

## Laws and statutes

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

- [EU General Data Protection Regulation 2016/ 679](#)

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](#).

- [Data Protection Act 5.12.2018/1050](#) (in Finnish)

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.

- [National Institute for Health and Welfare regulations to harmonise the requirements for information management within social services and healthcare](#) (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 1/2015: Key information security requirements applicable to Class A information systems used within social services and healthcare](#) (in Finnish)

[Appendix 1: Information security requirements applicable to Class A systems and operating environments \(PDF 326 KB\)](#) (in Finnish)

- [Specification of the purpose of use of healthcare equipment and materials](#) (in Finnish)

Guidelines issued by the National Supervisory Authority for Welfare and Health (Valvira) for the specification of the purpose of use of healthcare equipment

- [Andalucia application certification requirements](#)

A compendium of recommendations for the design, use and evaluation of mobile health applications, designed to improve the quality and safety of such applications. The recommendations relevant to wellbeing applications are part of the approval criteria for applications which are proposed to be integrated with Kanta PHR.

- [Code of Conduct on privacy for mHealth apps](#)

EU guidelines on the information security of mobile health applications. The guidelines are referred to in the approval criteria for applications which are proposed to be integrated with Kanta PHR.

A government bill for a new Client Data Act is undergoing parliamentary review. Once ratified, it must be taken into account when developing wellbeing applications.

- [Government bill for an Act on the Electronic Processing of Client Data in Healthcare and Social Welfare](#). The Act forms the basis for the specification of Kanta PHR and, consequently,
  - the personal consent to allow professionals to access one's wellbeing data
  - the release of data for research purposes, subject to the consent of the person concerned
  - the utilisation of Kanta client data stored in wellbeing applications, subject to the consent of the person concerned
  - acting on behalf or with the authorisation of a minor