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CROSS-BORDER MEDICINE CONSULTATIONS ON CLOUD COMPUTING

Introduction

The possibility of a remote medical service delivery with the use of telemedicine technologies is changing present-day healthcare practices. The advanced methods of transmitting medical data or images either next door or overseas are increasingly more often applied in healthcare systems of European countries. They also introduce new quality of medical services between the EU countries in the area of the so called cross-border healthcare as they do not only enable an interactive and mutual communication between specialists, medical clinics and research networks in a particular country but also between specialists and centers abroad. However, such a seemingly natural stage of telemedicine evolution faces significant practical problems. Due to the current technological progress, the advanced hardware and specialist software ceased to constitute barriers for the introduction of telemedicine technologies. The most substantial limitations in their implementation are involved with legal and organizational issues, the lack of mechanisms of financing telemedicine procedures from public means and also with the inactivity as regards widespread information policy that would explain the concept of telemedicine and the opportunities of its application in healthcare. Moreover, the idea of cross-border teleconsultation remains an area that is not fully clear as regards the security of storing and processing patients' data. The above factors impede or stop investments on the part of service providers that are interested in the implementation of teleconsultations within the framework of their medical activities. The purpose of that text is to give a brief characteristics of the selected conditions for the

provision of remote healthcare services in the context of the necessary practical steps to be taken and to focus on the most significant aspects concerning the application of cloud computing technology in that area.

Teleconsultation – remote medical services

The increasing potentials and range of the functionality of present-day ICT systems widens the horizons of contemporary medicine. The so called tele-medicine is the most promising trend in the mutual penetration of the fields of high-technology and medical sciences. The national law does not provide a generally accepted and clear definition of that term. Most commonly it is referred to as *“the transfer of medical data from one remote area to the other with the use of electronic communication in order to prevent diseases, maintain the health, ensure and monitor patients’ healthcare, educate patients and persons that provide healthcare services, and to support the workers of healthcare and other employees. It is a remote medical diagnosis, consultation and treatment that can be applied synchronously (in real time) or asynchronously”*¹, or *“ the use of medical information exchanged from one site to another via electronic communications to improve patient’s clinical health status*². The existing technologies make it possible to provide medical services irrespectively of location or even time. Diagnostics, health consultancy, treatment and monitoring patient’s health are the examples of the growing number of medical activities that can be done from a distance. The technologies that enable an interactive communication between patients and healthcare workers or between at least two medical workers that may be located in remote areas and/or different time zones, as well as the mentioned above examples of medical services that can be provided remotely, can be used by telemedicine³. Telemedicine introduces several innovative categories of medical services (teleconsultations, tediagnosics, teletraining, teleresults/teleoperations) and it also revolutionizes the form of medical care (telecare).

The most important benefits of applying the telemedicine include the possibility of interactive communication between a patient and the doctor, which ensures the access to

¹ Martyniak J. *Podstawy informatyki z elementami telemedycyny*. Wydawnictwo Uniwersytetu Jagiellońskiego, Kraków 2009

² American Telemedicine Association, source: www.americantelemed.org/i4a/pages/index.cfm?pageid=1, (Accessed: 11.09.2014)

³ *Information for Health. An information strategy for the modern NHS 1998-2005. A national strategy for local implementation*. Source: http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4014469.pdf, (accessed: 09.09.2014)

qualified medical personnel, the reduction of the waiting time for the service, the decrease of the number of necessary doctor's visits, the transfer of knowledge and specialist competencies onto more effective diagnosis, prevention and treatment, efficient management of chronic diseases, the support to seniors and the stimulation of effectiveness of public expenditure on healthcare⁴. Due to the advanced technologies of digitized data teletransmission and the data processing integration, the provision of medical services ceased to be limited to the doctor-patient relation and the patient's personal visit to a healthcare institution. Telemedicine technologies created a new type of information relation between the service provider and recipient. It is the so called teleconsultation, defined as a "*possibility to transfer the images on a video link (including HD) in real time and conduct medical consultations or the possibility of on-line consultations after a presentation of a medical problem to a top specialist-consultant*"⁵. It should be remembered, however, that a remote medical consultation aims only at the facilitation of the information exchange process, which is indispensable as regards diagnostics and treatment diagnostics, and its purpose is not to replace the doctor in the process. The literature on the subject differentiates the so called synchronous (real-time, or interactive) and asynchronous (or off-line, store-and-forward, delayed) consultations. The difference concerns the presence of the patient and consulting specialist at both ends of the information channel at the same time. In the first case the condition for such a presence is met, while in the latter it is not required as the data and information concerning the patient are filed and then transmitted to the specialist. Both forms of remote consultations – depending on individual cases and the capabilities of consultation centers – are today an irreplaceable tool of interactive communication in the area of healthcare. The significance of such a contact is growing in significance in the context of the social, demographic and economic problems faced by European countries. However, the above mentioned challenges contribute to the development of telemedicine technologies. The ageing of population, together with the limited means to ensure 24-hour care for the elderly and an increasing number of chronically ill patients at their homes are the factors that influence significantly the implementation of remote forms of healthcare. Moreover, one should not neglect the growing problems with the

⁴ Czekierda Ł., Skalkowski K., *Aplikacje telemedyczne*. Multimedia preemntation, source: http://www.malopolskie.pl/Pliki/2013/Aplikacje_Telemedyczne-AGH.pdf, (accessed: 03.09.2014)

⁵ Bujok J., Gierek R., Olszanowski R., Skrzypek M., *Uwarunkowania rozwoju telemedycyny w Polsce. Potrzeby, bariery, korzyści, analiza rynku, rekomendacje*. Source: <http://medgo.pl/wp-content/uploads/2014/08/Raport-telemedycyna-fin-22.07.2014.pdf>, (accessed: 10.09.2014)

availability of specialist services for elderly patients and the increase of treatment and care costs in the cases when diseases are diagnosed at later development stages”⁶.

The above trends contribute also to the perception change of the contemporary functions of telemedicine. The specific health needs of the ageing population and the increasing economic burden of medical care systems that is related to the necessity to provide the access of healthcare services to the elderly are changing the prospects of the hitherto application of telemedicine from a tool for remote treatment to an advanced instrument of telecare and permanent medical supervision (telemonitoring, teleconsultations) over the patient in his/her home environment. It is estimated that 40-50% of the telemedicine system applications are used for such purposes⁷. However, the growing interest in the potentials offered by telemedicine that are complementary to conventional methods of diagnostics and therapy does not match the state of the preparation of the environment in which telemedicine modern technologies would function. That refers both to Poland and other European states. According to the Directive 2011/24/EU of March 2011 on the applications of patients rights in cross-border healthcare, Polish patients gained an easier access to healthcare services provided abroad. However, there are still numerous doubts concerning particular rules of the functioning of telemedicine systems in the field of cross-border care. Despite intensive EU operations that aim at the promotion of extending the scope of telemedicine services in member-states, the lack of clear legal regulations as regards the provision of telemedicine services in cross-border areas constitutes now one of the most significant barriers to the development of the European telemedicine sector. There are no regulations regarding the security of the transmission, storage and processing of personal and medical data of patients who take advantage of cross-border teleconsultation, and the standards of an appropriate description of telemedicine services rendered do not exist. Moreover, the issue of the responsibility of the provider of the remote telemedicine services has not been regulated yet.

Telemedicine services – European and national barriers

⁶ Kielar M., *Telemedycyna w opiece transgranicznej – czy chcieć znaczy móc?* Cześć pierwsza. Ogólnopolski Przegląd Medyczny 2014; 9: 53-54.

⁷ Jendra M., *Telemedycyna obniża jednostkowe koszty świadczeń*. Nowe Technologie IT w Ochronie Zdrowia, 2013; 2 (vol.II): 26-31.

In the light of current Polish legal regulations there are several reservations concerning remote healthcare services rendered by telemedicine technologies. The basic concept of *teleconsultation* remains ambiguous as regards its scope and the conditions of practical application in diagnostics and treatment. That statement can be illustrated by the examples of legal acts that do not create a friendly legislative climate or - even more- they make the development of widespread telemedicine in the Polish healthcare system more difficult. The first legal barrier can be found in Art. 42 of the Act of 5 December 1996 on medical profession, which states that (...) *doctor determines the health condition of a particular person after a personal examination, with reservation of cases regulated by separate provisions*⁸. However, the further provisions of the Act lack the specification of the cases when remote diagnostics could be conducted. Moreover, no principles along which a diagnostic teleconsultation should be performed are defined. Also art.9 of the Code of Medical Ethics states that (...) *doctor may begin treatment after examining the patient, with the exception when medical advice can be given remotely*⁹. Some more legal barriers to the development of telemedicine technologies appear in the Act of 27 April 2004 on healthcare services financed from public means (no opportunities to finance remote services), the Act of 6 November 2008 on patient's rights and Patient's Rights Ombudsman (the regulations regarding the protection of personal data and patient's sensitive data are not adjusted to the area of telemedicine services), the Act of 15 April 2011 on medical activity (the location where the advice is given is assigned to the location where the medical entity is registered) and in the implementing ordinances to the above acts^{10,11,12}. The report *Trends in computerization " e-Health Poland" in 2011-2015* stipulates the development of detailed legal regulations on telemedicine healthcare services; however, that document does not have

⁸ Act of 5 December 1996 on medical profession, Dz.U. (Journal of laws) No. 277, 1634, as amended), source: <http://isap.sejm.gov.pl/Download.jsessionid=2877DC4A3F621D55660313254A501EFD?id=WDU19970280152&type=3>, (accessed: 10.09.2014)

⁹ Kodeks Etyki Lekarskiej (Code of Medical Ethics), Naczelna Izba Lekarska. Source: http://www.nil.org.pl/__data/assets/pdf_file/0003/4764/Kodeks-Etyki-Lekarskiej.pdf, (accessed: 10.09.2014)

¹⁰ Act of 27 August 2004 on healthcare services financed from public means, Dz.U. (Journal of Laws) 2008, No. 164, item 1027 as amended, source: <http://isap.sejm.gov.pl/DetailsServlet?id=WDU20042102135>, (accessed: 10.09.2014)

¹¹ Act of 6 November 2008 on patient's rights and Patient's Rights Ombudsman, Dz.U. (Journal of Laws) 2009, No. 52, item 417), source: http://www.prawapacjenta.eu/var/media/File/Ustawa_o_prawach_pacjenta_i_rzeczniku_praw_pacjenta_06.11.2008_tekst_ujednolicony.pdf, (accessed: 10.09.2014)

¹² Act of 15 April 2011 on medical activity, Dz.U. (Journal of Laws) 2011 No. 112, item 654 (as amended), source: <http://isap.sejm.gov.pl/DetailsServlet?id=WDU20111120654>, (accessed: 10.09.2014)

legal validity¹³. The application of modern ICT technologies that could be used, among others, in telemedicine healthcare services is regulated by the Act of 28 April 2011 on healthcare information system and its implementing ordinances¹⁴. According to art. 36 of the Act, (...) *the Minister competent for health develops an education and information portal with the main aim to (...) disseminate the knowledge on the functioning of ICT systems in healthcare and telemedicine*. With reference to that entry, a parliamentary interpellation was raised to the Minister of Health in 2012, which concerned the Minister's position on the lack of legal provisions as regards telemedicine and the necessity to determine a development framework for remote healthcare services¹⁵. In his reply, the Minister of Health informed that ...(...) *the determination of telemedicine consultations as a method of fulfilling medical procedures financed by public means seems to be unjustified, as it is still a consultation that constitutes an element of a guaranteed provision*¹⁶. Such a position may lead to the conclusion that the Ministry of Health identifies telemedicine services with traditional medical consultations and, consequently, it underestimates the real need to develop national legal provisions that would directly regard telemedicine.

So far, telemedicine has not received a coherent legal act, either in the national or European law system, that would regulate the principles of its functioning in healthcare. That fact is indicated by the Communication from the Commission of the European Parliament on telemedicine for the benefit of patients, healthcare systems and society¹⁷. Consequently, the regulations regarding telemedicine services are dispersed and included in various legal acts of different hierarchy. According to the opinion of the European Economic and Social Committee, telemedicine should be treated as other medical services¹⁸. A similar opinion is

¹³ *Kierunki informatyzacji „e-Zdrowie Polska” na lata 2011-2015*, source:

<http://www.csioz.gov.pl/file.php?s=cD81Ng>, (accessed: 11.09.2014)

¹⁴ Act of 28 April 2011 in information system in healthcare, Dz. U. (Journal of Laws) No. 113, item 657, as amended.), source: <http://isap.sejm.gov.pl/Download?id=WDU20111130657&type=3>, (accessed: 11.09.2014)

¹⁵ Interpellation No. 7498 to the Minister of Health on the lack of legal provisions on telemedicine, Józef Lassota, Anna Nemš and Mirosław Pluta, 26 July 2012, source:

<http://www.sejm.gov.pl/sejm7.nsf/InterpelacjaTresc.xsp?key=37AFE9E1>, (accessed: 11.09.2014)

¹⁶ Reply to interpellation No. 7498 – Sławomir Neumann, minister of state in teh Ministry of Health, 27 August 2012, source: <http://www.sejm.gov.pl/sejm7.nsf/InterpelacjaTresc.xsp?key=1726DC5C>, (accessed: 11.09.2014)

¹⁷ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society of 4/11/08 KOM(2008)689, source: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0689:FIN:PL:PDF>(accessed: 11.09.2014)

¹⁸ *Opinion of the European Economic and Social Committee on the ‘Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society’* of 26/06/09 (2009/C 317/15),

expressed in the working document of the European Commission on the applicability of the existing EU legal framework to telemedicine services, which states that the specific solutions regarding telemedicine organization and finance do not justify a separate treatment of telemedicine services from other services although member-states can introduce their own regulations in that area¹⁹. According to the provisions of the Directive on services in the internal market, healthcare services (telemedicine including) are excluded from the so called services of internal market. However, the service status of telemedicine provisions results in the fact that they are subject to legal regulations concerning free circulation of goods and services^{20,21}. There are some documents that consider the issue of cross-border telemedicine services. The Directive on the application of patients' rights in cross-border healthcare states that a healthcare service that implements the so called cross-border telemedicine is provided in a member state on whose territory it is actually performed (the location of the service provider), while in the cases of the reimbursement of the costs of cross-border healthcare service (including telemedicine service) for an insured individual, a member-state can impose on that individual the same conditions, criteria of rights and legal and administrative requirements determined on a local, regional or national level that would be applied if a similar type of health service were provided in the territory of that member-state²². The issue of telemedicine is also considered by other European directives that are not discussed in that article, for example the directive on data protection²³, directives concerning medical devices^{24,25,26} and the directive on the protection of consumer in respect of distance contracts.²⁷

source: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:317:0084:0088:PL:PDF>, (accessed: 11.09.2014)

¹⁹ European Commission staff working document on the applicability of the existing EU legal framework to telemedicine services, Brussels, 6/12/21, SWD (2012) 414 final version , <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0414:FIN:EN:PDF>, (accessed: 11.09.2014)

²⁰ Directive 2006/123 of the European Parliament and of the Council of 12 December 2006 on services in the internal market, source: http://europa.eu/legislation_summaries/employment_and_social_policy/job_creation_measures/133237_pl.htm, (accessed: 11.09.2014)

²¹ Consolidated version of the Treaty on the Functioning of the European Union, source: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:083:0047:0200:pl:PDF>, (accessed: 11.09.2014)

²² Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, source: : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:pl:PDF>, (accessed: 11.09.2014)

²³ Directive 95/46/EC of the European Parliament and of the Council 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, source: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:pl:HTML>, (accessed: 11.09.2014)

²⁴ Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning

Teleconsultations in cloud environment

The above limitations concerning widespread implementation of telemedicine both in national and European healthcare systems affect the possibility to provide cross-border telemedicine services. The EU initiatives that aim at motivating the member-states to expand the scope of telemedicine services and to develop telemedicine and e-health in order to reduce health inequalities in different geographical regions face legal and organizational problems, which makes the development of remote healthcare between the member states more difficult. As a result, the hopes for the increase of the effectiveness of the European healthcare systems, the improvement of patients' life quality as well as the stimulation of innovativeness in health sector by a widespread use of telemedicine may turn out to be an uncertain and short-term perspective for the future²⁸. And that may be not enough, especially with the development of cross-border care that enables every European to have equal access to (both, public and private) healthcare provided on the territory of another member state. Consequently, EU documents under development reflect increasingly the requirements regarding greater clarity of legal regulations, the introduction of solutions that would increase the security of medical data being processed as well as the minimum data sets in patients' records shared by member-states²⁹. Moreover, new technologies emerge on the market that facilitate the use of the infrastructure, the system and ICT resources and may constitute a breakthrough in the cross-border remote provision of medical services. The technology of data processing in the cloud (cloud computing), which is becoming a contemporary standard in healthcare IT systems, is the most current and spectacular example³⁰. The objective of cloud computing is to develop a

the placing of biocidal products on the market, source: <http://eur-lex.europa.eu/legal-content/PL/TXT/PDF/?uri=CELEX:32007L0047&from=PL>, (accessed: 11.09.2014)

²⁵ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, source: <http://www.uokik.gov.pl/download.php?plik=1435>, (accessed: 11.09.2014)

²⁶ Directive 98/8/EEC concerning the placing of biocidal products on the market, source: http://www.urpl.gov.pl/system/files/PL/Produkty-biobojcze/pb_akty-prawne/Akty%20Prawne%20dotycz%20C4%85ce%20Produkt%C3%B3w%20Biob%20C3%B3jczych%20-%20Dyrektywy%20-%20w.pl/Dyrektywa_98-8-WE_pl.pdf?1281521039, (accessed: 11.09.2014)

²⁷ Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumer in respect of distance contracts, source: <http://www.uokik.gov.pl/download.php?id=259>, (accessed: 11.09.2014)

²⁸ European Parliament resolution of 8 March 2011 on reducing health inequalities in the EU (2010/2089) INI, source: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2012:199E:0025:0036:PL:PDF>, (accessed: 12.09.2014)

²⁹ eHealth Action Plan 2012-2020 – Innovative healthcare for the 21st century 6/12/12, COM (2012) 736, final version, source: http://www.toad.cor.europa.eu/ViewDoc.aspx?doc=cd%5Cnat-v%5Ccdossiers%5Cnat-v-027%5CPL%5CCDR2063-2013_00_00_TRA_PAC_PL.doc&docid=2921102, (accessed: 12.09.2014)

³⁰ Piecuch P., *Zastosowanie modelu cloud-computing w ochronie zdrowia*. Wydawnictwo Wiedza i Praktyka, Warszawa 2012, source:

model of information resources management in which the users do not cover the investment costs of their IT infrastructure but they rent particular infrastructure or application through the network. The new way of using the IT infrastructure and systems assumes physical separation of the data processing centre from the computer that plays the role of a terminal presenting the processing results³¹. It is assumed that a universal implementation of cloud computing in healthcare (to store the data, protect it against the loss and to authorize the access to it, etc.) facilitates the improvement of the quality of medical services and increases the effectiveness of the management and distribution of indispensable data to various locations³².

The growing number of various types of data to be processed by medical entities and an increasingly closer integration of patient's data and medical information that come from the IT systems of hospitals and other healthcare units require the assurance of the accessibility of data both in one place and simultaneously in different locations. That is of special importance as regards telemedicine systems which enable cross-border teleconsultations and require significant computing powers and prompt authorized access of users in different geographical regions to patients' medical data that is stored in various locations. The contemporary infrastructure of cloud computing evolves towards interactive applications that are available to numerous users at the same time. Cloud computing with real time functionality may constitute an information support that is indispensable to remote healthcare service provision in European healthcare systems. However, apart from the benefits and the promising potentials of the practical application of cloud computing in healthcare (both the current and future ones), the provision of cross-border medical teleconsultations with the use of cloud computing encounters significant barriers as regards legal provisions. The determination who decides on medical data and patient's data processing in the course of teleconsultations and who actually processes it, is a key issue. The dilemma has remained unsolved since passing the act on healthcare IT system, which was not preceded by the change of regulations regarding medical confidentiality. It can be concluded literary from the above regulations that only a doctor can be a healthcare cloud computing provider as – according to current legal provisions – patient's data can be transferred only by a doctor to another doctor and not to an

http://serwiszoz.pl/dane/MZ/pliki_ccms/pdf/4264302_55990a4a6eb42cd840d35773b9e3437b5d7dcb7c.pdf, (accessed: 12.09.2014)

³¹ Guidelines, principles and recommendations for the providers of services in the area of development and implementation of secure medical e-data processing, source: <http://www.csioz.gov.pl/indexDetail.php?id=246>, (accessed: 12.09.2014)

³² *Przetwarzanie w chmurze wkracza szturmem do europejskiej służby zdrowia – Press release*. Frost & Sullivan, source: <http://www.frost.com/prod/servlet/press-release.pag?docid=282684789>, (accessed: 12.09.2014)

external entity that is not defined by law. Having assumed the legislative acceptance of the provision of remote healthcare service by cloud computing, one should also remember about the legal limitations with regard to the processing of patient's medical data. First of all, the service provider is obliged to know what server will store the medical data to be processed, while according to Art. 74 of the Ordinance of the Minister of Health of 21 December 2010 on the types and scope of medical records and methods of their *processing the storage place of current internal records is determined by the entity*³³. Moreover, the service provider should point at the location where the data is processed. The Act of 17 February 2005 on computerization of activities of entities implementing public tasks obliges public entities, including public independent healthcare centers, to implement security policy³⁴. What is more, according to the Ordinance of 29 April, 2004 of the Minister of Internal Affairs and Administration on personal data processing documentation and technological and organizational conditions to be met by devices and computer systems used to process personal data³⁵, the security policy should include a list of premises where personal data is to be processed. As a result, the above legal limitations practically make it impossible for healthcare entities to implement public cloud computing to process patients' medical data but they do not exclude the possibility to use a private cloud. The existing legal situation results in the fact that virtual servers are applied and the resources of public cloud are shared among numerous computers and, consequently, it is impossible to determine, as it is required, the location where the data is stored and processed. In the case of a private cloud, there is a possibility of an exclusive assignment of the rented IT infrastructure to a particular entity (user). There is also one more, a slightly different option of a private cloud, referred to as enterprise private cloud. It is dedicated mainly to the networks of large healthcare units that have complex organizational structures and are supported by efficient IT services. Enterprise private cloud enables the provision of IT services to the whole organization by sharing the information resources with other organizational units within the organization.

³³ Ordinance of the Minister of Health of 21 December 2010 on the types and scope of medical records and methods of their processing. Dz.U. (Journal of Laws) 2010 No. 252, item 1697, source: <http://isap.sejm.gov.pl/DetailsServlet?id=WDU20102521697>, (accessed: 12.09.2014)

³⁴ Act of 17 February 2005 on computerization of activities of entities implementing public tasks. Dz.U.(Journal of Laws) 2005, No. 64, item 565, source: <http://isap.sejm.gov.pl/DetailsServlet?id=WDU20050640565>, (accessed: 12.09.2014)

³⁵ Ordinance of 29 April, 2004 of the Minister of Internal Affairs and Administration on personal data processing documentation and technological and organizational conditions to be met by devices and computer systems used to process personal data Dz.U. (Journal of Laws) No. 100, item 1024), Source: <http://isap.sejm.gov.pl/DetailsServlet?id=WDU20041001024>, (accessed: 12.09.2014)

The selection of a cloud solution adequate to the needs of a health unit is rather a technical issue while the security assurance of medical and patient's data that are processed when providing the services by remote service entities is a significantly more complicated problem. The issue is subject to heated discussion on the EU level. Due to the telemedicine service involves an international transfer of patient's sensitive and personal data, the process requires the standardization of all the data that are subject to electronic share. However, at present the discussions concern only three aspects that are crucial to the data share between the member states, i.e. methods of patient's authorization in the system, methods of patient's identification in the system and the minimum dataset that will have to be shared at EU level³⁶. In the opinion of experts, such an approach limits the issue only to comparatively simple solutions concerning the methods of patient's authorization and identification as well as the principles of sharing some part of the patient's medical records while what is really required are the regulations that would regard a full scope of data that is shared within cross-border teleconsultations. It should be emphasized that the implementation of telemedicine service between European countries will face problems resulting from the differences in healthcare systems and their medical IT systems, which has a direct impact on the security assurance of patient's personal and sensitive data. That is why some member states and groups are resistant to the idea of such data sharing on the European level without a prior harmonization of telemedicine solutions in the whole EU area. And that is not going to happen soon considering the hitherto achievements of the member states in that field and the still existing limitations in their legal systems. Thus, it seems that the best solution would be if EU concentrated its efforts on guaranteeing the flow of cross-border patients and the development of the mechanism of their authentication in the IT systems of countries that provide conventional healthcare service.

Project	Project objectives
PEPOL – Pan European Public Procurement Online	Facilitate the access of European business entities to public e-procurements
SPOCS – Simple Procedures Online for Cross-Border Services	Introduce simple online procedures in cross-border services
STORK – Secure idenTity acrOss	

³⁶ Minutes of the 22 meeting of Health Commission on 1 August 2012, Source: <http://www.senat.gov.pl/download/gfx/senat/pl/senatkomisjepisiedzenia/513/pos/022z.htm>, (accessed: 12.09.2014)

boRders linKed	Implement an interoperable cross-border system of electronic identification in the whole EU (or in some EU countries) to enable businesspeople, individuals and administrative workers to apply e-identity in every member-state
epSOS – European Patients Smart Open Services	Develop practical ICT framework and infrastructure in e-health to share patient's health data among healthcare systems of different EU countries
eCODEX	Improve cross-border access of individuals and companies to legal systems of other European countries and to eliminate practical and technical barriers in the area of cross-border e-justice in Europe
NETC CRDS	Enable viewing the data from e-cards of insured individuals or from a secure server as the confirmation of patient's rights
CALLIOPE	Develop Health Interoperability Roadmap , a document regarding current trends in e-Health and its implementation in national systems

Source: Authr's elaboration based on: Program Zintegrowanej Informatyzacji Państwa, Ministerstwo Administracji i Cyfryzacji (Programme of Integrated Computerization of the State, Ministry of Administration and Digitization) Warszawa 2013 and Kędzierski M., Informatyzacja ochrony zdrowia: główne aspekty, Ministerstwo Zdrowia (Computerization of health service: main aspects, Ministry of Health).

From such a point of view, the implementation of a cross-border teleconsultation system would be advisable in the subsequent stage of introducing coherent standardization mechanisms of data shared between European countries which would guarantee its security. However, some crucial operations on the long way to achieving the cross-border interoperability of health data sharing are currently being in progress. (see table 1.). Last November, *Guidelines on minimum patient dataset for electronic exchange* were accepted³⁷. The document defined organizational, technical and legal conditions that have to be met before transferring a single health dataset abroad. The list of such requirements gained a strong political support and, consequently, the new guidelines are to determine a realistic plan of action as regards the trends in defining and clarifying the principles of cross-border data sharing

The initiatives of EU countries for the sake of gradual harmonization and standardization of the telemedicine environment raise further questions concerning the assurance of comprehensive conditions for the development of remote, cross-border health services that apply cloud computing in our country. First of all, one should take a closer look

³⁷ Guidelines on minimum/nonexhaustive patient summary dataset for electronic exchange in accordance with the cross-border Directive 2011/24/EU, source: http://ec.europa.eu/health/ehealth/docs/guidelines_patient_summary_en.pdf, (accessed: 13.09.2014)

at the specific conditions of teleconsultations offered by healthcare service providers in Poland. Due to the limited space of the article, the authors concentrated on the most significant – in their opinion – issues of Polish law that should be considered by every service provider that is interested in the application of telemedicine technology in the provision of cross-border health services. First, some terms require explanation. For example, the notions of *teleconsultation* and *telediagnosics* are often used as synonyms while they differ both from the point of view of theory and practice. Thus, telediagnosics, i.e. a fundamental activity that can be proceeded with the application of telemedicine instruments, refers to medical diagnosis made on the basis of particular medical data that is sent by telephone and/or ICT networks (e.g. the Internet), while teleconsultation aims at comparing the previous diagnostic or therapeutic procedures with the current patient's health condition and making decision on following or changing the method of treatment. The terms *the sick* and *the patient* should also be differentiated. Although the colloquial meanings of both terms overlap, the differentiation between them has legal consequences. The fact of being sick in the legal sense of the word means the necessity to contact a doctor. Once the doctor starts diagnosing, treating or rehabilitating, the sick individual becomes a patient (a service beneficiary). A sick person has the right to contact a doctor in any way (i.e. also with the use of the telemedicine tools that are not subject to any regulations that would ban or restrict the availability of particular methods). What is more, a sick person can use the telemedicine tools in order to contact and consult a health problem not only with a doctor but also with any medical professional³⁸. Nevertheless, the provision of healthcare services based on telemedicine tools involves legal liability for the violation of patient's rights. There is also the question of the duty of due diligence in the course of treatment. That should be understood as the performance of any medical and health services that are indispensable as regards the health condition of a sick person, the appropriateness and effectiveness of the treatment as well as the commitment to implement any available technological and scientific developments (i.e. the telemedicine tools including). In such sense, the failure to use these tools - when they constitute the only or a better communication form with a patient or they are a device that enables the contact in an indispensable form on an adequate level - may be interpreted as the lack of due diligence in the treatment process. Practical doubts may be raised by the use of telemedicine tools in the

³⁸ Ordinance of the Minister of Labour and Social Policy of 27 April 2010 concerning classifications of professions and professional specialties for the needs of labour market and the scope of its usage, Dz.U. (Journal of Laws) 2010, No. 82, item 537, source:<http://zielonalinia.gov.pl/upload/baza-aktow-prawnych/066.pdf>, (accessed: 14.09.2014)

provision of information to the patient. Current regulations do not exclude such a form but the scope of the information shared must be complete every time (that involves the information channel quality and capacity in the process of sharing the data between the sick individual/the patient and the doctor/medical professional.) Moreover, technical drawbacks of the telemedicine tools may have particularly disadvantageous consequences (legal ones, including) in the cases of the lack of personal contact between the sick/patients and the doctors and/or medical professionals.

Methods that would guarantee complete security of telemedicine services and full protection of personal and medical data of patients with the prevention against unauthorized access to the information are the area of particular significance. It seems that the following two verification mechanisms should play a key role, i.e. patient verification by personal signature during the patient's visit to the entity providing telemedicine service and the application of a safe e-signature that is verified by a qualified certificate, and the verification of service provider that ensures a precise identification of the person providing teleconsultations. The issue of the security of patient's personal and sensitive data being stored and processed during the consultation is related directly to the question of the methods of filing the remote medical services by the service provider. First of all, it is necessary to obtain patient's written agreement for cross-border consultations every time such procedure is started. From a practical point of view, such a documentation should be performed in a rather conventional form (i.e. the completion of appropriate boxes, descriptions) but limited to the indispensable minimum. A full description of the teleconsultation should be registered by audio/video files although there are no legal provisions on such a form of documentation. The telemedicine solutions in the Polish healthcare system are given within the framework of the so called P5 project that is coordinated by the Healthcare IT System Centre. The purpose of that ambitious project that is referred to as *Electronic platform of telemedicine services of the Ministry of Health, the National Health Fund and the network of highly specialized hospitals* is to develop a national ICT system that would provide the access to registration and accounting resources with regard to highly specialized medical services. The resources will be also used by the central and local public administration. The functionalities of the project in question will include, among others, remote off-line (*copy and send*) doctor-to-doctor consultations in the area of radiology, cardiology and pathology as well as remote real-time doctor-to-doctor consultations with the application of tele- and video-conference tools. According to primary assumptions, the total costs of the project were to amount up to 56 m

zlotys and the functionalities were expected to be implemented by the end of this year. Unfortunately, the project did not receive EU subsidy and an application for funding it will probably be submitted within the next EU budget for 2014- 2020.

Conclusion

Mutual co-operation of remote healthcare services between two (or more) member states results in a better utilization of the entities' diagnostic and therapeutic potentials, improves the quality of the service and increases the opportunity to conduct scientific research on more numerous numbers of patients. Moreover, it offers the comfort of treating patients in their own countries with the possibility to extend the service by consultations provided by foreign specialists³⁹. A telemedicine co-operation (for example, in the form of a co-operation agreement) between entities in different member states should be commenced after the medical and office staff of both entities have met personally. Then, detailed principles and the scope of healthcare service should be defined, especially with regard to technical, financial and legal aspects concerning the telemedicine arrangements to be applied. The assurance of complete security of the medical and personal data of the telemedicine patients that are stored, sent and processed should be of particular interests for entities starting the cooperation. The cloud computing infrastructure may constitute precious technological and service support at various levels of the development and functioning of cross-border medical consultations. Moreover, legal and technical issues must be determined with regard to the accepted model and scope of telemedicine cooperation and the optimal type of cloud computing. The arbitrarily determined rules of the financial settlement of telemedicine services do not affect their accessibility as long as remote medical consultations are accessible on the market of both member states in which the cooperating entities are functioning. However, more serious practical problems emerge which are related to legal requirements that were mentioned before and regard the scope of medical registers, medical confidentiality, the protection of patient's rights and the guarantee of full security of personal and sensitive data being processed. The choice of the adequate law to cross-border telemedicine services as well as the jurisdiction of the court settling disputes may be stated in the agreement signed by both parties. Despite several legal, documentation and protection issues related to the security of

³⁹ von Zanthier J., Dziurzyńska A., *Telemedycyna transgraniczna w kontekście europejskim*, source: http://www.kigmed.eu/pliki/konferencja_2012-11-13/Henning_von_Zanthier_-_Radca_Prawny.pdf, (accessed: 14.09.2014)

data being processed, the functioning of the telemedicine cooperation between European entities is practically possible. That fact is testified by the telecooperation between the Charité hospital in Berlin and a hospital in Tartu (Estonia) or the cooperation between 21 Polish and 21 German hospitals within the EU Model Telemedicine Region POMERANIA. Thus, one should hope that the regulations under development that define the future framework of the functioning of modern telemedicine technologies and cloud computing will follow the examples of achievements that can already be put into practice.

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Abstract

The opportunity to provide remote healthcare services with the use of telemedicine technologies change the image of healthcare systems. Due to current technological progress the advanced hardware and software cease to constitute the barriers for the practical application of telemedicine technologies. The most significant limitations in that area are related mainly to legal and organizational issues, the lack of mechanisms to finance telemedicine procedures from public means and to the passivity as regards the information policy concerning the increasing potentials of telemedicine. Interactive teleconsultations introduce new quality of medical services offered among the member states in the area of the so called cross-border care. The opportunity to process data by cloud computing is a comparatively new solution that can constitute a breakthrough in the provision of remote cross-border medical services. That technology is becoming a contemporary standard of IT systems in the European healthcare systems. The article presents selected legal and organizational issues that influence the possibility of applying cloud computing in remote cross-border medical consultations.