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LEGAL ISSUES OF MEDICAL DATA PROCESSING BY CLOUD COMPUTING

The concept of cloud computing appears increasingly more often in all entities that function in the healthcare sector. That refers both to the patients, the service providers and the system regulator, i.e. the Parliament, the Ministry of Health and its departments. The healthcare sector provides for the development of major projects with the application of a cloud computing model, e.g. computerization of medical records¹, starting from 1.08.2018, as the only acceptable form of medical documentation and the introduction is expected of widespread reporting by medical entities on every patient's visit in the form of messages sent to the System of Healthcare Information, which is based on a cloud computing system. There are plans for the nearest future to apply cloud computing as regards e-prescriptions, referrals and orders. Work is also conducted on the development of e-sick leaves. The entities that are deeply involved in computerization and bear the cost burden of the changes face the necessity to choose the tools of health data processing that are most effective and economically beneficial from their perspective. It seems that cloud computing is the most natural option.

Thus, a question arises about the legal condition of the entity that is going to, or already is, process² the data in the cloud and whether such operations are legal in the light of current legal regulations. The situation is made even more complicated as there is no official opinion on that subject given by institutions that are responsible for healthcare data, which belong to the group of so called sensitive data³.

In Poland there are no regulations concerning data processing, health data including, by the technology of cloud computing. However, the lack of solutions concerning that problem

¹ Act of 26 June 2014 on amendments to the Act on information systems in healthcare Dz.U. (Journal of Laws) of 2014, item 998

² Art.7 pt 2 : data processing is understood as any operations on personal data such as data collection, recording, developing, altering, sharing and deleting, especially when conducted in information systems Act of 29 August 1997 on personal data protection. Dz.U. (Journal of Laws) of 2014, No 133, item 883

³ Art. 27 – Act of 29 August 1997 on personal data protection Dz.U. (Journal of Laws) 2014, No. 133, item 883

does not mean that there are no general regulations that can be used in the analysis of the acceptability of data processing in the cloud.

The aim of the article is to present the current and draft legal regulations from the point of view of their application to health data processing and ensuring their security and confidentiality in the cloud.

The following regulations should be distinguished:

- regulations that concern the issues of electronic medical documentation as the most significant carrier of the patient's health. That group includes, first of all, legal acts referring to medical documentation with a particular consideration of the ones in the electronic form and the regulations concerning the part of medical documentation to be filed⁴;
- regulations concerning the rules of procedure with personal data collected by healthcare service providers when rendering the service. The major issue here is the regulations on personal data protection⁵;
- regulations concerning database protection with a particular consideration of databases that include health data and are run by entities obliged to do so by the Act on healthcare information system⁶.
- several legal provisions included in the Act on healthcare information system⁷ and in the Act on computerization of the activities of entities performing public tasks⁸ together with administrative ordinances.
- regulations that ensure an adequate level of network integrity, services and information transfer⁹ provided by operators (telecommunication services providers).

Entities that process health data – the range and type of data processed and the forms of data organization.

Health data can be processed by the following authorized groups:

⁴ Act of 14 July 1983 on national archive resources and archives Dz.U. (Journal of Laws) 1983, No 38, item 173 together with administrative ordinances

⁵ Act of 29 August 1997 on personal data protection Dz.U. (Journal of Laws) 2014, No 133, item 883 83

⁶ Act of 27 July 2001 on database protection. Dz.U.(Journal of Laws) 2001 No. 128, item 1402

⁷ Act of 28 April 2011 on healthcare information system Dz.U. Journal of Laws) 2011 No. 113, item 657

⁸ Act of 17 February 2005 on computerization of activities of entities implementing public tasks. Dz.U.(Journal of Laws) 2005, No. 64, item 565

⁹ Act of 16 July 2004 – Telecommunication Law. Dz. U. (Journal of Laws) 2004, No.171, item 1800

- patient whose data is processed,
- healthcare service provider,
- entity that is empowered by law and in the range defined by regulations (of e.g. National Health Fund – NFZ),
- entities that provide cloud resources, infrastructure and other services as well as entities responsible for data transmission in teleinformation networks.

Obviously, in some cases, a health services provider can run its own, the so called, private cloud that is fully professional and secured in compliance with adequate standards. However, that is usually the case of major and economically strong entities and it can be assumed that in the future, with the development of services dedicated to healthcare, such a solution will play an auxiliary role to clouds dedicated to healthcare. Alternatively, entities can operate the so called personal clouds. i.e. ones that are based on small home servers or take advantage of small commercial networks that are accessed by the Internet. They are designed to collect and share private information, browse and send data from any personal computers connected to the Internet or from the increasingly common smartphones. Although personal clouds function in the same way as private clouds of professional users, their main feature is that they are simple to install by an average PC user¹⁰. Such clouds are usually not suitable to health data and information processing.

Each of the above listed groups is governed by different legal provisions and, consequently, is subject to different scope of regulations, obligations and duties. In some of the cases the regulations are the same; they refer to more than one entity but the scope differs, e.g. in the Act on personal data protection, a healthcare entity is often referred to as administrator while a patient as a legal entity.

Entities that possess health data and information:

- **Patient**

The patient has the right to the information about his/her health¹¹. According to

¹⁰ Commission on Internal Market and Consumer Protection of EP, *Chmura obliczeniowa – Ekspertyza* (Cloud computing – expert opinion), source: [http://www.europarl.europa.eu/RegData/etudes/etudes/join/2012/475104/IPOL-IMCO_ET\(2012\)475104_PL.pdf](http://www.europarl.europa.eu/RegData/etudes/etudes/join/2012/475104/IPOL-IMCO_ET(2012)475104_PL.pdf), accessed: 30.10.2014

¹¹ Art. 31, Act of 5 December 1996 on medical profession, Dz.U. (journal of laws) 1997, No. 28, item 152
Art. 9. 1. Patient has the right to information about his/her health. Act of 6 November 2008 on patients' rights and the commissioner for patients rights, Dz.U. (Journal of laws) 2009, No. 52, item 417

some regulations there is an obligation to inform the patient on situations related to health, sometimes under legal penalty. That refers to provisions that regard contagious diseases¹², transplants¹³, medical experiments and blood sampling. The patient has also the right to obtain medical information from healthcare service provider¹⁴. In the cases defined by law, other entities can obtain health data, also after the patient's death.

It depends on the patient how the information that he/she has received will be used. Among other options, the data and information can be collected and processed by cloud computing. However, in such cases legal provisions do not provide protection¹⁵ as that is the case of legal persons processing their data for personal or home purposes and they are not regulated by the Act¹⁶. In such cases, the regulations on professional confidentiality of healthcare service providers do not apply either. Such a solution is offered by the Google and Microsoft which developed PHR (Personal Health Record) online services which enable storing and sharing health data of individuals in the WWW. The new services of the IT giants are available only to the US inhabitants.¹⁷

- **Medical entities; other entities offering health services**

That group includes various entities that employ or order medical service to people who pursue medical professions and are obliged to the duty of professional confidentiality (doctors, nurses, lab diagnosticians, paramedics, psychologists, pharmacists) as well as people who are not obliged to confidentiality, i.e. people who do not offer medical services but render health services within their commercial activities (e.g.

¹² Art. 26. Act of 5 December 2008 on prevention of infectious diseases and medical care for patients suffering infectious diseases. Dz.U. (Journal of Laws) 2008, No.234, item 1570

¹³ Art. 12, section 1, Act of 1 July 2005 on removal, storage and transplantation of cells, tissue and organs. Dz.U. (Journal of Laws) 2005, No. 169, item 1411

¹⁴ Art.23 , Act of 6 November 2008 on patients' rights and the commissioner for patients rights

¹⁵ Art. 3a , Act of 6 November 2008 on patients' rights and the commissioner for patients rights,

¹⁶ Also European Parliament and Council Directive 95/46/WE of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data , art. 3 excludes from the application the processing of data "in the course of purely personal and household activities.

That loophole in the current legislation should be eliminated by, for example, introducing a clear condition that „services rendered to individuals whose activities are solely of personal character are subject to the same requirements as “entities that process ordinary data” -„ Chmura Obliczeniowa – Ekspertyza”

[http://www.europarl.europa.eu/RegData/etudes/etudes/join/2012/475104/IPOL-IMCO_ET\(2012\)475104_PL.pdf](http://www.europarl.europa.eu/RegData/etudes/etudes/join/2012/475104/IPOL-IMCO_ET(2012)475104_PL.pdf)

¹⁷ Microsoft HealthVault i Google Health

<http://www.pcworld.pl/artykuly/325790/Microsoft.HealthVault.i.Google.Health.html>

physiotherapists)¹⁸. The latter case results from the patient's right to confidentiality on the part of medical people, including people providing health services and information gained in relation to their medical profession¹⁹. Moreover, all people participating in personal data processing, sensitive data including, are subject to the so called computer confidentiality.²⁰ The confidentiality concerns the data and information available to the person concerned as well as the protection methods. Currently, there are plans to extend the list of people with the obligation of professional confidentiality to individuals who are training for medical professions and the ones that have access to medical documentation and are not medical professionals (e.g. secretaries). They will be obliged not to reveal and use the information they acquired while participating in the provision of healthcare services²¹. The abuse of the duty of confidentiality results in legal sanctions²².

- **Entities that provide resources, infrastructure and other services in the cloud.**

That group is varied. The services are provided by commercial entities both in Poland, EU and beyond. The group also includes various public institutions that are commissioned to perform tasks with the application of cloud computing, e.g. the Healthcare Information System (SIM) administered by the Center of Healthcare Information Systems (CSIOZ)²³. The tasks may be also delegated to commercial entities, e.g. running the electronic Platform of Public Administration Services (ePUAP) by the COMARCH company²⁴. The entities that offer cloud computing

¹⁸ Entities that are not registered as healthcare entities within the meaning of the Act of 15 April 2011 on medical activity, Dz.U. (Journal of Laws) 2011 No. 112, item 654

¹⁹ Art. 13, Act of 6 November 2008 on patients' rights and the commissioner for patients rights, Dz.U. (Journal of laws) 2009, No. 52, item 417

²⁰ Art. 39 Act of 29 August 1997 on personal data protection. Dz.U. (Journal of Laws) of 2014, No 133, item 883

²¹ Assumptions to the draft Act on amendments to the Act on patients' rights and the commissioner for patients rights and other acts, Warsaw, October 2013.

²² Art. 266, item 1, Act of 6 June 1997 on penal code, Dz.U. 1997 No. 88, item 553

²³ The SIM is administered by an entity that is competent for healthcare information systems and reports to the minister competent for healthcare, i.e. Centrum Systemów Informacyjnych Ochrony Zdrowia (Centre for Health Information Systems).

²⁴ Since the beginning of 2014, the PUAP is managed by the CPI (IT Projects Center). Before that it was done by the Comarch company. The Minister of Administration and Digitization delegated the CPI to run:

- PAP of the (Publications of Legal Acts by the Government Legislation Centre)
- SSDIP (Centralized System of Access to Public Information)
- SG BIP (homepage of the Public Information Bulletin), source: <http://www.reseller-news.pl/newsy/cpi-przejelo-od-comarchu-zarzadzanie-e-puap>

services are governed mainly by the provisions on electronic services²⁵ while the provisions of the Act on the protection of personal data are applied in relation to the protection of data processing. Moreover, there is a protection of the economic interests of entities that invest in developing a database²⁶. In the cases when the information collected in the database is confidential and unrevealed to the public, i.e. company technological, engineering and organizational data or other information of commercial value that the company took necessary measures to keep confidential, the provisions of the Act on combating unfair competition are applied²⁷.

- **Entities responsible for data transmission.**

The transmission of data is conducted by a group of entities that provide the access to on-line services, the so called *Internet Service Providers (ISP)*²⁸. They ensure an adequate integrity level of the network, services and the message transmission that are used by healthcare service entities to send health data to cloud providers. The provider of online services frequently provides the cloud. The role of such entities is significant as the entities that process health data cannot control the data being transmitted. They have to trust the entities that operate according to the regulations and are obliged to ensure the integrity and confidentiality of the data in relation to unauthorized people. In such cases the telecommunication law is applied.²⁹

Current and expected forms of patient's health data storage.

The medical data and information that are or will be sent to clouds exist currently in several forms as regards the terminology, contents and organization. The legislator applies various terms concerning the organization of data and information

The Act on information systems in health care uses such notions as *electronic document*, *electronic medical documentation*, *subscriber identity module*, *medical register*, *data included*

²⁵ Act of 18 July 2002 on providing services by electronic means. Dz.U. (Journal of Laws) 2002 No. 144 item 1204

²⁶ Act of 27 July 2001 on database protection. Dz.U.(Journal of Laws) 2001 No. 128, item 1402

²⁷ Proclamation of the Marshal of the Polish Parliament of 26 June 2003 on the proclamation of a uniform text of the Act on combating unfair competition, Dz.U. (Journal of Laws) 2003 No. 153, item 1503

²⁸ http://pl.wikipedia.org/wiki/Internet_Service_Provider

²⁹ Section VII: Confidentiality of telecommunications and protection of end-user data protection (Tajemnica telekomunikacyjna i ochrona danych użytkowników końcowych). Act of 16 July 2004 – Telecommunications Law Dz.U. (Journal of Laws) 2004, No. 171, item 1800

in medical documentation and databases containing personal data and medical data of individuals.

The notions are defined and presented in a graphical way in Figure 1.

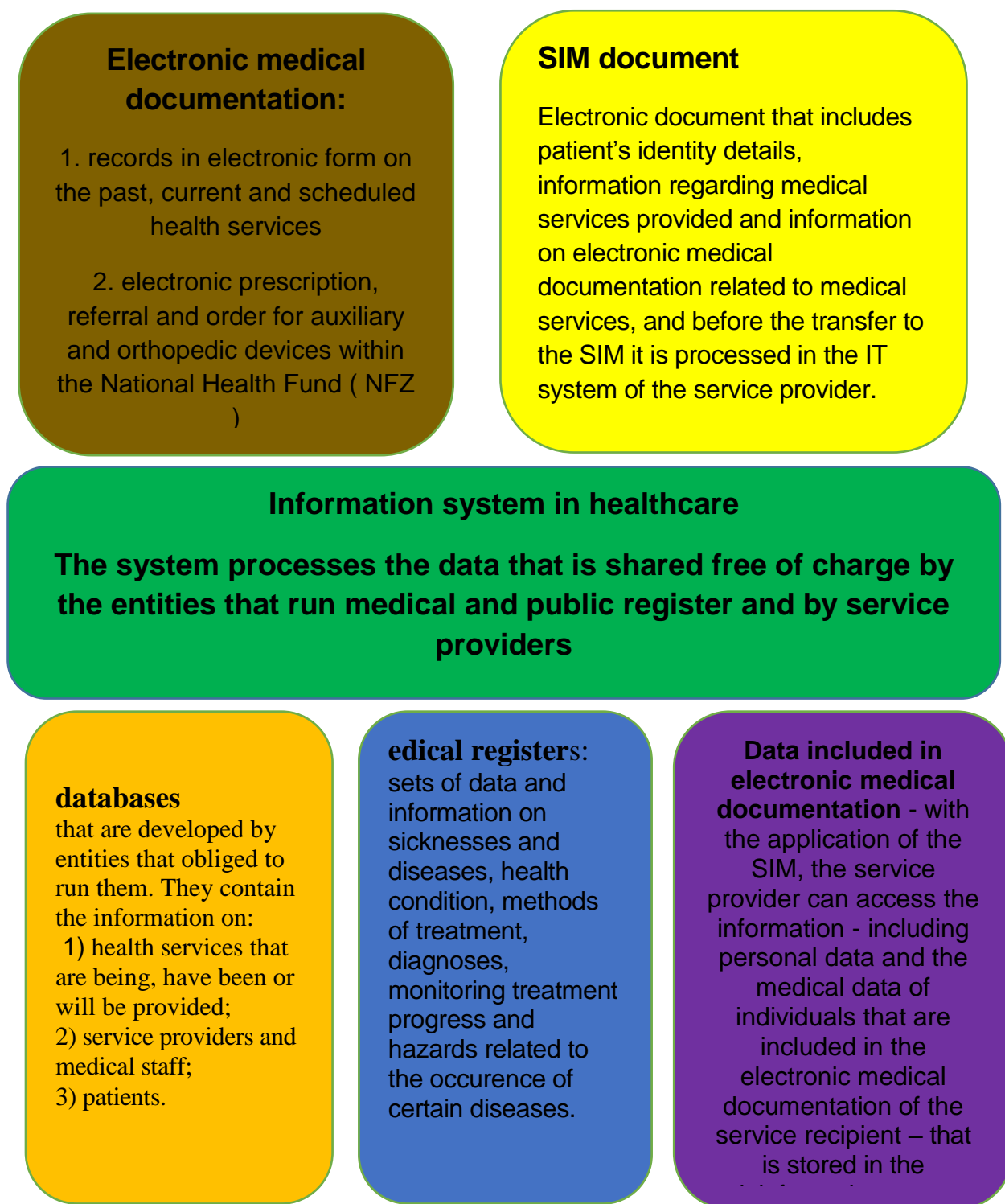


Fig.1. Forms of health data storage in the light of legal provisions

Source: Authors' development based on the Act on information systems in healthcare

Service providers keep **electronic medical documentation. It is the basic carrier of data and information on patient's health. Electronic medical documentation**³⁰ includes information on the past, current and scheduled health services. The minimal scope of data included in medical documentation is defined in the Act on patient's rights³¹ and the implementing acts³². There is a separate kind of medical documentation that includes electronic prescriptions, electronic referrals and orders for auxiliary and orthopedic devices. Such documents make it possible for the patient to obtain particular healthcare services and medications. Currently, work is being conducted on the electronic sick leave.³³

The analysis of legal provisions points out to the fact that both e-referrals and e-prescriptions will function as data carriers separate from electronic medical documentation. The data and information included in electronic referrals, orders and prescriptions will be placed in the Order Module of the Healthcare Information System. The module will contain the data on all prescriptions that were prescribed and purchased as well as the orders.

The act defines the SIM document as a document including patient's identity details, the information regarding healthcare services and the information on the electronic medical documentation related to medical services. The document is processed in the IT system of the service provider and transferred to the SIM. The patient confirms the fact of receiving the service. It should be noted that the document is developed by the service provider that runs the electronic medical documentation in the healthcare entity or at the pharmacy. In the cases when individual medical data are shared from the teleinformation system of the healthcare entity, the patient's consent is required (Table 2). The decision on the scope of data shared is made by the patient through the authorization of the access to the data. In exceptional cases provided by law, the service provider can authorize the access by entering the data into the teleinformation system on the basis of the service recipient's ID card, passport, any other identity document or a document confirming the right to particular healthcare service.

³⁰ Art.2, item 6, Act of 28 April 2011 on healthcare information system Dz.U. (Journal of Laws) 2011 No. 113, item 657

³¹ Art. 25, Act of 6 November 2008 on patients' rights and the commissioner for patients rights, Dz.U. (Journal of Laws) 2009 , No. 52, item 417

³² Ordinance of the Minister of Justice of 6 November 2013 amending the ordinance on the types and scope of medical documentation in healthcare institutions as regards imprisoned persons and its processing, Dz.U. (Journal of Laws) 2013 item 1524

³³ On 30.09.2014, the government accepted the scheme introducing e-sick leaves, which will be sent to the ZUS (National Health Fund) without the necessity of sending paper copies. E-sick leaves will be introduced in 2015; however, until the end of 2017, they will be applied together with paper equivalents. The amendments concerning maternity benefits will enter into force 14 days after the Act is announced.

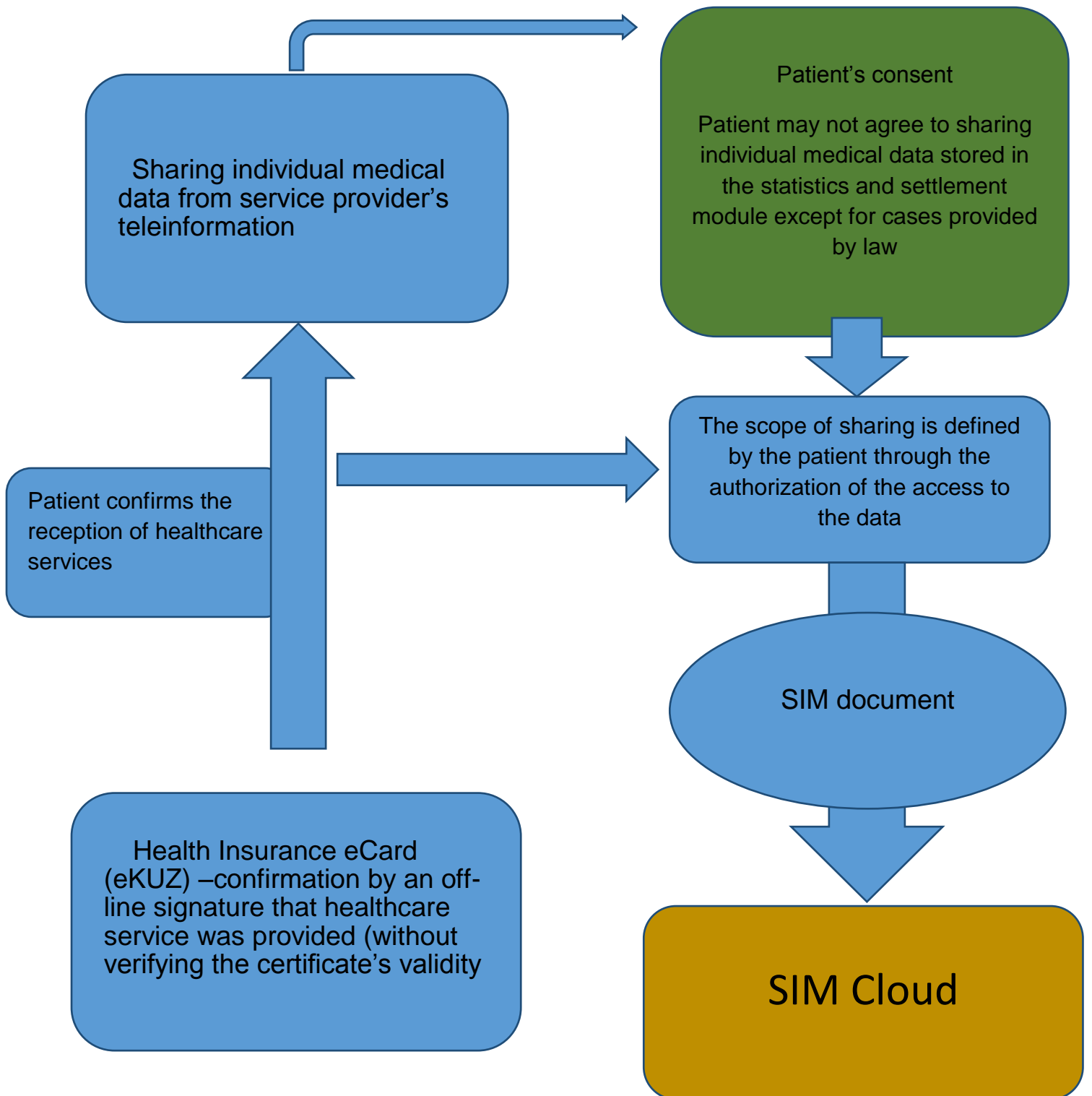


Fig.2. Model of data sharing with the Healthcare Information System

Source: Authors' development based on the Act on information system in healthcare

The act also uses the term of *data included in medical documentation*. The service provider can access the data through the SIM - that includes personal data and individual medical data in the electronic medical documentation of the patient that are collected in the teleinformation system belonging to other service providers – in the cases when it is indispensable for the continuity of treatment or diagnostic procedure. The electronic medical documentation can be shared with authorized entities through electronic transmission of data in the form of messages. The development and transmission of messages includes:

- the ordering entity sends a request for electronic medical documentation to the SIM;
- the SIM receives the electronic request for electronic medical documentation;
- the authorization of the ordering entity is verified;
- after a positive verification, the request for the electronic medical documentation is sent by the SIM to the service provider to which the request was directed;
- a medical employee of the service provider that is sharing the electronic medical documentation prepares the message;
- the medical employee of the service provider that is sharing the electronic medical documentation uses a secure signature or a signature authenticated by the ePUAP (electronic Platform of Public Administration Services) trusted profile to validate the message;
- the message is sent to the ordering entity by the service provider that is sharing the electronic medical documentation;
- the ordering entity confirms the reception of the message in the SIM and the teleinformation system of the service provider that is sharing the electronic medical documentation

The above procedure is presented in Fig.3.

The administrator of the SIM defines the logical structure of the electronic medical documentation that is shared with the service providers in the SIM. The electronic documentation consists of hierarchical data structures with regard to all kinds of medical records and multimedia files that are particularly the result of image diagnostics. The sharing of the electronic medical documentation with the authorized entities is conducted by an electronic transmission of data in the form of messages through the Electronic Platform for eCollection, Analysis and Sharing of Digital Medical Records .

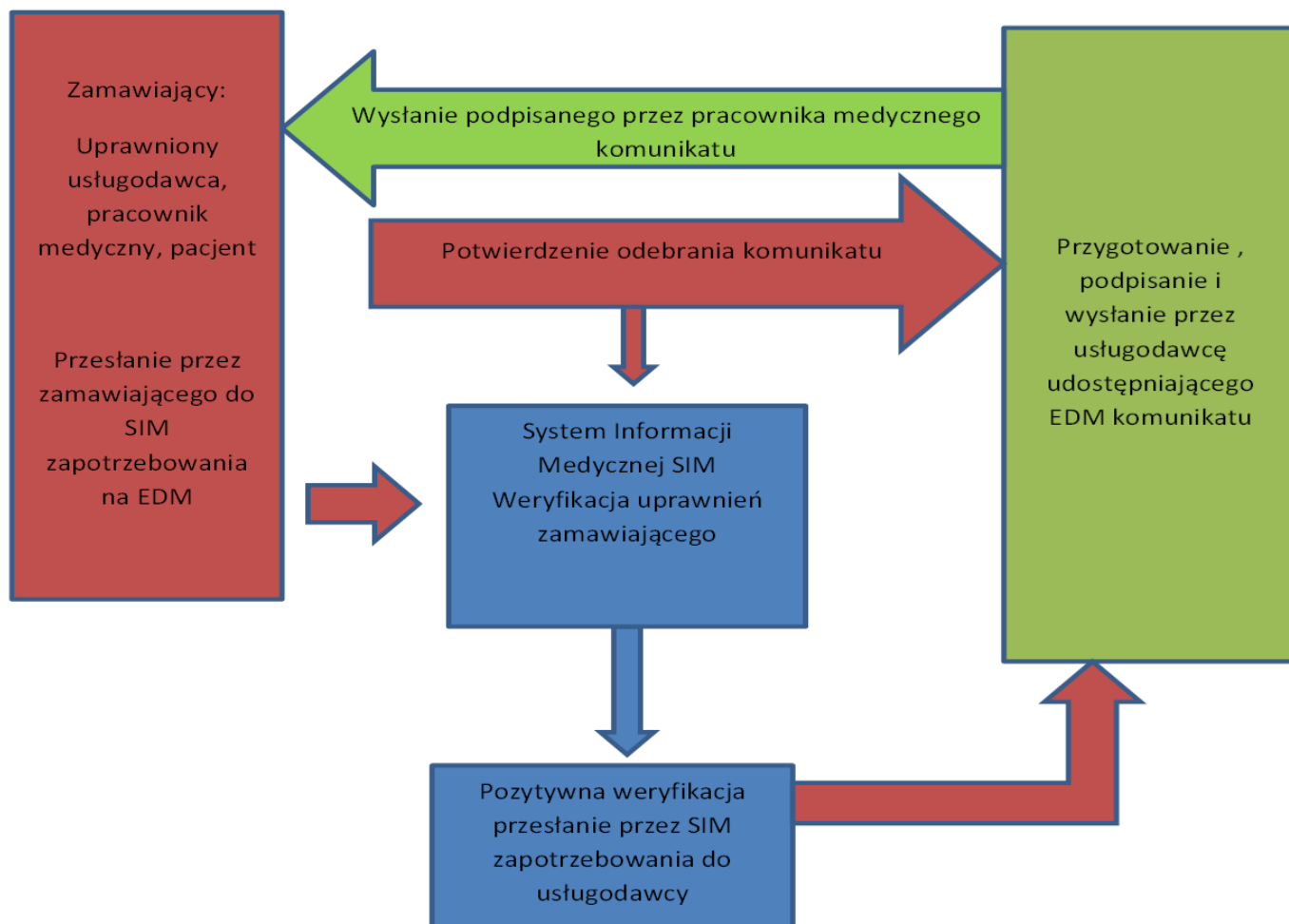


Fig.3. Medical documentation sharing procedure through the Healthcare Information System (SIM)

Source: Authors' development based on Ordinance of Ministry of Health of 28 March 2013 on requirements related to Healthcare Information System

The organizational and technological conditions have been defined as regards the processing, sharing, authorizing and protecting against the loss of the electronic medical documentation shared by service providers with the SIM. That will be secured by:

- the denial of access to data in the case of an incomplete identification or authorization of the entity requesting for electronic medical information,
- the denial of access to data in the case of the lack of patient's consent to share it – with the exception of the data that is provided by law and indispensable to the payer;

- the application of technology and organizational means that ensure the protection of data being processed against an unauthorized alteration, loss, damage or destruction, that is adequate to the hazards and the category of data under protection;
- the maintenance of data integrity and credibility.

The information system includes databases that are created by entities obliged to run them and which contain the data on:

- the past, current and scheduled healthcare services,
- the service providers and medical staff,
- the service recipients.

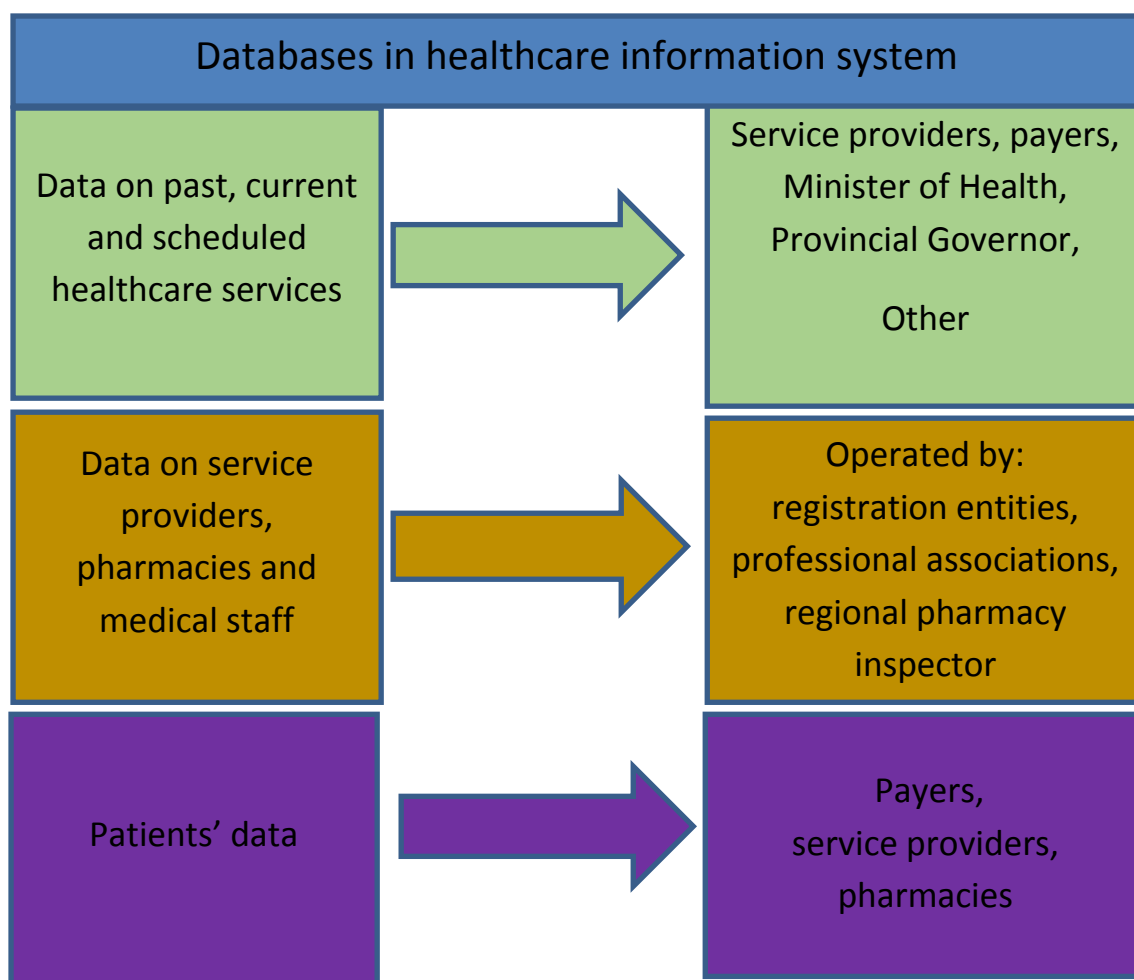


Diagram published by authors in: Trąbka W., Romaszewski A. (2013). Informatyzacja podmiotów leczniczych – jak przygotować gabinet na wejście dokumentacji elektronicznej?", praca zbiorowa, Fundacja Rozwoju Demokracji Lokalnej MISTiA, Kraków 2013.

Fig.4. Types of databases in the healthcare information system and entities obliged to operate them

Source: Authors' development based on the Act of 28 April 2011 on information system in healthcare

The scope of data collected in the **database of service providers** as well as in the electronically generated medical documentation of particular patients is defined by the Act on patient's rights and ordinances concerning medical documentation.

The patients are guaranteed the right to access their medical documentation, including the documentation being processed in databases, on the premises of the healthcare service provider.

Medical registers are another form of health data storage. They are constituted by sets of data and information on sicknesses, diseases, health condition, treatment and diagnostic methods, treatment progress and hazards related to the appearance of certain diseases. In Poland, the registers can be set up and developed or ordered to be conducted by the Minister of Health in order to:

- monitor the demand for healthcare services,
- monitor the health condition of the recipients of services,
- implement prevention strategies or health programs.

In the past few years, medical registers have been reorganized. After the act on the new information system came into force³⁴, a review of the existing registers was conducted. The Minister of Health was obliged – having analyzed the necessity of the register – to make the decision on its further operation. If the decision was negative, the entity in question was obliged to closed down the register, to destroy the databases and information carriers in the way that would make it impossible to reconstruct the data or to transfer it to adequate state archives³⁵.

The healthcare registers were set up on the basis of acts regulating various areas of health protection, e.g. the fields of infectious diseases, blood donations, transplantations. Each of the registers was regulated in detail by administrative regulations. Moreover, the new act on information system set up the registers of cancers³⁶, acute coronary syndromes³⁷ and a national register of cardiac surgery.

³⁴ Art. 53, Act of 28 April 2011 on information systems in healthcare, Dz.U. (Journal of Laws) of 2011, No. 112, item 657

³⁵ If the data and information stored in the register will constitute archival material within the meaning of the provisions of the Act of 14 July 1983 on national archives,

³⁶ Ordinance of the Minister of Health of 9 September 2014 on the Registry for Benign Cancer of Major Salivary Glands, Dz.U. (Journal of Laws) 2014, item 1246.

³⁷ Ordinance of the Minister of Health of 17 October 2013 on the National Registry for Acute Coronary Syndrome. Dz.U. (Journal of Laws) 2013, item 1234

When reorganizing and setting up new registers, the problem appeared of their compliance with the law. The problem is crucial also when taking into consideration the registers in the cloud. The Constitutional Tribunal decided on several aspects of the functioning of registers. According to the Tribunal, it is constitutional to collect personal data of potential bone marrow donors³⁸ while it is not acceptable to share the data from that register with the Minister of Health and the National Transplantation Board. At present the constitutionality of provisions that enable the creation of registers by way of regulations is being investigated at the request of the Ombudsman. According to the Ombudsman the provisions in question do not meet the requirement of statutory regulation as regards the issues of privacy and information autonomy of individuals and allow the Minister of Health to decide – among other things - on the creation and methods of running registers with personal data and sensitive data by means of ordinances. Consequently, according to the Ombudsman, the Minister can him/herself define all the basic elements of some medical registers, while the guidelines included in the authorization and the Act are too general to prejudge on the administrative character of the ordinance³⁹.

Apart from *medical registers*, other registers were founded that are of **key significance to the functioning of the system**:

- Central Register of Service Recipients, which contains patients' data;
- Central Register of Service Providers, where the data on service providers and pharmacies are processed;
- Central Register of Medical Workers.

The service provider uses a certificate to be authorized in the SIM. In the case of employees and service providers a certification system has been developed. A medical worker obtains a certificate in order to:

- authorize the electronic medical documentation;
- access the data that make it possible to obtain from the SIM the electronic documents that were provided by other service provider and to retrieve the data from those documents in the scope indispensable to conduct diagnostic procedures, ensure the

³⁸ The Ombudsman's complaint concerned the provisions of the Act on removal, storage and transplantation of cells, tissue and organs that refer to the storage and processing of the data of potential donors by Poltransplant – the Organization and Co-ordination Center for Transplantology. According to the Ombudsman, the storage of data regarding places of birth, addresses and the PESEL (Universal Electronic System for Registration of the Population) numbers is not necessary as a similar register of data is run by 15 other centers of marrow donors operating in Poland

³⁹ On 15 July 2014, the Constitutional Tribunal deferred the case for indefinite period. Source: <http://trybunal.gov.pl/rozprawy/komunikaty-prasowe/komunikaty-przed/art/6947-system-informacji-w-ochronie-zdrowia-przyznanie-ministrowi-wlasciwemu-do-spraw-zdrowia-kompetencji/s/k-3313/>

continuity of treatment and supply the service recipients with medicinal products and medical devices;

- access the data in the SIM that enable the exchange of data in the electronic medical documentation between service providers.

The certificate will be associated with the introduction of the Medical Specialist Card. The service providers and pharmacies will use the certificate to authorize in the SIM:

- the data on healthcare services provided to recipients that are transferred from the service provider's recording and information system;
- the corrections of the data on the past and scheduled healthcare services;
- the data on medical staff that provide the services.

The identification and authorization in the electronic medical documentation of the services provided will be conducted with the application of the KUZ (Health Insurance Card)

The discussion on the issues presented in this paper can be found in the article entitled: *Specific features of medical data in the aspect of cloud computing.*

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Abstract

There are no regulations in Poland as regards data processing, including health data, with the application of the cloud computing technology. However, the lack of the solutions to that problem does not mean that there are no general regulations that can be used in the analysis of the acceptability of data processing in the cloud. The aim of the article was to present current and scheduled legal provisions in terms of their application in health data processing and ensuring their security and confidentiality in the cloud. Among several regulations, the following ones should be mentioned: provisions concerning electronic medical documentation, provisions on the rules of procedures with personal data, provisions concerning the protection of databases with a particular consideration of health databases, several provisions included in the Act on information system in healthcare and the Act on computerization of the activities of entities performing public tasks together with administrative ordinances, as well as the regulations that ensure an adequate level of the integrity of network, services and message transfer by the telecommunication operators.