

Terms of supply for application suppliers

Kanta PHR

Kela, Kanta Services 12.2.2024





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Change history

Versio	Change	Made by	Date
1.0	First version of the terms of supply of a wellbeing application supplier	Kela, Kanta Services	12.2.2019
1.1	Sections 2, 3.1 and 4.1 have been specified. Section 4.1.1 "Integration service" and section 4.1.2 "Wellbeing application as a data-transmit- ting application" have been added. Also small changes and corrections.	Kela, Kanta Services	13.2.2020
2.0	Changes by virtue of the Client Data Act	Kela, Kanta Services	1.11.2021
2.1	Addition of storage of wellbeing data in MyKanta	Kela Kanta services	12.2.2024



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1 Description of the service

1.1 Parties using the service

The administrator and controller of the Kanta Personal Health Record (Kanta PHR) is the Social Insurance Institution of Finland (hereinafter "Kela").

Contact details:

Kela, Kanta Services

Telephone: 020 634 11 (switchboard)

Postal address: P.O. Box 450, 00056 Helsinki Street address: Nordenskiöldinkatu 12, Helsinki

Email: kanta@kanta.fi

Website: kanta.fi

The user of Kanta PHR (hereinafter the "user") may be every natural person who has a Finnish personal identity number.

The manufacturer of a wellbeing application (hereinafter the "application supplier") that has implemented the wellbeing application that enables the use of Kanta PHR and that accepts these terms of supply and the service description with its commitment.

1.2 Description of the service

Kanta PHR (hereinafter the "service") is part of the Kanta Services. Kanta PHR is a national data repository in which users can enter their own wellbeing data. Wellbeing data means data, which is produced and entered by the user themselves concerning their health and wellbeing and which they have entered in Kanta PHR with a wellbeing application or through MyKanta. The user can utilise the data they have entered for the promotion of their wellbeing.

The purpose of using wellbeing data is related to the promotion of the user's wellbeing and health. At the time of entering the data, the user assesses the significance of the data to be recorded in terms of their wellbeing. Wellbeing data means, for example, various measurement data (e.g. blood pressure, respiration rate), symptom evaluations, examinations and self-care plans.



The service is used in Mykanta and with wellbeing applications approved in accordance with the Client Data Act. The procedure related to the approval of wellbeing applications is laid down in the Client Data Act. Approved wellbeing applications can be viewed in the application list published on the kanta.fi website.

The user can enter their wellbeing data in the service and process it in MyKanta or with all the wellbeing applications to which they have granted user rights. The functionalities and the data content to be entered depend on the wellbeing application and its features. The user can also record, view and delete their data in the service via MyKanta.

Further information about the service is available to citizens in <u>the Wellbeing data</u> of the kanta.fi website and to application suppliers and system developers on the Kanta PHR page.

2 Purpose of the terms of supply

These terms of supply are applied to the Kanta PHR service. The terms of supply describe the relationship between Kela and the application supplier. Kela owns the rights to the service.

The application supplier must sign a commitment and accept these terms of supply and the terms of use of the service before the wellbeing application implemented by the application supplier can be connected to the Kanta PHR production environment and published in the Kanta PHR application list on the kanta.fi website.

The service does not include the right to use the Kanta logo or other Kanta or Kela emblems. The application suppliers must agree on the use of these separately in writing with Kela.

3 Kela's responsibilities and obligations

3.1 Maintenance of Kanta PHR

Kela is responsible for

maintaining the service, such as storing the data and ensuring the technical operation of the service to prevent the processing or sharing of well-being data via the service in contravention of the law or the EU's General Data Protection Regulation.

- deleting the data in accordance with the Client Data Act five years after the person's death if the user themselves has not deleted the data they have saved.
- the development process of the national data content of the service, and the maintenance and development of the service. Kela is entitled to make technical changes to the contents and implementation of the service.
- ensuring that the use and sharing of wellbeing data are recorded in the log register, as well as for keeping and destroying the log register.

Kela must not assign the task of data storage to outsiders and the data must not be transferred outside Finland. However, Kela may use subcontractors in the production and maintenance of the service as prescribed in section 14 of the Client Data Act.

Kela can integrate the wellbeing application with Kanta PHR (for production) when the wellbeing application meets the certification requirements and its data is found in Valvira's register for information systems.

Kela has the right to change the contents and terms of the service, for example, for the following reasons:

- · changes in legislation or in the interpretation of law
- instructions, orders or decisions issued by the authorities
- general changes in the operating environment of healthcare and social welfare
- changes in the technical operating environment
- ensuring the development, availability and data security of the Kanta Services
- other reasons related to the Kanta Services or the operation of a provider of the Kanta services

Kela is not responsible for

 the operation of the application suppliers or for any other errors or negligence in the production or use of the service which are due to the application suppliers.



- applications or information systems approved for the use of the service, their functionalities, maintenance, problems related to their use or the accuracy of data collected by them, and it is not responsible for their support services unless the problems in question are due to a reason attributable to Kela.
- the operation of other parties or errors or negligence in the provision or
 use of the service that are attributable to other parties, nor for any indirect
 or direct damage caused by the use of the service or an error, deficiency
 or fault in the service unless otherwise provided by mandatory law.
- the independent gathering of data by other parties into their own registers in addition to using the service and the use of the data in the registers and sharing it from there with other parties.

Kela will inform of new versions of client documents, the entry into force of changes, and measures required of the client on the kanta.fi website unless it is deemed appropriate in individual cases to notify of the matter in another way.

The time of entry into force of the changes is shown from the date of the client documents. The changed terms of supply and service descriptions are also applied to commitments that have been drawn up before the changes enter into force.

Kela aims to act in such a way that the service is available without interruption with the exception of unexpected technical faults. However, Kela may temporarily suspend the provision of the service for the duration of modification or repair tasks or general data communication outages or for the duration of data security breaches. Efforts will be made to implement interruptions caused by necessary update, maintenance or other similar tasks necessary for the functioning of the service in a planned way by notifying of the matter in advance, if possible. Kela aims to notify application suppliers of interruptions as early as possible.

Kela may close or suspend the connection of an application produced by an application supplier to the service also if the application supplier is in breach of these terms of supply or if an application supplier's wellbeing application integrated with the service or its user organisation jeopardises the appropriate functioning of national information system services. In these cases, the connection to the service will be closed until the application supplier can prove in a reliable manner that the situation has been remedied.



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3.2 Data communication interface and message delivery

Kela offers interfaces to the service for application suppliers. Kela is responsible for the functioning only from the interfaces towards the service environment. The interface enables the integration of the wellbeing applications implemented by application suppliers with the service, and it is responsible for sending and receiving messages. The data is deemed to have been received when the Kanta service has received the data and the wellbeing application has received an acknowledgement of receipt from Kela. In terms of server-based wellbeing applications, data communications between the service environment and the application supplier are encrypted with a certificate granted by the Digital and Population Data Services Agency.

3.3 Processing of personal data

In the processing of personal data, Kela complies with the EU's General Data Protection Regulation and the national Data Protection Act. More detailed information about the processing of personal data in the Kanta PHR service is available in the privacy policies.

3.3.1 Client register of the Kanta Services

Data related to the client account of the application suppliers and the contact details are entered in the client register of the Kanta Services. The client register of the Kanta services is a dataset maintained by the clients themselves and used for customer service and contacts between Kela and the client. The client register contains the contact details (e.g. name, address data, telephone number, role of contact person) related to the development and maintenance of the application supplier's wellbeing application (e.g. fault notice) and joint testing, as well as technical contact details (e.g. access point and system data) in relation to the Kanta PHR service. The provision of information is carried out by the client support of Kela and the Kanta Services.

The data in the client register of the Kanta Services is retained for 10 years after the client account has been terminated, after which the data will be destroyed. The original signed commitment documents shall be stored in Kela's document archive for 10 years after the termination of the client account, after which the data will be destroyed.

The application supplier undertakes to inform its contact persons of the above-mentioned processing and sharing of data.



Kela will receive the information from the application supplier by email. As a rule, the data is not shared or transferred outside the EU or the European Economic Area. Kela may share the contact details of the application supplier with other authorities taking part in the provision of Kanta Services if it is necessary in terms of the use of the Kanta Service.

Kela delivers to the Kanta Services – Information System and Application Supplier Register of the National Code Service of the Finnish Institute for Health and Welfare (THL) information about the application supplier (e.g. organisation name, postal address, business ID) after the application supplier has submitted the wellbeing application for joint testing in Kanta PHR and updates the information when the wellbeing application has been approved as part of the production environment.

Kela publishes the contact details of the application supplier and the data of the wellbeing application approved for Kanta PHR in the Kanta PHR application list on the kanta.fi website.

3.4 Maintenance and sharing of log data

Kela gathers log data on the use of Kanta PHR (<u>privacy policies</u>). The log data is not shared with the application suppliers. The retention time of log data is 12 years from the creation of log data, after which the data is destroyed.

3.5 Support for Kanta Services

Kela is responsible for support and advice with regard to the Kanta Services (Kela's technical support). Kanta support offers support services for citizens and application suppliers with respect to the use of and technical problems with Kanta PHR. The contact details of support are available on the kanta.fi website.

Support of the Kanta Services has been organised in accordance with practices and processes by virtue of the ITIL framework. Application suppliers use one joint service point for all contacts regarding the Kanta Services.

3.6 Provision of information

Information about the Kanta PHR service is provided on the kanta.fi website and by other means supporting communications, e.g. by email.

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4 Application supplier's responsibilities and obligations

4.1 Wellbeing application

The wellbeing applications implemented by the application supplier must comply with the laws, decrees and regulations valid at the given time and meet the national requirements, including certification requirements and specifications in the way they are valid at the given time. The application suppliers (manufacturers) of the applications and devices connected to Kanta PHR are responsible for correct functioning of the applications.

The application supplier is responsible for the following issues related to the wellbeing applications it has implemented:

- certification according to the Client Data Act and meeting the certification requirements and their costs (including the accessibility of the wellbeing application).
- appropriate testing of the service interfaces used in accordance with Kela's instructions. The application supplier is responsible for the joint testing of Kanta PHR, the accuracy of the information it has provided and the updating of the information.
- · data protection and information security.
- verification and approval of the requirements and, if necessary, certification (including joint testing and auditing of information security).
- towards its own clients, all matters related to the production and supply of
 the wellbeing application and the related notifications and support services. The application supplier must, e.g. notify of any maintenance outages and disruptions related to the wellbeing application and provide instructions in relation to them, as well as clarify any error situations related
 to the functioning of the wellbeing application.
- instructions for use and keeping the instructions up-to-date, and for delivering the instructions to users, as well as training on the wellbeing application for users.
- terms of service to its own clients. The application supplier must ensure
 that the user has become acquainted with the purpose of use and terms of
 use of the wellbeing application before starting the use of the wellbeing
 application.



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The application supplier is responsible for ensuring that it is entitled to use the user data in the service according to existing legislation. Based on the Client Data Act, Kela does not have the right to share data in Kanta PHR with application suppliers or other than the citizens themselves. The application suppliers do not have the right to process data entered in Kanta PHR pertaining to Kela's controllership.

The application supplier is responsible for ensuring that it is not possible to connect electronic material to the service with the wellbeing application that would disturb the functioning of the service, that is unsuitable for its purpose of use, that contains viruses or that infringes copyright or other rights.

The application supplier is responsible for the collection of user data into its own registers that it may carry out independently in addition to the use of the service, for the use of data in these registers and sharing it with other parties, as well as for informing the user of the collection of the data. The application supplier is obliged to notify the users of its wellbeing application if the wellbeing data is also recorded elsewhere than in the service.

The application supplier must monitor any changes to the key requirements for wellbeing applications and carry out the modifications required by the changes. Any key changes to the wellbeing applications must be reported to Kela by email to kanta@kanta.fi as well as to an information security inspection body so that the joint testing need of the application and its need for information security audit can be reassessed. The information security inspection body and Kela must be contacted in accordance with THL's regulation 4/2024 before the certificate or conformity certificate concerning the information security audit on the wellbeing application expires.

The application supplier is responsible for applying for the required certificate for a serverbased wellbeing application to be linked to the Kanta PHR service and for its administration.

4.1.1 Integration service

An integration service is a service that combines data into the Kanta PHR from different devices and/or applications. An integration service may be, for example, a service combining data from several self-measurement devices or a service transmitting data from a health-monitoring platform. The integration service is also subject to applicable criteria other than those where the integration service is mentioned separately.



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When a wellbeing application acts as an integration service, the application supplier is responsible for

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- the devices and/or applications that have joined the integration service where they have not joined Kanta PHR themselves
- notifying Kela if there are any problems with an application and/or device that has joined the service that may have an impact on Kanta PHR

4.1.2 Wellbeing application as a data-transmitting application

A data-transmitting application is a service that transmits data from Kanta PHR to various devices and/or applications. A data-transmitting application is also subject to applicable criteria other than those where the application is mentioned separately. As the controller of Kanta PHR, Kela does not have the right to share the data entered in Kanta PHR with third parties.

The application supplier must meet the following conditions when the wellbeing application acts as a data-transmitting application.

- it is responsible for other applications and/or devices connected to the application in accordance with the instructions and requirements provided, including certification requirements
- it must notify Kela if there are any problems with another application and/or device that has connected to the application with respect to meeting the requirements (for example, in the information security or data protection requirements) and, if necessary, block the use of another application and/or device that has connected to it, as well as its connections to Kanta PHR
- it must notify Kela of all applications and/or devices that are connected to it
 and their purposes of use, and to keep Kela up-to-date with regard to
 changes in the applications and/or devices that have connected to it (for
 example, new or removed applications and/or devices and changed purposes of use)
- it must request the user for their consent to transmitting the data in accordance with the EU General Data Protection Regulation.



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4.2 Validity of the data

The application supplier shall undertake to inform the user of the fact that it is responsible for the contents of wellbeing data they enter in the service.

The application supplier is responsible for

- ensuring that data entered in Kanta PHR with the application will not be altered by the application and that the application in itself will not prevent the accessibility of the recorded data.
- ensuring that the deletions of wellbeing data and the access rights of wellbeing applications made by the user in My Kanta Pages will be transmitted in the correct format to the application itself and to the other services connected to it.

4.3 Legality and monitoring of the processing of personal data

The application supplier is responsible for complying in its own operations with the EU General Data Protection Regulation, the Data Protection Act and other regulations related to the processing of personal data and for requiring that its users, personnel and subcontractors do the same. As the controller of its data, the application supplier is responsible for implementing the procedure relating to personal data breaches in accordance with Articles 33 and 34. In data protection and information security deviations, the application supplier must act in accordance with the key requirements related to certification.

Currently, based on the Client Data Act, Kela does not have the right to share data in Kanta PHR with application suppliers or others, only with the citizens themselves. The application suppliers do not have the right to process data entered in Kanta PHR pertaining to Kela's controllership.

The application supplier is responsible for the legality of the processing of personal data and for the monitoring and supervision of the legality of data processing in terms of its own organisation and the subcontractor it uses as prescribed by law.

4.4 Application supplier's technical operating environment

The application supplier is responsible for:



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- the procurement, costs, maintenance, technical functioning and use of equipment, software and data communications links of the wellbeing application to be connected to the Kanta Services, as well as for all its own costs of using the Kanta services.
- the delivery of data entered in the service from the end user to the interface provided by the Kanta Services.
- technical solutions used at its own expense to the interface offered by Kela, as well as for their maintenance and support services.
- time services of its own applications and information systems.
- the acquisition, maintenance and certificate revocation list processing of certificates required for the recognition, identification and signing of its own organisation and servers it uses in accordance with the certification policy of the Digital and Population Data Services Agency.

4.5 Notification of data and changes concerning the application supplier

The application supplier is responsible for ensuring that the data concerning itself is always up-to-date in the Kanta Services.

The application supplier must deliver to Kela, upon request, an account of complying with these terms of supply and the terms of the service description.

The application supplier is responsible for ensuring that Kela will receive

- information about ceasing of operations as an application supplier at least one month before the changes enter into force.
- information about the application supplier's decision to discontinue a wellbeing application or withdrawing it from the market at least one month before the changes enter into force.
- information about changes concerning technical connection data of the application supplier at least two weeks before the changes enter into force.
- at least one week before, information about such pre-agreed maintenance outages of the wellbeing application implemented by the application supplier, which have a significant impact on the use/accessibility of the Kanta PHR service and on customer support.
- without delay, information about extensive disruptions in the wellbeing application implemented by the application supplier, which result in a long



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interruption in the use of the application and which have an impact on the accessibility of Kanta PHR.

 information about changes concerning the client data of the application supplier (up-to-date data on contact persons and other contact details).

The client data is notified by email to kanta@kanta.fi. The application supplier is responsible for the accuracy of the data it has notified and for the fact that the application supplier has the right to share the data with Kela.

4.6 Reporting of disruptions, errors and deviations, and monitoring

If the application supplier notices a disruption or error situation related to the functioning of the Kanta Services, it is obliged to notify Kela of it via the Kanta Services support referred to in section 3.5.

If Kela notices a disruption or error situation, which may be caused by a wellbeing application implemented by the application supplier or by the action of a user of the application, Kela may demand that the application supplier provides an account of the reason of the disruption or error situation and oblige the application supplier to take part in the investigation of the disruption or error situation.

The application supplier undertakes to act in disruptions and error situations in accordance with Kela's instructions and to comply with <u>the instructions concerning disruptions and error situations</u> in the Kanta Services published on the Kanta website.

The application supplier must notify all users of the wellbeing application of significant deviations in the wellbeing application. The application supplier must notify Kela and Valvira of significant deviations in the wellbeing application.

The application supplier must monitor and assess the experiences of using the wellbeing application during production use with an up-to-date, systematic procedure.

4.7 Application supplier's partners and subcontractors

The application supplier is responsible for the action and negligence of the partners and subcontractors it uses in the implementation and provision of the wellbeing application in the same way as for its own action and negligence.



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5 Other parties taking part in the provision of the Kanta Services

The following information systems from parties other than Kela are used in the production of the Kanta Services:

- Healthcare certification services (the Digital and Population Data Services Agency DVV)
- Role and attribute service (the National Supervisory Authority for Welfare and Health Valvira)
- National Code Service (the Finnish Institute for Health and Welfare THL)

The following other parties take part in the production, guidance and supervision of the Kanta Services:

- Digital and Population Data Services Agency (DVV)
- National Supervisory Authority for Welfare and Health (Valvira)
- Finnish Transport and Communications Agency Traficom
- National Institute for Health and Welfare (THL)
- Finnish Medicines Agency Fimea
- Ministry of Social Affairs and Health (STM)

The general guidance and supervision of the certification services in healthcare and social welfare services managed by DVV are the joint responsibility of STM and the Ministry of Finance (VM).

For its part, the Data Protection Ombudsman guides and supervises the enforcement of the Act on the Electronic Processing of Client Data in Healthcare and Social Welfare and the Act on Electronic Prescriptions in accordance with the powers provided for it.

Regional State Administrative Agencies guide and supervise the enforcement of the Act on the Electronic Processing of Client Data in Healthcare and Social Welfare and the Act on Electronic Prescriptions in accordance with the powers provided for them.

6 Misconduct, negligence and liabilities

If Kela notices any negligence or misconduct in the activities of the application supplier, the supervision of which is the responsibility of the supervisory authority referred to in section 5, Kela shall notify the authority concerned of the negligence or misconduct.



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If a significant error or problem arises in a wellbeing application implemented by the application supplier, having an impact on the functioning of the Kanta Services, the application supplier must correct the error without delay and, if necessary, prevent access to the service until the error has been corrected.

If the data protection or client or patient safety may be compromised by a wellbeing application and the deficiencies have not been redressed within the prescribed period set by the supervisory authority, the supervisory authority may ban the use of the wellbeing application until the feature that compromises safety has been redressed. Kela may block the wellbeing application's access to the Kanta services it maintains if the functioning of national information system services is compromised by a wellbeing application connected to them or by its user organisation. The connection to the Kanta Services will be closed until the application supplier can prove in a reliable manner that the situation has been remedied.

Kela is not responsible for any indirect or direct damage caused by the use of the Kanta service or by an error, deficiency or fault in the service unless otherwise provided by mandatory law.

The application supplier is responsible for any faults, errors and deficiencies caused by its wellbeing application and for the extra costs and expenses incurred by them to Kela. These costs and expenses may incur from investigation measures and remedial measures carried out due to the faults, errors and deficiencies. Kela has the right to demand compensation from the application supplier for such costs and expenses after notifying the application supplier of the matter in advance.

If the application supplier or a third party acting on behalf of the application supplier has caused a fault, error or deficiency through wilful conduct, serious negligence or criminal acts (e.g. denial-of-service attack), Kela has the right to demand for and the application supplier is obliged to compensate Kela in full for the loss and for the extra costs resulting from the conduct.

If personal data has been processed unlawfully, the application supplier is obliged to take the necessary measures on its own initiative.

Criminal liability is provided for by the Criminal Code of Finland (39/1889). Furthermore, administrative sanctions are defined in the EU's general data protection regulation.



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7 Charges collected by Kela concerning the use of the Kanta Services, and their invoicing

User charges collected on the use of statutory Kanta services and the due dates of the charges are determined by the decree of the Ministry of Social Affairs and Health valid at any given time.

For the present, Kanta PHR is a free service to the user and the application supplier.

8 Connecting a wellbeing application to Kanta PHR and termination of the application

A wellbeing application can be deployed for production use and connected to Kanta PHR after the wellbeing application meets the certification requirements, its data is found in the Valvira register of information systems, and the wellbeing application's certificate on data security audit is in force. A wellbeing application produced by an application supplier is connected to the production environment of the Kanta PHR service, and the obligations by virtue of the terms of supply and the service descriptions will enter into force after the application supplier has provided a signed commitment and, as part of the commitment, accepted these terms of supply and the service description of the service with its terms. The commitment is signed by a person with a procuration right in accordance with an extract from the trade register, an extract of the register of foundations, an extract of the register of associations, or an extract of the minutes of the administrative body deciding on the application supplier's procuration right. In addition, the application supplier must deliver other required information necessary for production use (e.g. in relation to the application and the application supplier's contact points) within the agreed schedule.

Service-specific instructions on the termination of the use of the service are described in the service description, which is appended to the commitment.