

# DIGITALIZATION OF HEALTHCARE SERVICES AND THE IMPACT ON LEGAL REGULATIONS

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## *Abstract*

*This paper examines the impact of healthcare digitization and telemedicine on legal regulations within Romania. It highlights how telemedicine, initially limited, gained prominence during the COVID-19 pandemic through legislative adaptations, enabling remote consultations, diagnostics, and monitoring. The Romanian legal framework, including Law no. 95/2006 and OUG no. 196/2020, has evolved to incorporate telemedicine services, aligning with European directives on data protection and interoperability. The ongoing national digital strategy aims to modernize health infrastructure, enhance data security, and expand telehealth accessibility, especially in underserved areas. However, this transformation introduces new legal challenges, particularly regarding medical liability, evidentiary issues, and platform responsibility. The lack of specific regulations for digital malpractice and documentation complicates accountability, necessitating legislative updates to clarify responsibilities and ensure fair patient protection. The study underscores that digitalization offers significant opportunities for improved healthcare access and efficiency but requires careful legal adaptation to address emerging risks and uphold the integrity of the doctor-patient relationship. Ultimately, ongoing legislative reforms are essential for balancing technological advancements with legal and ethical standards in the Romanian healthcare system.*

## **1. INTRODUCTION**

*Telemedicine isn't just the new frontier of healthcare; it's a return to its most essential service – accessibility (dr. Sven Jungmann). We are used to looking at the advancement of information technology largely from the perspective of its contributions at the technical level. We follow with interest how technology finds its resonance in fields such as medicine, justice or education, but we also fail to look at the socio-human impact of these advances. Through the vision he expresses, Dr. Sven Jungmann points out exactly this: telemedicine is increasingly democratizing a service that by its essence must be accessible to everyone. Medical services, whether those of the prevention type or those in the field of treatment, must be available to anyone, and telemedicine, as an *adjunct* to classic services, is aimed at those who, for one reason or another, cannot travel, those who want a second opinion, an interpretation of results, a verification of the administration of the treatment or other procedures that lend themselves to being performed remotely. However, Dr. Jungmann's point of view is not endowed with complete accuracy, because, on the one hand, it democratizes access to medical services, but, on the other hand, it makes it inaccessible to those who, unfortunately, do not have access to technology. However, of interest for this paper is less the socio-human impact of the new telemedicine services, but the impact it has on the regulatory system in our country.*

The notion of *digitization* translates into the action of *numerically encoding information*. Simply put, by moving from the traditional, physical, unfolding level to the computerized one. *Medical services* cannot be digitized in their entirety, at least not at the current level of knowledge, however in all medical specializations there are services that lend themselves to being carried out online. Decision no. 1.133/2022 shows which are the medical services that are the subject of telemedicine services. These are teleconsultation services (establishing the diagnosis, monitoring, interpretation of results and investigations, prophylactic and therapeutic indications), teleexpression (exchange of opinions, information on a case), teleassistance (help offered by a doctor to another practitioner, at a distance), teleradiology and telepathology (electronic transmission of radiological or anatomopathological images at a distance, for the purpose of their interpretation), telemonitoring (remote

monitoring of health status and adjustment of treatment). The impact of the digitization of these services in the field of *legal regulations* concerns that set of rules that relate specifically to the field in question. In Romania, telemedicine is regulated by a specific legislative framework, which includes both primary and secondary normative acts. Non-exhaustively, we will recall, and then we will deal more extensively in the paper, that it is Law no. 95/2006 on health reform: this law forms the basis of the health system in Romania and has been amended to include provisions on telemedicine; Emergency Ordinance no. 196/2020 - was adopted to amend and supplement Law no. 95/2006, introducing specific regulations on the provision of remote medical services through telemedicine; The methodological norms for the application of OUG no. 196/2020 (these norms establish the details regarding medical specialties and the list of services that can be provided through telemedicine; the conditions for the organization and operation of telemedicine services; the modalities for providing telemedicine services; the responsibility for establishing the quality of telemedicine services and verifying its compliance).

In this context, we wonder how the modern path of generalized digitalization has shaped an entire system, in this case, the medical one? In order to answer, we will be guided by two main directions of discussion: we will seek to clarify what telemedicine represents, from a legal point of view, and what rigors it has brought to the doctor-patient relationship (point 2) and how the digitalization of the medical system as a whole has occurred, together with the forms of liability that this has generated (point 3).

## **2. TELEMEDICINE – IMPLEMENTATION AND EFFECTS IN THE DOCTOR-PATIENT RELATIONSHIP**

To begin with, we will briefly mention the legal means by which telemedicine was introduced into the Romanian legislation, while following some major contexts that favored the implementation of measures of this type (2.1). We will then see how the law changed the clinical interaction on the patient-doctor, patient-system levels (2.2).

### **2.1 The evolution of telemedicine regulation in Romania and at European level**

Until the outbreak of the health crisis caused by the COVID-19 pandemic, the use of telemedicine in Romania was limited by the lack of clear regulation. Although the concept was not completely unknown, in the absence of an express prohibition, the legislative framework was insufficient for its widespread application. An early example is the initiative in 2009, when an emergency telemedicine system was put into operation, meant to facilitate collaboration between hospitals via videoconferencing and monitoring of vital signs, with the support of two coordination centers: one in Bucharest and the other in Târgu Mureş. Later, in 2018, the amendments to Law 95/2006 included, at a declarative level, the telemedicine IT components in the health system infrastructure, but without generating effects applicable in practice. It was only in the context of the pandemic, when the pressure on the medical system increased considerably, that the authorities had to adopt concrete measures. Thus, by GD no. 252/2020, during the state of emergency, remote medical consultations were allowed. Subsequently, OUG no. 70/2020 extended this possibility, establishing a temporary framework valid until September 30, 2020, through which medical services such as primary medicine or specialized outpatient clinic could be offered through remote means of communication. These initiatives have demonstrated the need to make flexible regulations permanent, adapted to the modern realities in the medical field. During the COVID-19 pandemic, the legal framework did not use the term "telemedicine", but regulated the provision of remote medical services for certain categories of patients, in an exceptional context. However, these consultations are equivalent to teleconsultations, and the regulations for their settlement were established only in 2020. Thus, the adopted law allows the use of telemedicine in a permanent way, providing a viable alternative to face-to-face consultations, for services included in the basic or minimal package of medical services, regardless of the context of the pandemic. The new regulation clearly defines the procedures that can be carried out through telemedicine, including the establishment of diagnoses, the interpretation of investigations and the continuous monitoring of patients' health status. However, this form of remote medical consultation is a challenge for doctors, as the clinical examination will be carried out exclusively on the basis of verbal communication with the patient, without the possibility of directly observing the symptoms. The law provides that the patient will be informed about the limits of teleconsultations and will be directed to go to the office or call 112 if the symptoms worsen. Another important aspect of the new regulations is that medical

documents (prescriptions, referral notes and recommendations) can be issued electronically, being validated through the Information System for Electronic Prescription (SIPE), without the need for a holographic signature or the doctor's initial. The law also provides for the reimbursement of remote consultations by the CNAS, based on the same regulations as in the case of traditional consultations. The implementation of this legislative framework represents a significant progress in adapting the Romanian medical system to the new technological realities, and the expectations are that this process will continue to evolve, with a positive impact on the accessibility and quality of health services.

The European Commission has been addressing e-health and telemedicine since 1999, recognising their potential to improve healthcare and actively involve patients in managing their health. In this context, the "e-Europe" initiative was launched, aiming at the full integration of the European Union into the emerging information society. In 2008, the Commission defined telemedicine as the method of delivering healthcare services at a distance, highlighting the benefits for patients and health systems. Directive 2011/24/EU was an important step, facilitating patients' access to cross-border healthcare and promoting cooperation between Member States. Key European regulations for e-health include the Data Protection Directive 95/46/EC, the E-Commerce Directive 2000/31/EC, and the Medical Devices Directive. These regulations create a legal framework that supports the development and implementation of telemedicine services in the European Union.

In the European Union and globally, the way telemedicine is regulated varies significantly from country to country. A 2021 study conducted in 20 countries (19 in Europe and Israel) identifies three main types of approach: a group of 9 states (Belgium, Czech Republic, Denmark, Finland, the Netherlands, Norway, Spain, Sweden and the United Kingdom) have not adopted special laws for telemedicine, considering it part of the existing legislation for physical consultations; another group of 9 countries (France, Germany, Hungary, Italy, Portugal, Russia, Turkey, Ukraine and Israel) have introduced legislative changes to incorporate telemedicine; finally, Switzerland is a special case, where it is regulated only in some cantons. Slovakia, on the other hand, did not regulate or implement telemedicine in 2021. Israel, for example, has practiced telemedicine since the 90s, without specific regulations, the legislation being introduced only in 2019. In the case of France, telemedicine has been included in legislation since 2009, but it was only in 2013 that it was implemented in an experimental setting, and was subsequently expanded and regulated in more detail in 2017 and 2021. In Germany and Italy, legislation does not explicitly regulate telemedicine, but there are regulations and guidelines that allow it to be practiced under certain conditions. In the Netherlands and Spain, there are general regulations and recommendations, but without a clear legal framework for telemedicine. In the UK, telemedicine is regulated by standards and codes issued by regulatory authorities, and in Poland, telemedicine has been regulated since 2011, with the possibility of reimbursement of consultations [1][2]. This diversity of regulations shows how differently telemedicine is approached in different health systems, and the experiences of each country can provide valuable lessons for the development of more coherent regulations at European and global level.

Telemedicine, as a model for carrying out medical services, has changed the nature and dynamics of the relationship between patient and doctor. It is interesting to see what are the new parameters under which this relationship takes place, given the extensive digitalization in the system, but also the obligations that come with it.

## **2.2 Legislative changes brought by the digitization of the doctor-patient relationship**

The National Strategy for Digitization in Health 2024-2030 aims to transform the health system in Romania by implementing and integrating digital technologies, in order to improve access to medical services, their efficiency and the quality of the medical act. In the context in which digitalization plays an increasingly important role globally, Romania aims to modernize the health infrastructure, increase interoperability between health institutions and develop innovative solutions that meet the needs of patients and professionals in the field. One of the fundamental objectives of the strategy is to create a unitary, secure and interoperable technological framework that ensures better connectivity between hospitals, clinics and other healthcare entities. This digital system will facilitate quick and secure access to patients' medical information, given that electronic patient records will become a standardized practice, in accordance with European data protection regulations, such as Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data (GDPR). Thus, relevant information will be available in real time, which will contribute to a more efficient management of treatments and the reduction of medical errors. Another key objective of the strategy is to expand and develop

telemedicine services, in accordance with the norms provided by Law no. 95/2006 on health reform, in order to ensure access to specialized medical consultations, especially in isolated or disadvantaged areas. Through digital platforms, patients will be able to benefit from remote consultations, and doctors will be able to monitor their health status in real time, thus promoting a more accessible and flexible health system. The strategy also emphasizes the importance of continuous professional training of medical personnel, in order to familiarize them with new technologies, an essential process for the successful implementation of digitalization, according to Emergency Ordinance no. 141/2021 on the development of digital skills of health professionals. This training process will ensure the correct and efficient use of new digital tools. Another significant aspect of the strategy is the regulations and legislative policy, which will ensure the implementation of an adequate legal framework for the protection of patients' personal data and for their proper management in the digital environment. Compliance with European rules, including Directive 2002/58/EC on the privacy of electronic communications, will be a fundamental principle, given the major cybersecurity risks associated with the storage and processing of sensitive health data. To ensure the effective implementation of the strategy, the Romanian authorities will work closely with the European institutions and the private sector, aiming to attract European funds and make the optimal use of national financial resources. Also, clear mechanisms will be established to monitor and evaluate the progress of the implementation of the strategy, in order to adjust the measures according to the technological evolution and the needs of the health system. At the same time, among the challenges identified are the resistance to change of medical personnel and health institutions, but also the risks related to the protection of personal data, which require highly effective cybersecurity solutions, regulated by Law no. 362/2018 on cybersecurity measures. These challenges need to be managed very carefully, as the success of digitalisation in healthcare depends to a large extent on the ability of institutions to ensure both the adoption of technologies and the protection of patient data. The National Health Digitalization Strategy 2024-2030 represents an important step in the modernization of the Romanian health system, being a complex process that involves both the development of a solid IT infrastructure and the adaptation to new technologies and regulations. By implementing this strategy, Romania aims not only to improve the quality and accessibility of health services, but also to ensure a more efficient and transparent management of health resources.

This would be, in short, the main legislative echo of the implementation of telemedicine. At least an echo of the first intention, because the resonance of the concept materializes in the remodeling of an entire system, as we will see.

### **3. DIGITIZING A SYSTEM AND MEDICAL LIABILITY**

Beyond the "micro" effects brought by telemedicine, i.e. those in the doctor-patient relationship, the most palpable and concrete relationship for the ordinary citizen, there are, obviously, the "macro" effects, those that have repercussions on an entire system (3.1) and that lead to new forms of legal-medical liability (3.2).

#### **3.1 Digitization of the public health system – obligations and legislative changes for institutions**

Within the process of digitization of the Romanian health system, the responsibilities of the central authorities, especially the Ministry of Health (MoH) and the National Health Insurance House (CNAS), are regulated by a complex regulatory framework, which aims to ensure an efficient transition to a digitized, interoperable system in accordance with European standards. In this context, Romania, although it benefits from the necessary infrastructure for the implementation of digitalization, lags behind the European Union average, according to the European Commission's report on the evolution of digitalization in 2023. He points out that, despite the progress in the field of IT infrastructure, Romania is experiencing difficulties in the effective digitization of public services, including in the health sector. According to Law no. 95/2006 on health reform, the central authorities are responsible for implementing an integrated information system that ensures an efficient management of medical services and facilitates patients' access to treatments. A significant example of the challenges encountered in this process is the Single Integrated Information System (SIUI), an essential component in the management of relations between CNAS, medical service providers and insured. According to Order no. 1006/2014 for the approval of the regulations regarding the use of the SIUI, this system should ensure both the record of taxpayers and the management of the funds allocated to health insurance. However, technical problems and persistent malfunctions, including in terms of updating data, lead to interruptions in the operation of this

system, thus affecting the efficiency of the entire process of reporting and monitoring health services. Such shortcomings underline the need to revise the applicable legislation to ensure a more efficient integration of information systems, but also a better collaboration between the state institutions responsible for providing data to the SIUI. Regarding the protection of personal data, another fundamental aspect in the digitalization of health, the Romanian authorities are obliged to comply with the European regulations on the matter, as provided for in Regulation (EU) 2016/679 on the protection of personal data (GDPR), which imposes strict measures to protect sensitive patient information. Article 5 of the GDPR sets out the fundamental principles for the processing of personal data, including legality, transparency and purpose limitation, which must be applied at all stages of the digitalization of the healthcare system.

Another relevant normative framework in this regard is Law no. 362/2018 on Romania's cybersecurity, which regulates the cybersecurity measures to be implemented by all public institutions, including CNAS and the Ministry of Health, in order to protect the IT infrastructures used in the management of medical data. According to this law, the authorities are obliged to adopt technical and organizational measures to prevent cyberattacks and protect health systems against security risks. The interoperability of health information systems is another key objective in the digitalisation process, regulated in the European context by Directive 2011/24/EU on patients' rights in cross-border care, which stipulates the need for interoperability between the health systems of the Member States of the European Union. Article 14 of that directive requires Member States to ensure, by means of national measures, the exchange of health information between health institutions and the promotion of the use of electronic health records, including for patients receiving cross-border treatment. In this context, the CNAS and the Ministry of Health have the obligation to develop and implement IT platforms that allow the reporting and monitoring of health services in a transparent and efficient way. An important instrument in this process is Law no. 672/2002 on internal public audit, which regulates the audit procedures applicable to public institutions. According to this law, the authorities are obliged to ensure transparency and fairness in the management of public funds allocated for digitization and to implement a digitized audit system, which allows real-time verification of the performance of the health system [4].

Thus, the successful implementation of digitalization in the Romanian health sector depends not only on investments in IT infrastructure, but also on compliance with a clear regulatory framework, which regulates the protection of personal data, cybersecurity, interoperability of systems and transparency of audit procedures. CNAS and the Ministry of Health are directly responsible for coordinating this process and ensuring that the measures implemented comply with national and European legal regulations. The implementation of an integrated and interoperable IT system, in accordance with European and national legislation, will contribute to achieving the digitization objectives set at European Union level and will ensure faster and more efficient access for patients to quality health services.

In this context, problems specifically arise related to evidence and documentation in relation to the consultations carried out online. That is why it is important to analyze, as a final point, how the current malpractice rules apply in the digital context.

### **3.2 Adapting the legal framework on medical liability in a digital context**

The digitalization of the healthcare system has brought with it a number of advantages, but also significant legal challenges. Emerging technologies such as teleconsultations and e-treatments have been widely adopted, providing faster and more efficient access to healthcare services. However, their emergence has raised important questions in the field of law, in particular as regards the application of malpractice rules. The current legal framework is not clear enough to regulate all aspects of medical errors in the digital environment, and the need for legislative adjustments is becoming increasingly evident.

In Romania, medical malpractice is regulated by Law no. 95/2006 on health reform, which defines malpractice as any medical act performed in violation of the deontological norms, which leads to damage to the patient. In this context, malpractice can manifest itself in various forms, from diagnostic errors to treatment or procedural errors. These rules are applicable to both traditional consultations and teleconsultations or e-treatments. As regards teleconsultations and e-treatments, national regulations do not provide for a specific legal framework that directly addresses medical errors that may occur in these areas. Instead, the general rules of malpractice apply,

but with specific adjustments related to the characteristics of the digital environment. For example, according to Order no. 1318/2006 on the regulation of telemedicine activity and Regulation (EU) 2017/745 on medical devices, the use of information technologies in the medical field requires careful monitoring of the quality of services and the diagnostic process, as well as the protection of patients' personal data, according to Regulation (EU) 2016/679 on the protection of personal data (GDPR).

One of the most controversial aspects of digital malpractice is evidentiary issues. In the digital context, having clear evidence becomes much more difficult, given the virtual nature of consultations. Traditionally, evidence in medical malpractice cases included patient records, signed documents, or expert testimony. In the case of teleconsultations, however, the evidence may be much more difficult to obtain, given the fact that the entire consultation is conducted remotely, and the audio and video recordings of the consultations may not be sufficient to establish guilt [5]. Law no. 95/2006, in accordance with Law no. 272/2004 on the protection and promotion of children's rights, regulates the documentation of medical activities and data protection, and in the case of telemedicine, increasing the degree of data security and digital archiving becomes essential.

An essential aspect in the digital context of medical malpractice is the clarification of the responsibility between the doctor and the provider of the teleconsultation or e-treatment platform. Although the doctor remains responsible for the medical act itself, the platform provider has the obligation to ensure the proper functioning of the technology and IT infrastructure. Law no. Regulation (EC) No 455/2001 on electronic signatures and Directive 2000/31/EC on electronic commerce set out the responsibilities of e-health platform providers in ensuring a secure and reliable system. In this respect, any technical failure of the platform or any security breach affecting the diagnostic process may incur partial liability on the part of the provider, and the doctor could be exonerated from liability if technological deficiencies were the causes of the error [6]. At the same time, Directive 2011/24/EU on patients' rights in cross-border care underlines the responsibility of Member States to regulate patient protection and to establish clear procedures in case of medical errors, regardless of the nature of the consultation (physical or digital). This requires close collaboration between national authorities and technology platform providers to ensure an interoperable, safe and efficient telemedicine system.

Another significant aspect of digital malpractice is the challenges of evidence. In the case of online consultations, documenting medical errors can be much more complicated than in the case of traditional consultations. Given that most consultations take place through telemedicine platforms, audio and video recordings are essential to determine if the doctor followed the correct procedures and if the diagnosis was an adequate one. In Law no. 95/2006, medical documents must be kept in electronic archives, and patients must consent to participate in online consultations, an aspect also regulated by Law no. 675/2001 on the protection of personal data. Thus, in the evidentiary process, the question arises of the validity of these recordings and compliance with the rules of confidentiality and data protection.

In international jurisprudence, there are already relevant examples of cases of digital malpractice. In a case in the United States, the Supreme Court ruled that providers of telemedicine platforms can be held liable for technical errors that led to diagnostic errors, even if the doctor did not make a direct error in the patient's care. Also, in France, a malpractice case related to a diagnostic error following a teleconsultation led to the establishment of additional rules on the interoperability of telemedicine platforms and the protection of patient data.

#### **4. CONCLUSIONS**

In conclusion, the analysis highlights the fact that the digitalization of medical services, especially the implementation of telemedicine, has led to a profound transformation of the regulatory framework and legal-medical responsibilities in the Romanian health system. The legislative process has evolved gradually, culminating in the adoption of specific regulations in the context of the pandemic, which have facilitated and clarified the possibility and conditions of providing healthcare services remotely. At the same time, the national digitalization strategy for the period 2024-2030 aims to create an interoperable, secure and equal access system, in line with European standards, such as GDPR and Directive 2011/24/EU. At the same time, this digitalization has generated new challenges in the field of liability, mainly in terms of evidence and the delimitation of liability between the doctor and the provider of the technological platform, aspects that require further legislative clarifications. The lack of specific regulations for errors in telemedicine and the difficulties of documentation in the virtual

environment require a reassessment of malpractice rules, in order to ensure a clear and fair accountability in this new context. Thus, the transformation of the health system through digitalization represents both an opportunity and a challenge, requiring continuous legislative adaptation to protect patients' rights, ensure the accountability of doctors and guarantee a safe, efficient and fair health system.

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