data in the register, the purposes of the processing and which data shall be processed. The regulations will also specify the data controller's duty to make such data accessible. The regulations may also provide further rules on the conservation, disposal and the delivery of patient documentation by private institutions in specialist health services.</p> <p>In fact, there is currently a proposal for draft Regulations on the Norwegian Health Archives and the health archive register (<i>helsearkivforskriften</i>) which is open for consultation until 1 April 2014.⁹⁰ It should be highlighted that, according to the aforementioned draft Regulations,⁹¹ the Norwegian Health Archives will only comprise material from the specialist health services (<i>spesialisthelsetjenester</i>) in terms of the Specialist Health Services Act. Archive material from the municipal health and care services fall outside the scope of the proposed regulations and the general Archives Act applies for such public entities.⁹²</p> <p>Section 8a, fifth paragraph of the Personal Health Data Filing System Act provides a statutory basis for the enactment of regulations to provide</p>
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⁹⁰ Available in Norwegian with an explanatory commentary at <http://www.regjeringen.no/pages/38562836/horingsnotat.pdf>

⁹¹ See Consultation Document, in Norwegian, *Høringsnotat Forslag til forskrift om Norsk helsearkiv og Helsearkivregisteret (helsearkivforskriften)*, n 52, p. 15.

⁹² Ibid.

	<p>Archives Act, section 9, and its regulations</p> <p>Personal Data Act, section 27</p>	<p>further rules on the conservation, scrapping (in Norwegian ‘kassasjon’) and the delivery of patient documentation by private institutions in specialist health services. The proposal for draft Regulations on the Norwegian Health Archives and the health archive register (<i>helsearkivforskriften</i>) provides further rules on scrapping e.g. section 19 which deals with inactive patient medical records where the patient’s year of death is not known, and section 21 which permits scrapping of certain old patient medical records which have been digitalized. The main rules on deleting deficient data and against storing unnecessary personal data are in the Personal Data Act and the Personal Health Data Filing System Act.</p> <p>According to section 9(c) of the Archives Act, it is forbidden to scrap/discard (<i>kassere</i>) archive material which is subject to an obligation to be archived and to an obligation to be delivered (for archival purposes). However, an exception to this rule is where there is an administrative decision by the Data Protection Authority regarding erasure in terms of the Personal Data Act or the Personal Health Data Filing System Act. In such exceptional cases, the Director General of the National Archives of Norway shall be consulted by the Data Protection Authority prior to it delivering its administrative decision regarding erasure. The relevant provisions are section 28 (prohibition against storing unnecessary personal data – see above) and section 27 (rectification of deficient personal data) of the Personal Data Act and section 26 (rectification of deficient personal health data) of the Personal Health Data Filing System Act.</p> <p>Section 27 of the Personal Data Act provides: “If personal data which are inaccurate or incomplete or of which processing is not authorized, the controller shall on his own initiative or at the request of the data subject rectify the deficient data. The controller shall if possible ensure that the error does not have an effect on the data subject, for instance by notifying recipients of disclosed data. The rectification of inaccurate or incomplete personal data which may be of significance as documentation shall be effected by marking the</p>
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	<p>Personal Health Data Filing System Act, section 26</p>	<p>data clearly and supplementing them with accurate data.</p> <p>If weighty considerations relating to protection of privacy so warrant, the Data Protection Authority may, notwithstanding the second paragraph, decide that rectification shall be effected by erasing or blocking the deficient personal data. If the data may not be destroyed pursuant to the Archives Act, the Director General of the National Archives of Norway shall be consulted prior to making an administrative decision regarding erasure. This decision shall take precedence over the provisions of sections 9 and 18 of the Archives Act of 4 December 1992 No. 126.</p> <p>Erasure should be supplemented by the recording of accurate and complete data. If this is impossible, and the document which contained the erased data therefore provides a clearly misleading picture, the entire document shall be erased.</p> <p>The King may prescribe regulations containing supplementary provisions as regards how to effect rectification.”</p> <p>Section 26 of the Personal Health Data Filing System Act provides:</p> <p>“If personal health data which are inaccurate, incomplete or of which processing is not authorized are processed pursuant to sections 5, 7 and 8, the data controller shall on his own initiative or at the request of the data subject rectify the deficient data. The controller shall if possible ensure that the error does not have an effect on the data subject. If the personal health data have been disclosed, the controller shall notify recipients of disclosed data.</p> <p>The rectification of inaccurate or incomplete personal health data which may be of significance as documentation shall be effected by marking the data clearly and supplementing them with accurate data.</p> <p>If weighty considerations relating to protection of privacy so warrant, the Data Protection Authority may, notwithstanding the second paragraph, decide that rectification shall be effected by erasing or blocking the deficient personal health data. If the data may not be destroyed pursuant to the Archives Act, the Director General of the National Archives of Norway shall be consulted prior to making an administrative decision regarding erasure. This decision shall take</p>
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	Health Research Act, section 38	<p>precedence over the provisions of sections 9 and 18 of the Archives Act of 4 December 1992 No. 126.</p> <p>Erasure should be supplemented by the recording of accurate and complete data. If this is impossible, and the document that contained the erased data therefore provides a clearly misleading picture, the entire document shall be erased.</p> <p>Sections 42 to 44 of the Health Personnel Act shall apply to rectification and erasure of personal health data in personal health data filing systems established for therapeutic purposes. The second and third sentences of the first paragraph apply correspondingly.”</p> <p>Section 38, Health Research Act, regulates the time that medical research data may be kept. It states that data must not be stored for longer than is necessary to complete the project. The regional committee for medical and health research ethics may rule that documents that are necessary for auditing the project must be kept for five years after the final report on the research project has been sent to the Committee. If the data are not going to be kept thereafter in accordance with the Archives Act or other legislation, they must be anonymised or deleted. The regional committee for medical and health research ethics may rule that data shall be kept for longer than aforesaid in the previous paragraph. Conditions may be attached to this kind of ruling.</p>
<i>Are there different archiving rules for different providers and institutions?</i>		Yes. 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>	Regulations on Patient Records, section 15	<p>Yes. See above.</p> <p>Section 15, third paragraph of the Regulations on Patient Records provides inter alia that upon the assignment or closure of the institution, the institution’s management may decide that patient medical records shall be transferred to another institution. Where a formal inter-institutional collaboration is ceased, the Regulations on the inter-institutional patient medical records apply (see section 6b, Personal Health Data Filing System Act). The patient may object to such transfer</p>

	<p>Health Research Act, section 11</p>	<p>Moreover, personal health data may not be used for purposes that are incompatible with the original objective without the consent of the research participant, unless otherwise laid down in law (section 32, second paragraph).</p> <p>Section 11 of the Health Research Act regulates situations where there is a new or changed use of the health data. Section 11, first paragraph provides that in the event of substantial changes to the research project, new consent must be obtained in accordance with Section 13 if the changes are deemed to have consequences for the participant's consent. Section 11, second paragraph states that if it is difficult to obtain new consent, the regional committee for medical and health research ethics may approve new or changed use of previously collected human biological material or personal health data without new consent being obtained. This may only be applied if the research in question is of significant interest to society and the participants' welfare and integrity are ensured. The regional committee for medical and health research ethics may specify conditions for use.</p> <p>Note section 35 of the Health Research Act which specifies when access to use personal health data collected by the health service may be given for medical and health research purposes. It states that the regional committee for medical and health research ethics may decide that personal health data can or shall be handed over by health personnel for use in research, and that this may be done notwithstanding the duty of confidentiality. The same applies to data gathered by the health service. This may only be applied if the research in question is of significant interest to society, and the participants' welfare and integrity are ensured. The regional committee for medical and health research ethics may specify conditions for use. The rules on the duty of confidentiality pursuant to Section 7 apply accordingly to the party that receives the data. The Ministry may by regulations issue further provisions concerning the use of confidential information in research.</p>
<p><i>Are there health data that cannot be</i></p>	<p>Health Personnel Act,</p>	<p>According to section 22 of the Health Personnel Act, the duty of</p>

<p><i>used for secondary use?</i></p>	<p>section 22</p> <p>Regulations on the <i>Kjernejournal</i>, section 11</p> <p>Health Research Act, section 32</p> <p>Health Research Act, section 8</p>	<p>confidentiality according to section 21 does not prevent information from being made known to the person that the information directly relates to, or to others, to the extent to which the person who is entitled to confidentiality gives his consent thereto. Nevertheless, an insurance company cannot get access or knowledge of data in those cases where the person that the information directly relates to, can be denied access according to section 5-1, second paragraph, of the Patient's Rights Act. (Section 5-1, second paragraph, of the Patients' Rights Act provides that the patient may be denied access to information in his or her medical records if this is absolutely necessary in order to avoid endangering the patient's life or serious damage to the patient's health, or if access is clearly inadvisable out of consideration for persons close to the patient.)</p> <p>In the case of the national <i>Kjernejournal</i>, it is forbidden to disclose information on the data subject to the employer, insurance company or the public prosecutor even if the data subject consents.</p> <p>According to section 32, third paragraph, of the Health Research Act, personal health data may not be surrendered for insurance purposes, to employers, to the prosecuting authorities or to a court of law even if the person the data originates from consents to this.</p> <p>Section 8, Health Research Act provides that commercial exploitation of research participants, human biological material and personal health data in general is prohibited.</p>
<p><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></p>	<p>Personal Health Data Filing System Act, sections 7 and 8</p> <p>Personal Health Data Filing System Act, section</p>	<p>With regards to the local, regional and central personal health data filing systems according to the Personal Health Data Filing System Act, the various detailed rules on anonymization, de-identification and pseudonymization of data apply. See sections 7 and 8 of the Personal Health Data Filing System Act. (See earlier especially Table 2.1.2). See also above re certain health data that cannot be used.</p> <p>Moreover, section 10, Personal Health Data Filing System Act, provides that '[t]he Ministry may by regulations or by administrative decision</p>

	<p>10</p> <p>Health Research Act, section 4</p> <p>Health Research Act, section 32</p>	<p>order regional health enterprises and health enterprises, counties and municipalities to report de-identified or anonymous data for statistical purposes, including issuing further rules regarding the use of standards, classification systems and coding systems.'</p> <p>With regards to medical and health research, the provisions of the Health Research Act apply. The term 'medical and health research' is defined as an activity conducted using scientific methods to generate new knowledge about health and disease (section 4 (a)). This Act inter alia lays down requirements for the organization and execution of medical and health research (chapter 2), and also requires application for prior approval and a duty to notify the regional committee for medical and health research ethics (chapter 3).</p> <p>See also section 32 abovementioned, in particular, first paragraph, third sentence of the Health Research Act which provides that the degree of personal identification in the health data must not be greater than is necessary to serve the intended purposes.</p>
<p><i>Does the law say who will be entitled to use and access this data?</i></p>	<p>Health Research Act, section 32 and Section 34</p>	<p>See section 32, Health Research Act, above.</p> <p>Section 34 deals with the processing of health data:</p> <p>Personal health data may be processed, compared and surrendered in keeping with the objective of the research project, any consents, authority to process data pursuant to Section 33 and in accordance with the research protocol.</p> <p>In the event of approval pursuant to Chapter 3, the regional committee for medical and health research ethics may deny comparison or surrender of data if this is deemed to be medically or ethically unsatisfactory.</p> <p>Personal health data may be compared and surrendered to the person responsible for data processing or a person or body responsible for the research who has special authorisation to receive and process these data. Authority of this nature may be a licence or statutory provisions in legislation or regulations.</p>

	<p>Health Research Act, section 6; Regulations on the Organization of Medical and Health Research</p> <p>Health Research Act, chapter 8</p> <p>Health Research Act, section 37</p>	<p>Section 6 provides inter alia for rules on internal control. Section 6, second paragraph states that internal control must be carried out in a manner that is adapted to the size, nature, activities and risk factors of the research. Pursuant to section 6, third paragraph, the Regulations on the Organization of Medical and Health Research were issued in 2009 providing requirements concerning the research protocol and concerning internal control, and laying down provisions concerning the duties of the project manager and the person or body responsible for the research.</p> <p>Chapter 8, Health Research Act, deals with transparency and right of access to the research. Note, for example, section 40 which inter alia states that the research participants have the right to access to personally identifiable and pseudonym personal health data about themselves and information about the security measures used in connection with processing personal health data as long as such access does not jeopardise security.</p> <p>See also section 37, Health Research Act, on the transfer of medical research data from Norway to another country outside the European Economic Area.</p>
<p><i>Is there an opt-in/opt-out system for the secondary uses of eHealth data included in EHRs?</i></p>	<p>Personal Health Data Filing System Act, sections 7 and 8</p> <p>Health Research Act, sections 13 and 15</p>	<p>The establishment of local, regional and central personal health data filing systems according to the Personal Health Data Filing System Act, are permitted provided they are authorized according to that Act or another statute. (section 7, first paragraph; section 8, first paragraph).</p> <p>In the case of medical and health research projects, the main rule is that consent must be obtained from participants in medical and health research, unless otherwise laid down in law (section 13, first paragraph, Health Research Act). In the event of substantial changes to the research project, new consent must be obtained in accordance with Section 13 if the changes are deemed to have consequences for the participant's consent (section 15).</p>

	<p>Section 16, Medical Research Act, deals with the withdrawal of consent:</p> <p>Consent to take part in a research project may be withdrawn at any time (section 16, first paragraph).</p> <p>If a participant withdraws his/her consent, research on their biological material or personal health data must stop. A person who has withdrawn their consent may demand that their biological material is destroyed and that the personal health data are deleted or surrendered within 30 days (section 16, second paragraph).</p> <p>The right to demand destruction, deletion or surrender of biological material or health data pursuant to the second paragraph does not apply if the material or data have been anonymized, if the material has been processed and is now part of another biological product, or if the data have already been included in completed analyses (section 16, third paragraph).</p> <p>If particularly strong social or research considerations so warrant, the regional committee for medical and health research ethics may allow continued research on the material and defer destruction, deletion or surrender until the research project is concluded (section 16, fourth paragraph).</p>
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2.7. Requirements on interoperability of EHRs

2.7.1. Main findings

It has been and is a political objective to achieve ever higher levels of electronic interaction within the health and care sector (the so-called ‘*samhandlingsreformen*’).⁹³ On 28 June 2013, the Norwegian Ministry of Health and Care Services issued a “Consultation Paper proposing a new Medical Records Act and new Personal Health Data Filing Systems Act”.⁹⁴ This states that in the health and care sector, there are many different ICT systems which cannot communicate between themselves in a secure manner.⁹⁵ This makes collaboration and electronic communication of health data across institutions and, in some cases, even internally in an institution, challenging. The Consultation Paper states that, to ensure secure and effective electronic communication of health data, it is important to ensure a comprehensive ICT-architecture in the health sector.⁹⁶ It holds that all ICT-systems ought to use compatible and standardised solutions.⁹⁷ Moreover, systems ought to be able to communicate health data in an effective and secure manner such that patients and health care personnel at any time can trust that the data is correct, updated and accessible for those who have need for it.⁹⁸

All the institutions which provide health care are obliged to have a proper medical record system (see section 5-10 of the Municipal Health Care Act; section 3-2 of the Specialist Health Services Act; and section 4 of the Regulations on Patient Records). It is, however, the particular health care personnel member who provides health care who has a duty to enter and record information in terms of the Health Personnel Act (sections 39 and 40). The current body of rules is technology neutral and there is no requirement that a medical record shall be kept electronically. Section 6 of the Personal Health Data Filing System Act and section 46 of the Health Personnel Act provide that health data filing systems established for therapeutic purposes (*behandlingsrettede helseregistre*) may be kept electronically.⁹⁹ However, section 6, fourth paragraph, of the Personal Health Data Filing System Act provides a legal basis whereby regulations may be issued which lay down that data in personal health data filing systems established for therapeutic purposes shall be processed electronically. In fact, there is a proposal for regulations on ICT-standards in the health and care sector currently pending. The current draft of these regulations proposes:¹⁰⁰

- A *duty* to keep electronic records of health data filing systems established for therapeutic purposes;
- A duty to use standardised message exchange which, in the proposal, comprises 19 different message standards and one framework requirement;
- A requirement that institutions which are linked to the health network by means of an affiliation agreement with Norsk Helsenett SF (the Norwegian Health Network) at all times will have updated electronic address in the Address Register (*Adresseregisteret*).

Norsk Helsenett SF (“Norwegian Health Network”)¹⁰¹ is the provider of a national infrastructure for

⁹³ See website of Ministry of Health Care and Services, in Norwegian, <<http://www.regjeringen.no/en/dep/hod/Subjects/samhandlingsreformen.html?id=680424>>.

⁹⁴ *Høring: Forslag til ny pasientjournallov og ny helseregisterlov* (“Consultation Paper proposing a new Medical Records Act and new Personal Health Data Filing Systems Act”), 28 June 2013, in Norwegian <http://www.regjeringen.no/pages/38380934/Hoeringsnotat_helseregisterlov.pdf>.

⁹⁵ See, in Norwegian, “Consultation Paper proposing a new Medical Records Act and new Personal Health Data Filing Systems Act” n 94, p. 63.

⁹⁶ *Ibid.*

⁹⁷ *Ibid.*

⁹⁸ *Ibid.*

⁹⁹ See, in Norwegian, *Høringsnotat Forslag til forskrift om IKT-standarder i helse- og omsorgssektoren* (Consultation Paper on the Proposal for Regulations on ICT-standards in the Health and Care Sector), June 2013, p.6, at <<http://www.regjeringen.no/pages/38376370/HoeringsnotatHRA.pdf>>.

¹⁰⁰ See further, *ibid.*, p. 3.

¹⁰¹ Norsk Helsenett is owned by the Ministry of health and care services. It was founded as a state-owned enterprise July 1, 2009. See further <<http://www.nhn.no/english-1>>.

electronic communication in the health sector, *helsenettet* (“the health network”). In order to be linked to, and actually utilize, this network, the health service provider must enter into an “affiliation agreement” with the company. By force of this agreement, the entity admitted to the infrastructure is obliged to comply with the “Code of Conduct for information security in the healthcare, care, and social services sector” (Code of Conduct).¹⁰² By this mechanism, the health service providers ensure that the receivers of health-related data – i.e. collaborating partners of many kinds – within the network, meet the standards of the Code. Failing to meet the information security standards of the Code may lead to the exclusion of the contract-breaching entity.¹⁰³

¹⁰² This Code of Conduct is available in English at <<http://helsedirektoratet.no/lover-regler/norm-for-informasjonssikkerhet/english/documents-english/Sider/default.aspx>>. In Norwegian, it is known as *Norm for informasjonssikkerhet i helse-, omsorgs- og sosialsektoren* (abbreviated as *Normen*), see <<http://helsedirektoratet.no/lover-regler/norm-for-informasjonssikkerhet/Sider/default.aspx>>.

¹⁰³ See further ‘Code of Conduct’, website of the Norwegian Health Directorate <<http://helsedirektoratet.no/lover-regler/norm-for-informasjonssikkerhet/english/Sider/default.aspx>>. See also Electronic Messaging in Care Coordination, <http://www.nhn.no/english/2013_Meldingsutbredelse_ENG_KORR1_ferdig.pdf>.

2.7.2. Table on interoperability of data requirements

Questions	Legal reference	Detailed description
<p><i>Are there obligations in the law to develop interoperability of EHRs?</i></p>		<p>There is a proposal for regulations on ICT-standards in the health and care sector currently pending. The current draft of these regulations proposes:</p> <ul style="list-style-type: none"> - A <i>duty</i> to keep electronic records of health data filing systems established for therapeutic purposes; - A duty to use standardised message exchange which, in the proposal, comprises 19 different message standards and one framework requirement; - A requirement that institutions which are linked to the health network by means of a contract with Norsk Helsenett SF (the Norwegian Health Network) at all times will have updated electronic address in the Address Register (<i>Adresseregisteret</i>). <p>It has also been and is a political objective to achieve ever higher levels of electronic interaction within the health and care sector (the so-called ‘<i>samhandlingsreformen</i>’).¹⁰⁴</p>
<p><i>Are there any specific rules/standards on the interoperability of EHR?</i></p>	<p>Contractually applicable terms in the Code of Conduct for information security in the healthcare, care, and social services sector” (Code of Conduct).</p>	<p>Norsk Helsenett SF (“Norwegian Health Network”) is the provider of a national infrastructure for electronic communication in the health sector, <i>helsenettet</i> (“the health network”). In order to be linked to, and actually utilize, this network, the health service provider must enter into an “affiliation agreement” with the company. By force of this agreement, the entity admitted to the infrastructure, is obliged to comply with the “Code of Conduct for information security in the healthcare, care, and social services sector” (Code of Conduct). By this mechanism, the health service providers ensure that the receivers of health-related data – i.e. collaborating partners of many kinds – within the network, meet the standards of the Code. Failing to meet the information security</p>

¹⁰⁴ See website of Ministry of Health Care and Services, in Norwegian, <<http://www.regjeringen.no/en/dep/hod/Subjects/samhandlingsreformen.html?id=680424>>.

		<p>standards of the Code, may lead to the exclusion of the contract-breaching entity.</p> <p>There are also the proposed draft regulations on ICT-standards in the health and care sector currently pending – see above.</p>
<p><i>Does the law consider or refer to interoperability issues with other Member States systems?</i></p>		<p>No. See above.</p>

2.8. Links between EHRs and ePrescriptions

2.8.1. Main findings

One of Norway's central personal health data filing systems is the National Database for Electronic Prescriptions (*Nasjonal database for elektroniske resepter*) set up in terms of section 8, third paragraph, no. 9 of the Personal Health Data Filing System Act. In terms of the Regulations on the ePrescriptions Register (*Reseptregisteret*), issued pursuant to section 8 paragraph 4 of the aforementioned Act, the collection, storage and processing of information in the ePrescriptions Database shall take place electronically (section 1-1, second paragraph). The ePrescription system is thus based on the existence of the National Database for ePrescriptions.

For an ePrescription to be prescribed, it presumes that the health care personnel who prescribed it has access to the ePrescriptions Database into which that prescription will then be registered. There are specific regulations on the processing of medical data in the national database for electronic prescriptions (Regulations on the ePrescriptions Database - *reseptformidlerforskriften*). These provide inter alia that upon requesting medicine, medicinal items or medicinal food products, the requesting party shall register the prescription in the ePrescriptions Database (section 2-1 first paragraph). However, according to the transitory provisions of the Regulations on the ePrescriptions Database (section 8-1), the Health Department may, with regards to the introduction of ePrescriptions, take decisions to make exemptions from the obligation to notify the requisition of medicine, medicinal items or medicinal food products. However, such exemptions cannot apply beyond 2015.

Moreover, the health care personnel writing the ePrescription would need to have access to that health care personnel's local medical records for that patient (*pasientjournal*), i.e. on that health care personnel's own medical records system, not to any central (i.e. national) record-keeping system. This is in order to comply with the duty of every health care personnel providing health care in terms of the Health Personnel Act to enter and keep patient records according to section 39 of the Act, as well as section 8 of the Regulations on Patient Records.

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>	Personal Health Data Filing System Act, section 8, third paragraph, no 9	One of Norway's central personal health data filing systems is the National Database for Electronic Prescriptions (<i>Nasjonal database for elektroniske resepter</i>) ¹⁰⁵ set up in terms of section 8, third paragraph, no.9 of the <i>Personal Health Data Filing System Act</i> . The ePrescription system is thus based on the existence of the National Database for ePrescriptions. ¹⁰⁶ See also below.
<i>Can an ePrescription be prescribed to a patient who does not have an EHR?</i>	Health Personnel Act section 39; Regulations on Patient Records, section 8. Regulations on the ePrescriptions Database (<i>reseptformidlerforskriften</i>)	The health care personnel (e.g. family doctor) writing an ePrescription would need to have access to that health care personnel's local medical records for that patient (<i>pasientjournal</i>), i.e. on that health care personnel's own medical records system, not to any central (i.e. national) record-keeping system. This is in order to comply with the duty of every health care personnel providing health care in terms of the Health Personnel Act to enter and keep patient records according to section 39 of the Act, as well as section 8 of the Regulations on Patient Records. ¹⁰⁷ Moreover, for an ePrescription to be prescribed, it presumes that the health care personnel who prescribed it has access to the ePrescriptions Database into which that prescription will be registered.

¹⁰⁵ This should not be confused with another central register – the Norwegian Prescription Database (NorPD) – established in terms of section 8, fourth paragraph of the Personal Health Data Filing System Act and the Regulations on the Norwegian Prescription Database (*Reseptregisteret*). In terms of section 1-1, second paragraph these regulations, the collection, storage and processing of information in the Norwegian Prescription Database (NorPD) takes place electronically. The NorPD contains a complete listing of all prescription drugs dispensed by pharmacies since 2004. Drugs supplied to hospitals and nursing homes are included, but not at an individual level. The database also contains information about the prescription of drugs to animals. All the pharmacies in Norway register prescriptions electronically, and the information is sent to NorPD in pseudonymised form. Individuals are anonymised using a unique pseudonym to replace the social security number. This makes it possible to link drug use to individuals without knowing who they are. See further Norwegian Institute of Public Health website <http://www.fhi.no/eway/default.aspx?pid=240&trg=Main_6664&Main_6664=6898:0:25,7843:1:0:0:::0:0>.

¹⁰⁶ This is also based on discussions with representatives of the Norwegian Directorate of Health.

¹⁰⁷ This is also based on discussions with personnel from the Norwegian Directorate of Health.

		In practice, there would be a link between the electronic patient medical journal and the generation of the ePrescription which would be sent to the Norwegian Prescription Database ¹⁰⁸ (NorPD or, in Norwegian, <i>Reseptregisteret</i>).
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- *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>	Regulations on the ePrescriptions Database (<i>reseptformidlerforskriften</i>) Health Personnel Act section 39; Regulations on Patient Records, section 8.	For an ePrescription to be prescribed, it presumes that the health care personnel who prescribed it has access to the ePrescriptions Database into which that prescription will then be registered. There are specific regulations on the processing of medical data in the national database for electronic prescriptions (Regulations on the ePrescriptions Database). These provide inter alia that upon requesting medicine, medicinal items or medicinal food products, the requesting party shall register the prescription in the ePrescriptions Database (section 2-1 first paragraph). However, according to the transitory provisions of these Regulations, the Health Department may, with regards to the introduction of electronic prescriptions, take decisions to make exemptions from the obligation to notify the requisition of medicine, medicinal items or medicinal food products. However, such exemptions cannot apply beyond 2015. See section 8-1 of the Regulations on the ePrescriptions Database. Moreover, the health care personnel writing the ePrescription would need to have access to that health care personnel's local medical records for that patient (<i>pasientjournal</i>), i.e. on that health care personnel's own medical records system, not to any central (i.e. national) record-keeping system. This is in order to comply with the duty of every health care personnel providing health care in terms of the Health Personnel Act to

¹⁰⁸ See n 105.

		enter and keep patient records according to section 39 of the Act, as well as section 8 of the Regulations on Patient Records. ¹⁰⁹
<i>Can those health professionals write ePrescriptions without having access to EHRs?</i>		No. See above.

¹⁰⁹ This is also based on discussions with personnel from the Norwegian Directorate of Health.

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

- *Good practices*

Most patient medical records are today spread in the different institutions, clinics and locations from where a patient would have obtained medical help. It has been a political aim in Norway that relevant and necessary patient data follow the patient and are available for health care personnel who provide health care, irrespective of where the patient may have previously obtained health care and irrespective of how the health sector is organised. Another aim is that new digital applications may be directly accessible to patients via the Internet. These aims were put forward in the White Paper *Én innbygger – én journal* (One inhabitant – one patient record).¹¹⁰

Moreover, the contents of patients' medical records are today still somewhat written in 'prose' and only to a very little extent stored as structured text.¹¹¹ A prerequisite for effective and secure electronic communication between health care personnel is that information is kept electronically in the respective institution. Although several of these institutions have electronic patient medical record systems as well as administrative systems, much of the communication between the actors is still carried out through the use of paper-based and diverse electronic solutions.¹¹² To facilitate that the use of ICT-standards promotes secure electronic interaction and exchange inside and between institutions, the Consultation Paper proposing draft regulations on ICT-standards in the health and care sector was published in June 2013 and is currently pending.¹¹³ The draft regulations, inter alia, are proposing that there should be a duty on institutions to use standardised message exchange.¹¹⁴

The Data Protection Authority has issued a report, in Norwegian, *Strategi for godt personvern i helsesektoren* (Strategy for good data protection in the health sector) of June 2011, which is still pertinent and relevant. In this report, the Data Protection Authority states that it gives high priority to the health sector as this is a large user of sensitive personal data. In particular, new solutions and the new legal framework in the sector shall safeguard privacy in a better manner, especially in light of the type/form of the medical health register and the individual's right to self-determination. In addition, the health sector shall positively contribute to a strengthening of access control and logging of data. Finally, the individual needs to keep oversight and control of information about himself. With regards to central personal health data filing systems (*sentrale helseregistre*), the report states that, where new health registers of this type are created, it is important that data protection is embedded in the design of such registers from the start. A good data protection principle is that such health registers distinguish between the patient's identity and the medical health data, and that these are stored in different locations. Moreover, the report recommends that privacy-enhancing technologies should be used as much as possible. In fact, Annex III of the report lists the 7 Foundational Principles for Privacy by Design developed by Dr. Ann Cavoukian. With regards to medical and health research, the report states that data protection and information security implications should be assessed and attended to early in the application process by the project manager and the REC. Hereto the following principles are applied to the central health register:

- It is important to find a good balance between how knowledge needs and patients' privacy must be maintained;
- The patient should not be identified to a greater extent than is necessary to fulfil the purpose of

¹¹⁰ See n 7; see also, in Norwegian, 'Consultation Paper proposing a new Medical Records Act and new Personal Health Data Filing Systems Act', n 15 p. 16.

¹¹¹ See Consultation Paper, n 15 p. 54.

¹¹² See, in Norwegian, the 'Consultation Paper proposing draft regulations on ICT-standards in the health and care sector', n 28, p. 3.

¹¹³ Ibid.

¹¹⁴ See further, section 2.7.1 of this report.

- the register;
- Health information and identity information should be kept separate. The best policy is to store identity information externally;
- The most radical and sensitive health records should be based on the consent of the patient; and
- Citizens must generally be allowed to opt out of registration in health records.

A prerequisite for effective and secure electronic communication between health care personnel is that information is kept electronically in the respective institution. Although several of these institutions have electronic patient medical record systems as well as administrative systems, much of the communication between the actors is still carried out through the use of paper-based and diverse electronic solutions. To facilitate that the use of ICT-standards promotes secure electronic interaction and exchange inside and between institutions, the Consultation Paper proposing draft regulations on ICT-standards in the health and care sector was published in June 2013 and is currently pending. The draft regulations, *inter alia*, are proposing that there should be a duty on institutions to use standardised message exchange.¹¹⁵

A number of potential legal barriers and challenges to development of EHRs in Norway have been raised and have been and are sought to be addressed in the various White Papers, discussion and consultation documents proposing new laws and regulations in the health sector such as the proposal for a new Patient Medical Record Act, the proposal for a new Personal Health Filing System Act, etc. The challenges, potential legal barriers and also proposals for addressing such challenges are discussed in the next section below.

- ***Potential legal barriers***

- *Various laws, intricate provisions*

Among the main challenges existing today is the fact that the legal framework for patient medical records, personal health data filing systems used for therapeutic purposes and those used for secondary purposes, is intricate and spread in and across various statutes and regulations. The current Personal Health Data Filing System Act, for example, regulates both personal health data filing systems used for therapeutic purposes and those used for secondary purposes. One of the aims of the proposed draft bill for a new Patient Medical Records Act and for a draft bill on a new Personal Health Data Filing System Act is to have a clearer scope for each of these draft statutes: the proposed Patient Medical Records Act will regulate patient medical records and personal health data filing systems used for therapeutic purposes – i.e. primary use – whereas the proposed bill for a new Personal Health Data Filing System Act will regulate secondary use of personal health data.¹¹⁶

- *Requirements that are too technical?*

The Regulations on health information security (*helseinformasjonssikkerhetsforskriften*) are not yet in force. One main reason why these regulations have not as yet been brought into force is that several health service providers find the regulations too technically strict and demanding to put into effect. For example, section 11 would permit ‘read-only’ access across institutions provided the health data is structured as provided in section 3(2) of the regulations. According to the interviewees from the Data Protection Authority, from a data protection perspective, the requirement for such data to be structured data is not exaggerated or unreasonable in light of the purposes of these regulations.

¹¹⁵ See further, section 2.7.1 of this report.

¹¹⁶ See, in Norwegian, ‘Consultation Paper proposing a new Medical Records Act and new Personal Health Data Filing Systems Act’, n 15, p. 81, p. 116.

- *Limitations on the sharing of health data between health personnel*

The Personal Health Data Filing Systems Act makes a distinction between *direct access* to health data whereby the health care personnel himself or herself can search for it, and that of having the health data provided to him or her.¹¹⁷ Direct electronic access to health data is, as a main rule, limited only to those who work under the instructions of the data controller or of the data processor (section 13).¹¹⁸

It is possible for health care personnel to request access to health data for single patients across institutions, but under very specified conditions and with the consent of the patient. Provided certain conditions are met, the health care personnel may have such medical data provided to them, but they cannot be allowed to themselves directly search for such data.¹¹⁹

The restrictions in section 13 of the Personal Health Data Filing System Act also apply in addition to the rules on confidentiality in the Health Personnel Act. Section 13 does not provide a legal basis for any exception to the rules on confidentiality.¹²⁰ According to sections 25 and 45 of the Health Personnel Act, confidential information can only be communicated when it is necessary to provide proper health care. The rules on confidentiality regulate which health data may be given access to and when access may be given, but such rules are silent on how or in what way access to the data may be given.¹²¹ The data controller and data processor have a duty to ensure there is satisfactory information security (section 16, Personal Health Data Filing System Act).

Thus, the possibility of health care personnel to search themselves for health data in a personal health data filing system used for therapeutic purposes in a different institution than that to which the health care personnel belongs can, as a main rule, only be provided once there is express consent from the data subject.¹²²

One of the objectives of the White Paper *Meld. St. 9 (2012-2013) Én innbygger – én journal*¹²³ is that relevant and necessary patient medical data shall be available for the health care personnel who provide health care, irrespective of where the patient may have obtained health care or of how the health care sector may be organised at any time.¹²⁴ The Department of Health and Care Services has thus proposed that the current requirement in section 13, third paragraph, that the data subject's consent is required in order for collaborating health care personnel in other institutions to obtain access to relevant and necessary health data should not be included in the proposed draft bill for a new Patient Medical Record Act.¹²⁵ According to the Department, it should be the data controller who decides in what manner health data shall be made accessible, including who shall be given authorisation to search directly for data, unless it is otherwise provided for in some other law.¹²⁶

- *The notion of 'de-identified' and 'pseudonymous' data*

The rules on delivery, combining and use of health data from the central personal health data filing systems have turned out to be unclear and difficult to use by the actors in the sector. There have often been differences in interpretation of the terms anonymous and de-identified data.¹²⁷ The Department for Health and Care Services is thus proposing that these two terms be replaced by the term 'indirectly

¹¹⁷ Consultation Paper, n 15 p. 89.

¹¹⁸ Ibid.

¹¹⁹ Ibid.

¹²⁰ Ibid.

¹²¹ Consultation Paper, n 15 p. 90.

¹²² Ibid.

¹²³ See n 7.

¹²⁴ See Consultation Paper, n 15 p. 90.

¹²⁵ Ibid, p. 93,

¹²⁶ Ibid, p. 92.

¹²⁷ Ibid, p. 152.

identifiable health data’ in the proposed draft bill for a new Personal Health Data Filing System Act.¹²⁸

- *The creation of personal health data filing systems (helseregistre) without consent*

As mentioned earlier in this report (section 2.2.1), a difference of interpretation has arisen between the Data Protection Authority and the Ministry of Justice’s legal section with regard to the extent to which the Data Protection Authority is competent to licence certain personal health data filing systems and whether such data filing systems ought instead to be established by specific regulations.

The Department of Health and Care Services, in the Consultation Paper proposing a new Personal health data filing system Act, is proposing that though the main rule ought to be that one obtains consent from the data subject and a licence from the Data Protection Authority, there is need for ‘faster more flexible procedures’ to be able to set up new personal health data filing systems.¹²⁹ The Department is thus proposing that the draft new bill on Personal Health Data Filing Systems will provide a general legal basis for the King in Council (i.e. the Government) to issue regulations to establish personal health data filing systems.¹³⁰ This proposal would apply equally for all types of such filing systems, even those set up without the consent of the data subject, in terms of further specified conditions.¹³¹

The Norwegian Medical Association, out of inter alia privacy concerns, takes a different position. It holds that the conditions in the proposed bill under which personal health data filing systems that are not based on consent from the data subjects may be created are so discretionary (*skjønnsmessige*) that the authority to approve such new filing systems must vest in Stortinget.¹³² The Medical Association holds that if the legislator still decides to vest authority in the Government to create non-consent based personal health data filing systems by way of regulations given pursuant to the proposed draft bill, it is important that the proposed statute specifies in detail the criteria and grounds for when such filing systems may be set up.¹³³

¹²⁸ Ibid.

¹²⁹ Ibid, p. 128.

¹³⁰ See *ibid*, p. 128.

¹³¹ Ibid.

¹³² See the statement from the Norwegian Medical Association on the *Høring: Forslag til ny pasientjournallov og ny helseregisterlov* (“Consultation Paper proposing a new Medical Records Act and new Personal Health Data Filing Systems Act”), n 15, in Norwegian <http://www.regjeringen.no/pages/38380933/den_norske_legeforening.pdf>, p. 5.

¹³³ Ibid.