

Laws and statutes

Wellbeing applications linked with Kanta PHR must conform to prevailing laws, decrees and statutes. It is necessary to review these provisions as part of the application development process:

- [Act on the Electronic Processing of Client Data in Healthcare and Social Welfare \(the Client Data Act\) \(703/2023\) \(finlex.fi\)](#) (in Finnish)

Kanta PHR and the related wellbeing applications are based on the Client Data Act. In accordance with section 73 of the Client Data Act, a person can use wellbeing applications or a citizen interface to enter and process their wellbeing data in Kanta PHR, where they can utilise the data to promote their wellbeing. The person has the right to decide on the use, amendment and deletion of their own data in Kanta PHR. According to section 73 of the Client Data Act, Kela is the data file controller for the use of wellbeing data entered in the Kanta PHR service, which is part of the national information system services (Kanta Services). Kela is also the organiser of national information system services, such as Kanta PHR.

Chapter 12 of the Client Data Act provides for the key requirements for wellbeing applications, among other things. Wellbeing application providers are responsible for the design and production of the application, for example. The wellbeing application must be certified in accordance with the Client Data Act.

- [EU General Data Protection Regulation \(GDPR\) 2016/ 679 \(eur-lex.europa.eu\)](#) (in Finnish)

The GDPR is the law governing the processing of personal data. The GDPR provides for the protection of natural persons with regard to the processing of personal data and on the free movement of such data. The Regulation specifies how individuals, companies and organisations are to handle personal data. European Commission guidelines for applying the Regulation are available on the website [Reform of EU data protection rules \(ec.europa.eu\)](#).

- [Data Protection Act 1050/2018 \(finlex.fi\)](#) (in Finnish)

As a national law, the Data Protection Act supplements the EU's General Data Protection Regulation. Governs the protection of basic privacy rights in the context of handling personal data. Also intended to drive development of and compliance with best practices in the area of information processing. The Act is primarily applied to the automatic processing of personal data and to registries containing personal data. The Data Protection Act is applied within the scope of application of Article 2 of the GDPR to automated processing of personal data and personal data files, for example.

- [National Institute for Health and Welfare regulations to harmonise the requirements for information management within social services and healthcare \(thl.fi\)](#) (in Finnish)

The National Institute for Health and Welfare in Finland has issued regulations which are designed to harmonise the requirements that information systems and information management solutions used in social services and healthcare must meet. The regulations concern the functionality, interoperability and information security of the solutions.

[Regulation 6/2021: The certification and key requirements of wellbeing applications linked with Kanta PHR \(PDF 400 kB\) \(thl.fi\)](#) (in Finnish)

[Appendix 1: Key requirements for wellbeing applications \(xls 213 KB\) \(thl.fi\)](#) (in Finnish)

- [Medical devices \(fimea.fi\)](#)

Fimea supervises the regulatory compliance of medical devices and the operators in the sector in Finland.

- [Act on Certain Medical Devices Specified in EU Directives 629/2010 \(finlex.fi\)](#) (in Finnish)
- [Privacy code of conduct on mobile health apps \(digital-strategy.ec.europa.eu\)](#)

EU Commission guidelines on the information security of mobile health applications. The guidelines are referred to in the key requirements for wellbeing applications to be linked with Kanta PHR and in the security audits of these applications.