TECHNICAL SPECIFICATION

ISO/TS 23535

Health informatics — Requirements for customer-oriented health cloud service agreements

Contents

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Healthcare services go beyond the boundaries of physical providers, such as clinics or hospitals. Cloud computing, cognitive computing, virtual reality/augmented reality, IoT, robot and wearable devices have contributed to enhanced accessibility and provide value to customer health, addressing customer demand for tailored healthcare services. Modern ICT is the catalyst to the promotion of customer engagement and empowerment, especially through cloud-based services.

Cloud computing offers shared and configurable collections of computing resources and services that, typically over the Internet, are made available with minimal management effort. It eliminates the distinction between the physical and virtual resources by providing access from various devices such as wearable, wellness devices and mobile phones. There are six key characteristics of cloud computing:

— broad network access,

— measured service,

— multi-tenancy,

— on-demand self-service,

— rapid elasticity and scalability, and

— resource pooling;

and three service models:

— Software as a Service(SaaS),

— Platform as a Service (PaaS), and

— Infrastructure as a Service (IaaS).

Cloud computing is expected to bring substantial and practical impact to healthcare services from a customer perspective. Customers may enjoy by a contract customer-centric health services from the cloud provider. The cloud provider offers a variety of benefits to its customers, such as predictive disease analytics and evidence-based management of chronic diseases.

Health cloud services have evolved into a knowledge platform on which customer health data, including generic data, are collected through multi-model data collection channels, and are made accessible anywhere by any device or application. These data are analysed by sophisticated analytical techniques such as artificial intelligence and inform personalized health-related advice and insights.

Health cloud services deal with critical and sensitive information related to life and health and are subjected to regulations such as HIPPA and GDPR. The quality and quantity of services vary, depending upon operating environments, supported devices, available intelligent analysis capacities, and service level agreements. Regardless of the duration of a service contract with the health cloud provider, it is important to establish standards for a minimum set of cloud service functions that ensures customer protection.

When a customer holds contracts with multiple health cloud service providers, it is important to ensure consistency of shared data between the providers. A clear demarcation of liability may be hard to obtain in a disastrous event when the customer subscribes to various cloud service models. In case of migrating from one service provider to another, there should be a method to validate the migration is carried out in compliance with health-industry-specific criteria (e.g., rules on customer health data transfer or deletion).

Healthcare is under transformation - manifested by the departure from the traditional face-to-face healthcare services between stakeholders, such as hospitals, caregivers, and patients. In addition, the general acceptance of customer empowerment is enabled by widespread dissemination of web technology and cloud computing, creating various healthcare services such as virtual hospitals,

telehealth, online visit, and mobile health management. Health cloud services offer computer-customer interviewing, home telehealth, and health monitoring through wearable/wellness devices.

The purpose of this document is to classify key characteristics of a cloud service agreement from the perspectives and interest of the customer and to provide an agreement list pivotal to the provision of customer-oriented healthcare service.

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1 Scope

This document describes a core set of cloud service agreements for customer-oriented health cloud services.

This document covers a customer-oriented cloud service agreement that can be used in healthcare organizations and public health centers that use health cloud services.

This document defines key characteristics in the health cloud service agreement that are indispensable in providing optimal health/healthcare management functionalities. Privacy and security features are considered outside the scope of this document and are covered in ISO/TR 21332.

The purpose of this document is to present matters to be considered (e.g., cloud type, components, key characteristics) by stakeholders involved in the implementation of cloud computing in hospitals or healthcare organizations. The potential users of this document are mainly 1) IT managers of hospitals, 2) hospital management, and 3) cloud service providers and cloud partners that provide services to healthcare institutions.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
application capabilities type
cloud capabilities type (3.2) in which the *cloud service customer* (3.9) can use the *cloud service provider's* (3.10) applications

[SOURCE: ISO/IEC 17788:2014, 3.2.1]

3.2
cloud capabilities type
classification of the functionality provided by a *cloud service* (3.5) to the *cloud service customer* (3.9) based on resources used

[SOURCE: ISO/IEC 17788:2014, 3.2.4]

3.3
customer-oriented
relating to the needs and interests of individual customers, including businesses