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THE PATIENT'S HEALTH ELECTRONIC FILE *VS*. THE RIGHT TO PRIVATE LIFE

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ABSTRACT: *Recently, the Constitutional Court of Romania admitted an unconstitutionality exception invoked directly by Ombudsman, through it found that the provisions of art. 30 para. (2) și (3) and the expression "the health electronic file system" in the content of art.280 para. (2) of Law no.95/2006 regarding the reform in the field of health are unconstitutional. In arguing this solution, the Court retained the patient's health electronic file, regulated by the provisions declared unconstitutional, contains all patient's private medical data, which are protected by art.26 and art.34 of Constitution and by art.8 of the European Convention on Human Rights. The Court retained that the state has the obligation that, in the situation of regulating, through law, of an electronic system for managing the patients' medical data, that can be accessed at national level, to grant the confidential character of the medical data, through normative acts of the level of law, and that it is not sufficient that the protection of the medical data to be fulfilled through administrative normative acts which are characterized by high instability and inaccessibility [see also Decision no.17 on 21 January 2015, Decision no.51 on 16 February 2016, and Decision no.61 on 17 February 2017]. But the analyzed legal provisions don't contain, per se, any legal measure which could be qualified as a guarantee of the right to private life, such that the Court found the infringement of art.26 of Constitution. Also, the Court retained that these guarantees cannot be assured by an administrative normative act, in the circumstances that secondary legislation should be limited at organizing the enforcement of the same guarantees. Consequently, the Court found the infringement of art.1 para. (5) of the Constitution, as well. This is not the first time when the Court underlines the importance of protection of patient's medical data confidentiality through the constitutional and conventional provisions regarding the right to private life. The Court pronounced also other decisions regarding the same issues and underlined the importance of regulating expressly the conditions in which the medical data can be divulgated during the patient's life and after his death [see Decision no.1429 on 2 November 2010], actually according to the European Court of Human Rights case-law. Thus, the usage of electronic devices and of certain electronic applications, projected to be used at national level, on the purpose of curing patients with celerity, is allowed only if the private life of the patients is respected.*

KEY WORDS: *patient's health electronic file, the right to private life, national electronic system, unconstitutionality, the effectiveness of the infralegal legislation*

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1. INTRODUCTIVE CONSIDERATIONS

"Health information technology (HIT) is the application of information processing involving both computer hardware and software that deals with the storage, retrieval, sharing, and use of health care information, data, and knowledge for communication and decision making. This technology represents computers and communications attributes that can be networked to build systems for moving health information."[1]

Health information technology (health IT) specialists are those persons who manage patient's health information, from technical point of view. "Depending on their position, health IT professionals might build, implement, or support electronic health records and other systems that store patient-related data. They know what data is needed, where is it stored, and how the data is used."[2]

The right to private life is ensured in Romania, by article 26 of Constitution, which has, according to article 20 paragraph 1 of Constitution, as minimum standard of legal protection, the provisions of article 8 of the European Convention on Human Rights. According to these, the notion of "private life" has a broad meaning, which doesn't cover only the private sphere of personal relations, but also "the individual right to conclude and develop relationships with other natural persons", the definitory element of the right to private life consisting in the interhuman relationships. (Toader & Safta, 2015)

The medical data or information consist in the past and present healthy condition of the patient. They let one know, on the one hand, about the patient's anatomic characteristics, and, on the other hand, about the diseases that the patient has suffered during his whole life and the treatments he has followed.

In Romania, article 30 paragraph (2) and (3) of Law no.95/2006[3], stipulates the existence of *patient's health electronic file*, which is further regulated by Government Decision no.34/2015 through that the methodological norms on the modality of using and completing the patient's health electronic file were approved. According to article 1 paragraph 1 of the Government Decision no.34/2015, patient's health electronic file, is a component of the informational sanitary system and consists in electronic records consolidated at national level, containing medical data and information that are relevant for doctors and patients. Also, there is applicable in Romania, 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, which states at paragraph (25), that the rights to private data protection represents a fundamental right, recognized by article 8 of the European Union Charter of Fundamental Rights, under the circumstances that the assurance of continuity of medical assistance between different countries depends on the transfer of private data on the health of patients.

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[1] Asian Hospital and Healthcare management, *Role of Information Technology in Medical Science*, https://www.asianhhm.com/articles/role-information-technology-medical-sciences, 11.09.2018.

[2] University of Wisconsin, *What Do Health Information Technology Specialists Do?*, https://himt.wisconsin.edu/about-himt/what-health-it-professionals-do/, 11.09.2018.

[3] Law no.95/2006 on the reform in the field of health, republished in the Official Journal of Romania, Part I, no.652 of 28 August 2015.

2. RECENT CASE-LAW OF THE CONSTITUTIONAL COURT OF ROMANIA

In the above-mentioned conditions, the Constitutional Court of Romania, ruled, by the Decision no. 498 of 17 July 2018[4], that the phrase "*patient's health electronic file*", in the content of article 280 paragraph (2) of Law no.95/2006, is unconstitutional. In this case, the exception of unconstitutionality was invoked, according to article 32 of Law no.47/1992[5], directly in front of the Court, by the Ombudsman of Romania who considered that article 30 paragraph (1) of Law no.95/2006 infringes the constitutional provisions of article 1 paragraph (5), on the obligation to respect the Constitution and its supremacy and the laws in Romania, article 26 on the private life, and article 53 on the restriction on the exercise of certain rights or freedoms.

The main arguments of the Ombudsman of Romania regarded the legal way in which the protection of the medical data and information, which is recorded in the patient's health electronic file, is guaranteed by the Romanian state, as long as the medical information is protected by the constitutional and conventional legal stipulation on the private life. It has been shown that the criticized legal provisions present a broad degree of generality, despite the fact that they concern a sensitive field, respectively the medical information comprised in the patient's health electronic file; that the legislator limited his action at enunciating, in a generic manner, the obligation of utilization of patient's health electronic file, without concretely establishing appropriate warranties, meant to ensure the protection of personal data contained in this file. It has been also said that the legislator confined itself to regulating that a modality of using and completing the health electronic file will be established by methodological application norms, which will be approved by decision of Government. Thus, the analyzed legal provisions refer to normative acts with a legal force that is lower than the force of law, and so the utilization and completion of the health electronic file will be made according to a procedure which is not prescribed by law and, for this reason, "susceptible to be qualified as arbitrary".

These claims were caused also by the public move of some physicians and patients Romanian associations, which highlighted the possible negative effects of the health electronic file on both patients' private and professional life, because the legislation would not contain enough guarantees against the dissemination of the private medical information. On this occasion, it was said that there is a section named "Summary for Emergency Situations" in the health electronic file, which contains vital information for the patients, that is essential for physicians in emergency situations, in which "the patient is unconscious, or he cannot tell the physicians about his diseases and the allergies, or if he follows any medical treatment. In this section are included, among others, the patient's chronic diseases; the hematological and transmissible diseases, which are relevant for medical emergencies; the ongoing medications; and the lately admissions".[6] At the same time, it was said, that "this information is anytime accessible, for any physician from the

[4] Decision no. 498 of 17 July 2018, published in the Official Journal of Romania, Part I, of 26 July 2018.
[5] Law no.47/1992 on the organization and functioning of the Constitutional Court, republished in the Official Journal of Romania, Part I, no.807 of 3 December 2010.
[6] Decision no.498 of 17 July 2018, paragraphs 6-10.

public or private medical system, who is registered in the health electronic file system, and also the fact that pharmacies, medical labs, dental and any other medical services supplier in Romania, who is, by default, registered in the health electronic file system, can access anytime the medical information in any patient's file from Romania. This situation seems to be justified by the fact that the health electronic file system is a part of the platform of the health insurance system, which is mandatory used by the medical services suppliers, who are authorized, according to law, by those physicians who legally carry out their activity at these suppliers, for all the medical services granted to patients, related to the whole medical activities. But, according to article 3 of the Methodological Norms, "suppliers of medical services" means natural or legal persons who are authorized by Ministry of Health to offer medical services, medicines and medical equipment, according to the legal provisions."[7]

Having regard to these statements coming from the medical world, the Ombudsman concluded that the access to patients' medical information is allowed to a category of persons which is too broadly defined; that the objective criteria which should limit the access to the medical information stored in the files are missing; that the patients whose information is stored in the health electronic file do not have adequate legal guarantees against the abusive usage of their medical information and that the rules in force at that moment inspire the fear that the fundamental rights, that concern person's private existence in society, can be easily infringed.

The Romanian Constitutional Court, holding the mentioned unconstitutionality claims, by Decision no.498 on 17 July 2018, paragraphs 37-40, ruled that the health electronic file was established by law, without being stipulate which is the information that should be contained in the file; that the establishment of the health electronic file is a measure taken by the state, in fulfilling its obligations, ruled at article 34 of the Romanian Constitution, on the public health guarantee; and that the option of creating a modern system, through which the medical institutions should record patients' medical history, making this information accessible to patients and to healthcare and pharmaceutic professional by means of health electronic file, does not represent, *per se*, a limitation of the exercise of the right to private life, and could be an adequate measure given as an application of the right to health care.

The Court found that, indeed, according to article 30 paragraphs (2) and (3) and article 280 paragraph (2) of Law no.95/2006, the regulation of the following aspects seems to be sufficient: the establishment of health electronic file; the setting of the administrator of the electronic platform in the health insurance system, namely the National Health Insurance House, that the system of patient's health electronic file belongs to; the regulation of the obligation to ensure the mobility of the medical information stored in electronic format; the setting of the holders of the mentioned obligation; the hypothesis in which another electronic system is used –being mandatory that this system should be compatible with the system of the electronic platform in the health insurance field, in this case, the suppliers being asked to ensure the security and confidentiality conditions in the process of medical data transfer.

The Court found that the above-listed elements together constitute the basis of the organization and functioning of the new electronic system, created by the legislator, but

[7] Decision no.498 of 17 July 2018, paragraphs 6-10.

these aspects are far to represent, by themselves, guarantees of the right to private life, and that the analyzed law do not contain such guarantees. The Court also found that „the broad sphere of the notion of „medical institution" lead to the conclusion that an unlimited number of persons, in an unlimited number of situations, can introduce undetermined medical information in any files. Besides, the Court noticed that the notion of „mobility of medical information" is not defined by law; that means one cannot know what kind of medical information can be stored, which information shall be subjected to mobility, and who could access the information that became „mobile". More, the Court emphasized that the purpose for which the medical information is stored and could be used does not turn out from the provisions of the law."

Still the Court has drawn attention that it's not enough that the protection of medical information should be ensured by infra-legal legislation and that, in many cases, in its case-law, it highlighted that the secondary ruling acts, *exempli gratia*, decisions of Government, show a high degree of instability and inaccessibility. The Court found that such a way of regulating "is totally inadequate, jeopardizing, in an impermissible manner, the constitutional protection of the private life. This means, that the administrative authority can modify anytime the guaranteed standards associated to this right, by regulating some administrative normative acts, thus the citizen/patient being into the own hands of the administrative authority"[8]. The Court noticed that these secondary legal provisions, regulated for the application and enforcement of the law, should have technical character and that an adequate protection of the right to private life could be ensured only by law, in the meaning of *instrumentum*, and that, by these legal guarantees, the legislator should grant a special attention to the patient's consent.

In addition, the Court has drawn attention that the legislator has the constitutional obligation, stemming from the provisions of article 26 of the Romanian Constitution, not to make the medical act conditional upon the supply of medical information, in order to be stored in the health electronic file, because these are not linked by a direct correspondence. Also, the Court observed that the consent given by the patient, according to which his medical information can be stored in his heath electronic file, should be free and that it should be not given as a result of promising advantages, of medical or any other nature, because this would signify a vitiated consent. By referring to the case-law of the German Federal Constitutional Tribunal, namely at Decision 2 BVerfGE 45, 187, the Court found that, in such a hypothesis, the person is treated as an object and "the subjective principles characterizing the human being are disregarded, which is contrary to human dignity"[9].

Besides, the importance of medical information confidentiality was emphasized in the case-law of the Romanian Constitutional Court, for example, by Decision no.1429 of 2 November 2010[10], by which, the Court rejected the unconstitutionality exception of article 21 and 22 of Law no.46/2003[11] and found that the legal provisions regarding

[8] Decision no. 498 of 17 July 2018, paragraph 50.
[9] Decision no. 498 of 17 July 2018, paragraph 52.
[10] Decision of the Constitutional Court no.1429 of 2 November 2010 on the exception of unconstitutionality of provisions of article 21 and 22 of Law nr. 46/2003 on patient's rights, published in the Official Journal of Romania, Part I, no.16 of 7 January 2011.
[11] Law nr. 46/2003 on patient's rights, published in the Official Journal of Romania, Part I, no.3 of 3 February 2003.

confidentiality of medical information shall consider the interest of the patient, giving access to this information only to accredited suppliers of medical services, who take part to patient's treatment. On that occasion, the Court said that there is no equivalence between the qualified persons, who ensure the patient's treatment, and third parties, in the latter category being included the patient's relatives and inheritors, as well, because they are in different legal situations.

3. RELEVANT CASE-LAW OF THE EUROPEAN COURT OF HUMAN RIGHTS

The rights to health care is not regulated, *per se*, in the European Convention of Human Rights, the reason why, they make the object of the indirect analyzes of the European Court of Human Rights, in the light of application of the conventional provisions concerning the right to life [article 2 of the Convention], prohibition of torture [article 3 of the Convention], right to liberty and security [article 5 of the Convention], right to private life [art.12 of the Convention] (Schabas, 2015).

According to the case-law of the European Court of Human Rights, in the sphere of legal protection ensured by article 8 of the Convention is included also the medical information about patients [Decision of 17 January 2012, ruled in *Case Varapnickaitė-Mažylienė v. Lithuania,* paragraph 41], and the insurance of their security against unauthorized access, according the Convention, involves the positive obligation of the state to protect patient's private life, through a system of rules and guarantees regarding data protection [Decision of 17 July 2008, ruled in *Case I. v Finland*, paragraph 37]. Therefore, according to the case-law of the Court of Strasbourg, the medical information is included in the private data category [Decision of 10 October 2006, ruled in *Case L.L. v France*, paragraph 32], the reason why it shall pe processed according to the rules about this kind of information [Decision of 4 May 2008, ruled in *Case Rotaru v Romania*, paragraph 43]. It was shown, in the same case-law, that the confidentiality of medical information could be more important than the public interest to solve a criminal case, because it ensures both the respect for patient's private life and the trust in the healthcare professional and also in the healthcare services, in general [Decision of 17 July 2008, ruled in *Case* I. *v Finland*, paragraph 38]. Failure to ensure this protection could preclude the finding of the right medical treatment, by the persons who have certain diseases, and this could endanger the health of individuals [Decision of 6 June 2013, ruled in *Case Avilkina and others v Russia*, paragraph 45], and, in the case of transmissible diseases, the health of some whole communities [Decision of 25 February 1997, ruled in *Case* Z. *v Finland*, paragraph 95] (Grabenwarter, 2014).

But, concerning the decriminalization of the facts of retaining of data regarding fingerprints and DNA, in the case of some persons who were not convicted for committing infringements, in United Kingdom, the same supranational court held that this decriminalization does not infringe the principle of proportionality. With this occasion, the Court highlighted the importance of the DNA samples, stressing that they contain unique pieces of information about the patient, including information about his death, and also a unique genetical code, of great importance for the patient and for his relatives [Decision of 4 December 2008, ruled in *Case Marper v United Kingdom*, paragraphs 112 and 119].

Still the European Court of Human Rights found that disclosure of medical information could seriously affect the private life of the patients, and also their social and professional life, the patient being exposed to public outrage and to the risk of being ostracized [Decision of 17 January 2012, ruled in *Case Varapnickaitė-Mažylienė v Lithuania*, paragraph 44, or Decision of 6 June 2013, ruled in *Case Avilkina and others v Russia*, paragraph 45]. The European Court of Human Rights recognizes, in the same time, that the protection of the confidentiality of the medical information, could be overshadowed with respect to the necessity to investigate infringements, to trace the offenders and to ensure the publicity of judicial proceedings, when the latter are more important than the first.

4. THE INCIDENCE OF THE GENERAL DATA PROTECTION REGULATION

More, the stored information in the patient's health electronic file represent personal data, in the meaning of article 4 (1) of the General Data Protection Regulation[12], according to which "personal data" means "*any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person*". So being, irrespective of the physical or electronic format of the medical information, the operations of storing and consulting such pieces of information, made by the healthcare and pharmaceutical institutions in Romania, represent "processing" in the meaning of article 4 (2) of the same regulation, that says that processing "*means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction*".

As Law no.677/2001[13] was repealed, by article V paragraph (1) of Law no.129/2018[14], the General Data Protection Regulation is directly applicable in Romania. In these conditions, the protection of the medical information should be ensured, by the controllers, respectively by the healthcare and pharmaceutical institutions, at those standards directly resulting from the provisions of the European regulation.

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[12] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), published in the Official Journal of the European Union, L/119 of 4 Mai 2016.

[13] Law no.677/2001 on the protection of natural person with regard to the processing of personal data and on the free movement of such data, published in the Official Journal of Romania, Part I, no.790 of 12 December 2001.

[14] Law no.129/2018 on modification of Law no.102/2005 on establishment, organization and functionating of The National Supervisory Authority for Personal Data Processing, and repealing Law no.677/2001 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, published in the Official Journal of Romania, Part I, no.503 of 19 June 2018.

5. CONCLUSIONS

In agreement with the Decision no. 498 of 17 July 2018, I think that indeed there are positive obligations of the Romanian state, deriving from the provisions of article 34 of the Constitution of Romania, to act, in the purpose of ensuring the protection of the right to health care, at least at the level of protection which was assumed by Romania, through the ratification of those European and international acts, which regulate this right; the above-mentioned level of protection must be ensured, in terms of article 20 and 148 of the Romanian Constitution (Pop, 2016).

The constitutional right to health care shall be ensured only in close collaboration with the other fundamental rights, regulated in the Romanian Constitution; those fundamental rights with a direct impact shall include the right to private life. The exercise of these fundamental rights could be restricted, in exceptional situation, for any of the reasons which are expressly provided by article 53 of the Constitution.[15] In order that such a restriction should be legal, it has to fulfil, according to article 53 of the Constitution, the following conditions: to be provided by law, to be necessary in a democratic society, to be proportional to the situation having caused it, to be applied without discrimination, and without infringing on the existence of such right or freedom. (Tănăsescu & Muraru, 2008)

Besides, in the context of the analyses regarding the right of private life, in the light of its regulation in the European Union Charter of Fundamental Rights, one argued that the right to health care is, by its nature, linked to all the other fundamental rights, that guarantee together the human dignity. (Peers, Hervey , & Kenner, 2014) This is the reason why, one stated that article 35 of the European Union Charter of Fundamental Rights should be interpreted that the European Union grants a considerable importance to health care services, particularly when it is about defining and interpretation of the politics and activities of the Union[16].

So being, the right to health care is a complex ambivalent right, which is characterized by both a substantial and a procedural component[17], and its insurance implies not only the application of principle of subsidiarity[18], which, among many other aspects, implies the appreciation margin of the member states, that became *lex specialis* in relation with the general principle of sovereignty[19], but also a correct application of the principle of proportionality, which is extremely current in the regulation of the fundamental rights (Huscroft, Miller, & Webber, 2015).

Therefore, the development of an electronic system which shall include medical data, considering the positive obligation of the state to take measures in order to protect the right to health care, necessarily implies the positive obligation of the state to protect the patient's right to private life, regulated by article 26 of the Constitution.

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[15] Article 53 paragraph (1) of the Constitution: „*The exercise of certain rights or freedoms may only be restricted by law, and only if necessary, as the case may be, for: the defense of national security, of public order, health, or morals, of the citizens' rights and freedoms; conducting a criminal investigation; preventing the consequences of a natural calamity, disaster, or an extremely severe catastrophe*".

[16] C 15/74 *Centrafarm v Sterling Drug* (1974) ECH 1147.

[17] *Ibidem.*

[18] European Court of Human Rights, *Seminar to mark the official opening of the judicial year*, 30 January 2015, *apud* Cristina Teodora Pop, *Criminal Medical Liability*.

[19] See Decision of 1 July 2014, ruled in *Case S.A.S. v France*, paragraph 129.

But, I think that through the provisions of Law no.95/2006, the Romanian state did not pay any attention to these necessary guarantees, when the patient's health electronic file was regulated. For this reason, the regulation of the health electronic file, in the form that was declared unconstitutional, represented an infringement of the right to private life. In this circumstances, even if the analyzed regulation represented a legal interference in the right stipulated at article 26 of the Constitution, and even if it had a legitimate aim and it was adequate and necessary to such an aim, it didn't provide a fair balance between the competing interests, namely: the interest of the Romanian state to fulfil its obligation of ensuring the public health care, the interest of the natural persons to have their health care ensured and the interest of the latter to have their private life protected[20].

Thus, it is mandatory that the positive obligation of the state to ensure the public health care to be fulfilled with the compliance of the guarantees that are specific to the patient's right to private life (Schabas W. , 2015). In other words, the margin of appreciation of the state in the process of implementation of the constitutional, European and international provisions regarding the right to health care, can be exercised only by the manifestation of its active role and only by reference to its constitutional obligation to respect and to protect the private life. Therefore, the establishment of such a measure, as the regulation of the patient's health electronic file, in the process of application of the right to health care, shall pe accompanied by the adopting of some adequate measures for the purpose of ensuring the confidentiality of the medical records which are implied, and also the patient's access to his own medical records[21]. More than this, if the measured from the first category are established by law, *stricto senso*, it is mandatory that the related guarantees shall be established by a normative act of the same level. This is because the positive obligations steaming from the analyzed constitutional rights are correlative and interdependent, and for this reason they require the insurance of a fair balance between the level of their protection. Otherwise, the protection of a certain constitutional right, with a significant restriction on the exercise of other fundamental right, can substantially reduce, the positive effects of the regulation. Therefore, at normative level, the relation between the two constitutional rights referred to, should be characterized by complementarity and proportionality[22].

The obligation of the state to regulate the necessary guarantees for the protection of the right to private life, in the context of regulating the patient's health electronic file, is all the more important as the patient could be in a state of physical or emotional vulnerability, caused by his health condition, which could lead him, at one time or another, to consent to be applied certain legal provisions, such as those legal provisions found unconstitutional by the Decision no.498 of 17 July 2018 of the Constitutional Court of Romania, without invoking the absence of fair balance between the right to health care and his right to private life.

In the same time, the state is also obliged to establish the necessary measures in order to ensure the right to health care, in the hypothesis in which the patient does not consent to the collection and recording of his medical information, because his deprivation of

[20] Decision no.498 of 17 July 2018, paragraph 49.
[21] *Ibidem.* See the Decision of the European Court of Human Rights of 28 April 2009, ruled in *Case K.H. and others v Slovakia*, paragraphs 44-58.
[22] Decision no.498 of 17 July 2018, paragraphs 40-42.

adequate health services is equivalent not only to an infringement of the fundamental right stipulated at article 34 of the Constitution, but also to an infringement of the constitutional provisions on the rights to life and to physical and mental integrity.

Finally, all these considerations also imply the positive obligation of the state to ensure a normative framework that shall respect the human dignity, both in the case of the natural persons in the situation of being patients, and in the case of the persons empowered to record, to access and to use the medical information of the patients.