



HELSEPLATTFORMEN
for pasientens helsetjeneste

**Procurement of an
EHR solution
with adjacent systems and services**

Invitation to Dialogue

Appendix C6 Rules and Regulations

Case number: 2016/238



History

Version	Responsibility	Date	Comments/Changes
v1.0	Helseplattformen	02.02.17	Version v1.0 shared with the Contractors
v1.3	Helseplattformen	20.10.17	Version v1.3 shared with the Contractors
v1.5	Helseplattformen	02.11.17	Version v1.5 shared with the Contractors

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1 GENERAL

This Appendix provides an overview of the regulatory environment in Norway with respect to health law and data protection requirements.

The Contractor shall up to Effective Date have the risk of complying with the list of rules and regulations set out in this Appendix [Note: as this list is after the dialogue has been concluded] together with other requirement where the Contractor is the entity addressed by the rules and regulations.

After Effective Date the Contractor is responsible to implement and the Customer is responsible to pay (subject to the regime for changes with the exception for changes to the EHR solution that is made as part of a general update) for changes necessary to comply with new regulations.

In order to ensure a time and cost efficient implementation of any new regulations, the Contractor shall inform the Customer of any rules and regulations he should be aware that its EHR solution should be expected to comply with.

The Customer shall assist in getting access to regulatory authorities as considered necessary by the Contractor.

The Contractor is obliged to have a system for regulatory observation in the EEA area as well as in Norway. The Contractor is at the earliest possible time required to inform the Customer if regulatory proposals will require changes to the EHR solution. The Contractor shall inform the Customer what amendments that could be made (if any) to the regulatory proposals to remove or lessen the need for such changes.

2 LAWS AND REGULATIONS – OVERVIEW

Many laws and regulations have potential impact on the Customer's procurement of a new EHR solution. The following laws and regulations are to be considered the most important:

- The Norwegian Health Record Act ("pasientjournalloven")
- The Norwegian Regulation on access to health data across enterprises ("forskrift om tilgang til helseopplysninger mellom virksomheter")
- The Norwegian Personal Data Act ("personopplysningsloven")
- The Norwegian Personal Data Regulation ("personopplysningsforskriften")
- The Norwegian Regulation on ICT-standards in the health and care services ("IKT-standardforskriften")

A more extensive list of relevant laws and regulations is provided in *Chapter 10.1*.

The Norwegian Health Record Act contains specific data protection requirements which apply to health services. This Act is supplemented by the Norwegian Personal Data Act which contains general data protection requirements that apply to all sectors. Both Acts are based on the EU Data Protection Directive. More detailed requirements are outlined in regulations to these Acts and in codes of conduct.

Changes will have to be made to some of the mentioned acts and regulations when the EU Data Protection Regulation enters into force (2018). The new regulation is however not likely to influence the main lines and basic principles of Norwegian data protection and health law as outlined below.

3 PUBLIC AUTHORITIES

Several public authorities are involved in supervision and control of health services in Norway. The Norwegian Board of Health Supervision is the superior regulatory authority in this area. However, in relation to this procurement, The Norwegian Data Protection Authority is probably the most important body. The Norwegian Data Protection Authority supervises compliance with The Norwegian Health Record Act and The Norwegian Personal Data Act.

Providers of specialist health services often have their own data protection officer ("personvernombud"). The Norwegian Data Protection Authority delegates authority to the data protection officer to handle data protection issues when such issues arise in the enterprise. The influence of the data protection officer is in practice considerable.

4 LEGAL REQUIREMENTS

According to the Norwegian Health Record Act section 7, attention must be paid to the following legal requirements in connection with the implementation of an EHR solution:

- Confidentiality (professional secrecy)
- Prohibition of unlawful access to health data
- The right to object to processing of personal health data
- Right to information and right to access
- The obligation to keep patient records (documentation)
- Accessibility of health data
- **Information security** and internal control

The EHR solution must be designed, configured and implemented in a way that secures compliance with these legal requirements. While some of the requirements mentioned are well-known and not in need of further explanations, others should be elaborated. The last two requirements, accessibility of health data and information security and internal control represent subjects that are vital in the context of the Customer's procurement of a new EHR solution and are therefore elaborated below.

5 INFORMATION SECURITY AND INTERNAL CONTROL

The Norwegian Code of Conduct for information security ("the Code") sets out rather comprehensive and detailed requirements applying to the implementation and organisation of information systems such as EHR solutions in the health sector. The Code is legally binding on enterprises which are connected users of the Norwegian Health Network. Although the Code is

not formally binding upon other enterprises, the rules and principles set out herein are more or less regarded as mandatory throughout the sector.

The most important requirements relates to the following principles:

- Secure authentication methods
- Satisfactory authorisation procedures
- Sufficient system logs
- Sufficient firewalls and encryption mechanisms
- System requirements (configurations)

In addition to the specific system requirements and the organisational measures mentioned above, the Code also requires that the Customer enters into agreements with providers of ICT-systems-, services- or equipment when the provider gets access to personal data stored in the system (data processing agreement). The Customer must beyond that regularly carry out risk assessments and implement control mechanisms to ensure an appropriate level of risk. ICT-system- or service providers must assist the Customer in the carrying out of risk assessments.

The Customer must keep documentation of risk assessments and must also be able to demonstrate compliance with the technical and organisational measures mentioned above ("internal control obligation"). ICT service providers must in this respect provide the Customer with relevant documentation, e.g., descriptions of the systems used.

6 ACCESSIBILITY OF HEALTH DATA

Accessibility of health data represents in many ways a controversial issue. Rules concerning data flow must balance two main principles in health law and data protection law, namely the obligation of confidentiality and accessibility of health data, see *Chapter 4*.

In Norway, the rules with respect to data flows have changed over the last ten-fifteen years. Current legislation modifies previous regulations when it comes to data flows and allows for increased data sharing between enterprises and health professionals. Despite these changes, Norway still has rather strict rules in this area of law.

Current legislation allows enterprises to collaborate on a mutual EHR system. However, enterprises that decide to collaborate on such mutual solutions are subject to specific requirements set out in the Norwegian Health Record Act, Section 9.

Enterprises which collaborate in the sense of the Norwegian Health Record Act section 9 must also ensure access to the EHR solution for enterprises in the health sector which are not part of the collaboration, cf. the Norwegian Health Record Act section 19. If choosing to facilitate a system for direct access to the EHR system for other enterprises, the collaborating enterprises will have to comply with specific requirements set out in a regulation to the Norwegian Health Record Act section 19 paragraph 3.

Another aspect of data flows is the obligation to make health data available for research or related activities in the public interest when such activities are authorised by law. Certain

information shall also be reported to national registers and *Kjernejournal* (Summary Care Record), see *Appendix C0, Annex 2*.

An EHR solution as described in this document must be configured and implemented in a way that complies with the rules regarding data flows. The solution must have mechanisms to ensure confidentiality and prevent unlawful access and at the same time facilitate access and exchange of information when required.

7 ICT STANDARDS AND REGULATIONS

The Norwegian Regulation on ICT standards in the health sector requires the use of specific standards to be used in EHR systems and other patient oriented systems or registers. The regulation requires the software to have specific functionalities with respect to the exchange of electronic messages. The Norwegian Directorate of eHealth maintains a public catalogue listing obligatory and recommended standards.

Data protection by design and by default is a paramount requirement following the EU Data Protection Regulation article 25. Data protection by design and by default means that Helseplattformen must implement appropriate technical and organisational measures which are designed to implement data protection principles (e.g., pseudonymisation) and to use such configurations as default settings. The purpose is to integrate the necessary safeguards into the processing in order to meet legal requirements and to protect patients' interests. Helseplattformen involves a considerable risk of processing due to the amount of sensitive personal data processed. Thus, great emphasis will be put on data protection by design and by default.

8 COLLABORATION ON EHR SOLUTION

The Norwegian Health Record Act section 9 allows enterprises to collaborate on a joint EHR solution. Helseplattformen is based on this provision. The Norwegian Health Record Act section 19 points out the obligation to share relevant health data between collaborating enterprises, with the aim of treating a patient. This can be carried out in different ways, amongst other by electronic access between enterprises. Such access must be regulated in an agreement on equal terms as section 9. Collaboration is voluntary in both cases.

The Norwegian Health Record Act section 9 requires that the relevant collaborating enterprises enter into an agreement which sets out the intention and the extent of collaboration, how patients' rights are taken care of, liability for the processing of health data and information security issues, hereunder what happens to the data in the case of termination of the agreement.

The Norwegian Ministry of Health and Care Services might, according to the Norwegian Health Record Act section 9 last paragraph, issue a regulation laying down further and specific requirements for the collaboration. Such regulation is not yet adopted, but might be adopted in the future.

9 CONTRACTOR OBLIGATIONS

The collaborating enterprises will in the collaboration agreement entered into pursuant to the Norwegian Health Record Act section 9 state the liability for the processing of health data. Contractors to Helseplattformen will act as a data processor when providing the EHR solution.

Although liability for the processing of health data as a starting point rests with the collaborating enterprises as data controllers, in practice, the liability for information security and other related legal requirements mentioned in this Appendix will rest with the data processor according to the data processing agreement that will be entered into with the Contractor.

The EU Data Protection Regulation 016/679 which comes into force May 2018, will pose some new and extended obligations upon the Contractor acting as a data processor on behalf of Helseplattformen. The requirements will apply irrespective of the data processing agreement entered into between the parties. Inter alia, Contractor must keep records of all processing activities carried out on behalf of Helseplattformen and in general be able to demonstrate compliance with all relevant requirements set out in the Regulation, cf. the Regulation articles 28 and 30.

10 LAWS, REGULATIONS AND STANDARDS

This Chapter provides a list of the laws, regulations and standards that will apply for the solution. A list of laws, regulations and standards applicable specifically to the functional requirements is, in addition, enclosed in *T Appendix 1B*.

10.1 LAWS AND REGULATIONS

The table below provides a list of laws and regulations relevant for the EHR solution agreement. Note that this list is not exhaustive. For access to these laws and regulations, see www.lovdata.no. English versions of these laws and regulations, please see <http://app.uio.no/ub/ujur/oversatte-lover/>. However, the Contractor should be aware that these translated versions may not be updated.

Table 1 - Laws and regulations

ID nr.	Laws and regulations	Abbreviation	Link
L1	LOV-2014-06-20-42 Lov om behandling av helseopplysninger ved ytelse av helsehjelp	Pasientjournalloven	https://lovdata.no/lov/2014-06-20-42
L2	LOV-2014-06-20-43 Lov om helseregistre og behandling av helseopplysninger	Helseregisterloven	https://lovdata.no/lov/2014-06-20-43
L3	LOV-2000-04-14-31 Lov om behandling av personopplysninger ¹	Personopplysningsloven	https://lovdata.no/lov/2000-04-14-31
L4	LOV-1999-07-02-63 Lov om pasient- og brukerrettigheter	Pasient- og brukerrettighetsloven	https://lovdata.no/lov/1999-07-02-63
L5	LOV-1999-07-02-64 Lov om helsepersonell m.v.	Helsepersonelloven	https://lovdata.no/lov/1999-07-02-64
L6	LOV-1992-12-04-126 Lov om arkiv	Arkivlova	https://lovdata.no/lov/1992-12-04-126
L7	LOV-1999-07-02-61	Spesialisthelsetjenesteloven	https://lovdata.no/lov

¹ "Personopplysningsloven" will be deprecated and replaced with a new "personopplysningslov". Tentative date for this new law is 25. May 2018.

ID nr.	Laws and regulations	Abbreviation	Link
	Lov om spesialisthelsetjenesten m.m.		/1999-07-02-61
L8	LOV-2008-06-20-44 Lov om medisinsk og helsefaglig forskning	Helseforskningsloven	https://lovdata.no/lov/2008-06-20-44
L9	LOV-1999-07-02-62 Lov om etablering og gjennomføring av psykisk helsevern	Psykisk helsevernloven	https://lovdata.no/lov/1999-07-02-62
L10	FOR-2011-12-16-1258 Forskrift om etablering og gjennomføring av psykisk helsevern m.m.	Psykisk helsevernforskriften	https://lovdata.no/forskrift/2011-12-16-1258
L11	LOV-2015-05-07-25 Lov om donasjon og transplantasjon av organ, celler og vev	Transplantasjonslova	https://lovdata.no/lov/2015-05-07-25
L12	LOV-1994-08-05-55 Lov om vern mot smittsomme sykdommer	Smittevernloven	https://lovdata.no/lov/1994-08-05-55
L13	LOV-1995-01-12-6 Lov om medisinsk utstyr	Lov om medisinsk utstyr	https://lovdata.no/lov/1995-01-12-6
L14	LOV-1992-12-04-132 Lov om legemidler m.v.	Legemiddeloven	https://lovdata.no/lov/1992-12-04-132
L15	LOV-2011-06-24-30 Lov om kommunale helse- og omsorgstjenester m.m.	Helse- og omsorgstjenesteloven	https://lovdata.no/lov/2011-06-24-30
L16	LOV-1967-02-10 Lov om behandlingsmåten i forvaltningssaker	Forvaltningsloven	https://lovdata.no/lov/1967-02-10
L17	LOV-1992-09-25-107 Lov om kommuner og fylkeskommuner	Kommuneloven	https://lovdata.no/lov/1992-09-25-107
L18	LOV-1981-04-08-7 Lov om barn og foreldre	Barnelova	https://lovdata.no/lov/1981-04-08-7
L19	LOV-2000-06-23-56 Lov om helsemessig og sosial beredskap	Helseberedskapsloven	https://lovdata.no/lov/2000-06-23-56
L20	LOV-2011-06-24-29 Lov om folkehelsearbeid	Folkehelseloven	https://lovdata.no/lov/2011-06-24-29
L21	LOV-1970-01-16-1 Lov om folkeregistrering	Folkeregisterloven	https://lovdata.no/lov/1970-01-16-1
L22	LOV-2000-05-12-36 Lov om strålevern og bruk av stråling	Strålevernloven	https://lovdata.no/lov/2000-05-12-36
L23	LOV-2003-12-05-100k Lov om humanmedisinsk bruk av bioteknologi m.m.	Bioteknologiloven	https://lovdata.no/lov/2003-12-05-100
L24	FOR-2000-12-21-1385 Forskrift om pasientjournal av 21. desember 2000 nr. 1385	Forskrift om pasientjournal	https://lovdata.no/forskrift/2000-12-21-1385
L25	LOV-1981-05-22-25 Lov om rettergangsmåten i straffesaker	Straffeprosessloven	https://lovdata.no/lov/1981-05-22-25
L26	FOR-2000-12-15-1265 Forskrift om behandling av personopplysninger ²	Personopplysningsforskriften	https://lovdata.no/forskrift/2000-12-15-1265

² ["Personopplysningsforskriften"](#) will be deprecated on 25. May 2018.

ID nr.	Laws and regulations	Abbreviation	Link
L27	FOR-2015-07-01-853 Forskrift om IKT-standarder i helse- og omsorgstjenesten	Forskrift om IKT-standarder i helse og omsorg	https://lovdata.no/for-skrift/2015-07-01-853
L28	FOR-2014-12-17-1757 Forskrift om tilgang til helseopplysninger mellom virksomheter	Forskrift om tilgang til helseopplysninger	https://lovdata.no/for-skrift/2014-12-17-1757
L29	FOR-2007-12-21-1610 Forskrift om behandling av helseopplysninger i nasjonal database for elektroniske resepter	Reseptformidlerforskriften	https://lovdata.no/for-skrift/2007-12-21-1610
L30	FOR-2013-11-29-1373 Forskrift om håndtering av medisinsk utstyr	Forskrift om håndtering av medisinsk utstyr	https://lovdata.no/for-skrift/2013-11-29-1373
L31	FOR-2007-12-07-1389 Forskrift om innsamling og behandling av helseopplysninger i Norsk pasientregister	Norsk pasientregisterforskriften	https://lovdata.no/for-skrift/2007-12-07-1389
L32	FOR-2005-06-17-611 Forskrift om Norsk overvåkingssystem for antibiotikabruk og helsetjenesteassosierte infeksjoner	NOIS-registerforskriften	https://lovdata.no/for-skrift/2005-06-17-611
L33	FOR-2013-05-31-563 Forskrift om nasjonal kjernejournal	Kjernejournalforskriften	https://lovdata.no/for-skrift/2013-05-31-563
L34	FOR-2005-06-17-610 Forskrift om smittevern i helse- og omsorgstjenesten	Forskrift om smittevern i helsetjenesten	https://lovdata.no/for-skrift/2005-06-17-610
L35	FOR-2002-12-20-1731 Forskrift om internkontroll i helse- og omsorgstjenesten	Internkontrollforskrift i helsetjenesten	https://lovdata.no/for-skrift/2002-12-20-1731
L36	FOR-2000-12-15-1425 Forskrift om rapportering fra kommuner og fylkeskommuner	Forskrift om kommunal rapportering	https://lovdata.no/for-skrift/2000-12-15-1425
L37	FOR-2003-06-27-792 Forskrift om kvalitet i pleie- og omsorgstjenestene for tjenesteyting etter lov av 19. november 1982 nr. 66 om helsetjenesten i kommunene og etter lov av 13. desember 1991 nr. 81 om sosiale tjenester m.v.	Kvalitetsforskrift for pleie- og omsorgstjenestene	https://lovdata.no/for-skrift/2003-06-27-792
L38	FOR-2001-07-23-881 Forskrift om krav til beredskapsplanlegging og beredskapsarbeid mv. etter lov om helsemessig og sosial beredskap	Forskrift om krav til beredskapsplanlegging	https://lovdata.no/for-skrift/2001-07-23-881
L39	FOR-2004-06-25-988 Forskrift om elektronisk kommunikasjon med og i forvaltningen	eForvaltningsforskriften	https://lovdata.no/for-skrift/2004-06-25-988
L40	FOR-2011-08-22-894 Forskrift om kommunal beredskapsplikt	Forskrift om kommunal beredskapsplikt	https://lovdata.no/for-skrift/2011-08-22-894
L41	FOR-2011-12-16-1349 Forskrift om egenandel for kommunale helse- og omsorgstjenester	Forskrift om egenandel for helse- og omsorgstjenester	https://lovdata.no/for-skrift/2011-12-16-1349
L42	FOR-2012-08-29-842 Forskrift om fastlegeordning i kommunene	Forskrift om fastlegeordning i kommunene	https://lovdata.no/for-skrift/2012-08-29-842

ID nr.	Laws and regulations	Abbreviation	Link
			842
L43	FOR-2006-02-17-204 Forskrift om pseudonymt register for individbasert helse- og omsorgsstatistikk	Forskrift om IPLOS-registeret	https://lovdata.no/for-skrift/2006-02-17-204
L44	FOR-2003-04-03-450 Forskrift om kommunens helsefremmende og forebyggende arbeid i helsestasjons- og skolehelsetjenesten	Forskrift om helsestasjons- og skolehelsetj.	https://lovdata.no/for-skrift/2003-04-03-450
L45	FOR-2011-11-18-1115 Forskrift om kommunal betaling for utskrivingsklare pasienter	Forskrift om kommunal betaling, utskrivingsklare pasienter	https://lovdata.no/for-skrift/2011-11-18-1115
L46	FOR-2014-02-14-137 Forskrift om disponering av kontantytelser fra folketrygden under opphold i kommunal helse- og omsorgsinstitusjon og i helseinstitusjon i spesialisthelsetjenesten	Forskrift om kontantytelser fra folketrygden	https://lovdata.no/for-skrift/2014-02-14-137
L47	FOR-2009-10-02-1229 Forskrift om nasjonalt vaksinasjonsprogram	Forskrift om nasjonalt vaksinasjonsprogram	https://lovdata.no/for-skrift/2009-10-02-1229
L48	FOR-2000-12-01-1208 Forskrift om prioritering av helsetjenester, rett til nødvendig helsehjelp fra spesialisthelsetjenesten, rett til behandling i utlandet og om klagenemnd	Prioriteringsforskriften	https://lovdata.no/for-skrift/2000-12-01-1208
L49	FOR-2001-12-21-1476 Forskrift om innsamling og behandling av helseopplysninger i Dødsårsaksregisteret	Dødsårsaksregisterforskriften	https://lovdata.no/for-skrift/2001-12-21-1476
L50	FOR-2015-12-21-1813 Forskrift om dødsdefinisjon ved donasjon av organer, celler og vev	Forskrift om dødsdefinisjon ved donasjon	https://lovdata.no/for-skrift/2015-12-21-1813
L51	FOR-2005-02-04-80 Forskrift om tapping, testing, prosessering, oppbevaring, distribusjon og utlevering av humant blod og blodkomponenter og behandling av helseopplysninger i blodgiverregistre	Blodforskriften	https://lovdata.no/for-skrift/2005-02-04-80
L52	FOR-2015-12-07-1430 Forskrift om krav til kvalitet og sikkerhet ved håndtering av humane celler og vev	Forskrift om håndtering av humane celler og vev	https://lovdata.no/for-skrift/2015-12-07-1430
L53	FOR-2016-06-27-819 Forskrift om stønad til dekning av utgifter til undersøkelse og behandling hos leger	Forskrift om dekning av utgifter hos leger	https://lovdata.no/for-skrift/2016-06-27-819
L54	FOR-2015-12-07-1401 Forskrift om kvalitet og sikkerhet for humane organer beregnet for transplantasjon	Forskrift om humane organer til transplantasjon	https://lovdata.no/for-skrift/2015-12-07-1401
L55	FOR-2003-06-20-740 Forskrift om Meldingssystem for smittsomme sykdommer	MSIS-forskriften	https://lovdata.no/for-skrift/2003-06-20-740
L56	FOR-2000-12-01-1217 Forskrift om barns opphold i helseinstitusjon	Forskrift om barns opphold i helseinstitusjon	https://lovdata.no/for-skrift/2000-12-01-1217
L57	LOV-1998-07-17-56 Lov om årsregnskap m.v.	Regnskapsloven - rskl	https://lovdata.no/lov/1998-07-17-56

ID nr.	Laws and regulations	Abbreviation	Link
L58	LOV-2004-11-19-73 Lov om bokføring	Bokføringsloven	https://lovdata.no/lov/2004-11-19-73
L59	FOR-2007-06-29-742 Forskrift om genetisk masseundersøkelse av nyfødte	Forskrift om genetisk masseundersøkelse	https://lovdata.no/forskrift/2007-06-29-742
L60	FOR-2008-04-03-320 Forskrift om legemiddelhandtering for virksomheter og helsepersonell som yter helsehjelp	Forskrift om legemiddelhandtering	https://lovdata.no/forskrift/2008-04-03-320
L61	FOR-2007-12-21-1610 Forskrift om behandling av helseopplysninger i nasjonal database for elektroniske resepter	Reseptformidlerforskriften	https://lovdata.no/forskrift/2007-12-21-1610
L62	FOR-2015-03-20-231 Forskrift om krav til og organisering av kommunal legevaktordning, ambulansetjeneste, medisinsk nødmeldetjeneste m.v.	Akuttmedisinforskriften	https://lovdata.no/forskrift/2015-03-20-231
L63	FOR-2011-12-16-1256 Forskrift om habilitering og rehabilitering, individuell plan og koordinator	Forskrift om habilitering og rehabilitering	https://lovdata.no/forskrift/2011-12-16-1256
L64	FOR-2010-10-29-1380 Forskrift om strålevern og bruk av stråling	Strålevernforskriften	https://lovdata.no/forskrift/2010-10-29-1380
L65	FOR-2003-11-14-1353 Forskrift om innsamling og behandling av helseopplysninger i Norsk overvåkningssystem for resistens hos bakterier, sopp og virus	Resistensregisterforskriften	https://lovdata.no/forskrift/2003-11-14-1353
L66	FOR-1998-04-27-455 Forskrift om rekvirering og utlevering av legemidler fra apotek	Forskrift om legemidler fra apotek	https://lovdata.no/dokument/SF/forskrift/1998-04-27-455
L67	FOR-1998-12-11-1193 Forskrift om offentlege arkiv	Forskrift om offentlege arkiv	https://lovdata.no/dokument/SF/forskrift/1998-12-11-1193
L68	LOV-1997-02-28-19 Lov om folketrygd	Folketrygdloven	https://lovdata.no/lov/1997-02-28-19
L69	FOR-2016-03-18-268 Forskrift om Norsk helsearkiv og Helsearkivregisteret	Helsearkivforskriften	https://lovdata.no/forskrift/2016-03-18-268
L70	FOR-2007-06-28-814 Forskrift om stønad til dekning av utgifter til viktige legemidler mv.	Blåreseptforskriften	https://lovdata.no/forskrift/2007-06-28-814
L71	FOR-2009-12-18-1839 Forskrift om legemidler	Legemiddelforskriften	https://lovdata.no/forskrift/2009-12-18-1839
L72	Regulation (EU) 2016/679 of the European parliament and of the council of 27 April 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC	General data protection regulation (GDPR)	http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0679

ID nr.	Laws and regulations	Abbreviation	Link
L73	FOR-2016-12-20-1848 Forskrift om betaling frå pasientar for poliklinisk helsehjelp i spesialisthelsetenesta	Forskrift om pasientbetaling for poliklinisk helsehjelp i spesialisthelsetenesta	https://lovdata.no/for-skrift/2016-12-20-1848

10.2 APPLICABLE STANDARDS AND GUIDELINES

The table below presents an overview of selected standards and guidelines. Note that this list is not exhaustive. The purpose of providing the Contractor with this overview of standards and guidelines is to inform about some of the particular conditions that solution needs to operate within. For additional information regarding standards and guidelines that are relevant to health services in Norway, please refer to www.ehelse.no.

Table 2 - Standards and guidelines

ID nr.	Standards and guidelines	Comment	Link
SG1	Mandatory standards referred to in Referanse katalogen for E-helse, (e.g., IPLOS Funksjonell kravspesifikasjon)	Mandatory by law, cf. Forskrift om IKT-standarder i helse- og omsorgstjenesten.	https://ehelse.no/standarder-kodeverk-og-referanse-katalog/referanse-katalogen
SG2	The Code of Conduct for information security in the healthcare and care services	Mandatory for all organisations that have signed a connection agreement ("Tilknytningsavtale") with Norsk Helsenett.	www.normen.no
SG3	EPJ standard: Vedtak etter psykisk helsevernloven		https://ehelse.no/epj-standard-vedtak-etter-psykisk-helsevernloven-his-807022015
SG4	EPJ Standard: Tverrfaglig spesialisert behandling av rusmiddelmissbruk. Kravspesifikasjon og teknisk Standard		https://ehelse.no/epj-standard-tverrfaglig-spesialisert-behandling-av-rusmiddelmissbruk-his-10312011
SG5	Noark 5 Standard for Records Management	Noark 5 Standard for elektronisk arkiv	https://arkivverket.no/arkivverket/Offentleg-forvalting/Noark/Noark-5
SG6	National Register of Electronic Addresses	Adresseregisteret	https://ehelse.no/helseadministrative-registre/adresseregisteret
SG7	Volven		www.volven.no
SG8	EPJ Standard del 1 – 6 EPJ Standard del 1: Introduksjon til EPJ Standard (HIS 80505:2015) (PDF) EPJ Standard del 2: Tilgangsstyring, redigering, retting og sletting (HIS 80506:2015) EPJ Standard del 3: Journalarkitektur og generelt om journalinnhold (HIS 80507:2015) EPJ Standard del 4: Person, organisasjon mv (HIS 80508:2015)		https://ehelse.no/epj-standard-del-1-introduksjon-til-epj-standard-his-805052015



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	EPJ Standard del 5: Arkivuttrekk (HIS 80509:2015) EPJ Standard del 6: Felles funksjonelle krav (HIS 80510:2015)		
SG9	Veileder om medisinsk bruk av røntgen- og MR-apparatur		See especially Chapter 5 http://www.nrpa.no/dav/2e5ac2ed79.pdf
SG10	National quality indicators		https://helsedirektoratet.no/statistikk-og-analyse/kvalitetsindikatorer
SG11	Samhandlingsreformen. Rett behandling – på rett sted – til rett tid	St.meld. nr. 47 (2008-2009)	https://www.regjeringen.no/no/dokumenter/stmeld-nr-47-2008-2009-/id567201/
SG12	The Norwegian Patient Safety Programme: In Safe Hands		http://www.pasientsikkerhetsprogrammet.no/
SG13	WHO Surgical Safety Checklist		http://www.who.int/patientsafety/safesurgery/checklist/en/
SG14	National health preparedness plan		https://www.regjeringen.no/no/dokumenter/Nasjonale-helseberedskapsplan/id761213/
SG15	Veileder om legemiddelgjennomganger		https://helsedirektoratet.no/retningslinjer/veileder-om-legemiddelgjennomganger
SG16	DRG-systemet		https://helsedirektoratet.no/finansieringsordninger/innsatsstyrt-finansiering-isf-og-drg-systemet/drg-systemet
SG17	Innsatsstyrt finansiering (ISF)		https://helsedirektoratet.no/finansieringsordninger/innsatsstyrt-finansiering-isf-og-drg-systemet/innsatsstyrt-finansiering-isf
SG18	Takster for å fremsette refusjonskrav overfor HELFO		https://ehelse.no/takster
SG19	Strategi for persontilpasset medisin i helsetjenesten	Helsedirektoratet (2016), Nasjonal strategi for persontilpasset medisin i helsetjenesten 2017-2021 (IS-2446)	https://helsedirektoratet.no/Lists/Publikasjoner/Attachments/1192/Nasjonale%20strategi%20for%20persontilpasset%20medisin%20i%20helsetjenesten%20IS-2446.pdf
SG20	ISO/IEC/IEEE 29119 Software Testing		http://www.softwaretestingstandard.org/in



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			dex.php
SG21	Scorm 1.2, Scorm 2004 4 th edition, technical standard for e-learning	SCORM is a set of technical standards for e-learning software products.	http://www.scorm.com/
SG22	EU-forordningen for eID og tillitstjenester		https://www.regjeringen.no/no/dokumenter/gjennomforing-av-eus-forordning-om-elektronisk-identifisering-eid-og-tillitstjenester-for-elektroniske-transaksjoner-i-det-indre-marked---horing/id2464892/
SG23	Standards and guidelines: Standard for arkivavlevering av elektronisk pasientjournal til Norsk helsearkiv (EPJARK)		http://www.arkivverket.no/arkivverket/Arkivverket/Helsearkiv/Digital-avlevering-av-EPJ/Standarder-EPJ-avlevering