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# REGULATION OF DIGITAL HEALTHCARE SERVICES – (NOT) COVERED UNDER THE DIGITAL SERVICES ACT?

doc. JUDr. Soňa Sopúchová, PhD.

Comenius University in Bratislava, Faculty of Law Institute of Information Technology Law and Intellectual Property Law sona.sopuchova@flaw.uniba.sk

**Abstract:** The regulation of digital services is currently experiencing significant growth, primarily due to the adoption of new legal regulation at the European Union level, specifically the Digital Services Act. Digital services play a pivotal role in a country's economy by facilitating cross-border trade and enabling entrepreneurs to reach a vast user base, often comprising consumers. Despite their advantages, these services also entail substantial risks, particularly in relation to their widespread and more challenging-to-regulate usage. Alongside their positive impact, they also contribute significantly to the dissemination of illegal and harmful information. In recent years, there has been a notable development and utilization of new electronic information systems within the healthcare sector, accompanied by electronic healthcare services. This connection is not limited to the Covid-19 pandemic but is also a result of the dynamic evolution of information and communication technologies and their potential in healthcare provision. In this paper, the author analyzes the research question regarding which digital healthcare services in the Slovak Republic fall within the scope of the new European legislation. The author examined European regulations, focusing on the types of electronic healthcare services existing in Slovakia. By synthesizing and applying available information and rules to selected electronic healthcare services, the study concludes that the Digital Services Act has only a limited impact on the functioning of these selected digital healthcare services.

**Keywords:** electronic healthcare services, e-Health, healthcare digitization, digital healthcare services

#### Introduction

In 2022, the European Parliament and the Council of the European Union adopted a new legal regulation known as the Digital Services Act<sup>1</sup>. Its primary aim is to contribute to the proper functioning of the internal market for intermediary services by creating harmonized rules to establish a safe, predictable, and trustworthy online environment. This environment seeks to foster innovation while effectively protecting fundamental rights, including the principle of consumer protection.<sup>2</sup> The Digital Services Act is a long-awaited piece of legislation intended to regulate digital services meeting specific criteria. Simultaneously, in the same year, a month earlier, another legal regulation was adopted, also in the form of a regulation, known as the Act on Digital Markets.<sup>3</sup> This regulation establishes common rules to create competitive and fair digital sector markets for the benefit of all users across the European Union.<sup>4</sup> These two pieces of legislation have introduced significant changes to the digital services sector, affecting all digital service providers falling under their regulatory scope throughout the European Union.

The objective of this paper is to analyze and draw concrete conclusions regarding which digital healthcare services are subject to the new regulation and the corresponding requirements that apply to them. The rationale for selecting this research question arises from the dynamic nature of the development and implementation of electronic healthcare services. These services encompass a wide range of aspects, including electronic patient records containing personal data, online healthcare portals, virtual assistants, platforms for patient appointment booking, and healthcare professional reviews, among others. The research delves into the broader regulatory framework for these digital services, emphasizing aspects such as cybersecurity, data protection, privacy, and artificial intelligence.

Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on the single market for digital services and amending Directive 2000/31/EC (Digital Services Act).

<sup>&</sup>lt;sup>2</sup> Article 1, paragraph 1 of the Digital Services Act.

Regulation (EU) 2022/1925 of the European Parliament and of the Council of 14 September 2022 on competitive and fair markets in the digital sector and amending Directives (EU) 2019/1937 and (EU) 2020/1828 (Digital Markets Act).

<sup>&</sup>lt;sup>4</sup> Article 1, paragraph 1 of the Digital Markets Act.

In this paper, we formulate a fundamental hypothesis: digital healthcare services cannot be unequivocally categorized or aligned with the provisions of the Digital Services Act, resulting in a scattered legal regulation landscape within the Slovak Republic.

To provide context, it is essential to clarify the legal terminology prevalent in this field, as it may give rise to ambiguity in its correct usage. With the widespread adoption of information communication technologies (ICT)<sup>5</sup> in various spheres of life, terms like "informatization" and "electronicization" have emerged. While they share similar content, they are not synonyms. Informatization emphasizes processing information using ICT. electronicization is a narrower term, focusing on the introduction and utilization of electronic ICT in all activities. Another term often encountered is "digitalization," which involves the conversion of material content into a form processed by information communication technologies. Subsequently. terms "information service," "electronic service," or "digital service" may also be encountered. The term "electronic service" is quite general and we find several theoretical explanations for its definition. Author Bover defines electronic services as "interactive services that are provided on the Internet using modern telecommunications, information and multimedia technologies."6

In addition to theoretical distinctions among these terms, local legislation further defines specific technical terminology in the field of information technology from a legal perspective. For instance, "information technology" and "information system" are defined in Act no. 95/2019 Coll. on information technologies in public administration (referred to as the "Act on ITVS"). According to this law, information technology encompasses means or procedures used to process data or information in electronic form, including information systems,

<sup>5</sup> ICT are defined in many sources, e.g. UNESCO. Developing and Using Indicators of ICT Use in Education. Bangkok: UNESCO Asia and Pacific Regional Bureau for Education, 2003, p. 7.: "Information technology is understood as a term used to describe the elements of equipment (hardware) and computer programs (software) that enable us to access, retrieve, store, organize, manipulate and present information electronically. The category of hardware includes personal computers, scanners or digital cameras. Data storage programs and multimedia programs can be included in the software category. Communications technology is seen as a term used to describe telecommunications equipment through which information can be made available. This is mainly about telephones, faxes or television."

<sup>&</sup>lt;sup>6</sup> BOYER, K., HALLOWELL, R., ROTH, A. V. Eservices: operating strategy – a case study and a method for analyzing operational benefits. In: Journal of Operations Management. 2002, vol. 58, ed. 2, p. 175.

infrastructure, information activities, and electronic services.<sup>7</sup> An information system, as an example of information technology, represents a functional unit that ensures purposeful and systematic information activity through technical and programmatic means.<sup>8</sup>

While the aforementioned law does not explicitly address the term "communication technology," the legislator includes communication technology under information technology, given that part of information technology focuses on information activity, including data acquisition, processing, making available, transmission, archiving, and disposal. In practice, the term "digital technology" is also used to refer to electronic technology that creates, transmits, and processes data and information using binary code (ones and zeros), with each unit referred to as a "bit."

It is noteworthy that despite its title, the Digital Services Act does not provide a precise definition of the concept of digital services. Instead, it outlines the content of terms such as "**information society service**" and "**intermediary service**." These terms will be elucidated further in subsequent sections of the paper. For the purposes of this paper, the foundational terminological thesis to consider is that informatization, electronicization, and digitalization share a common denominator: information and communication technologies. These activities primarily occur through the use of ICT, often within the virtual realm of cyberspace and frequently via the global Internet.

## 1. Digital services in healthcare

Following the clarification of terms, it is evident that both European and Slovak strategic and legislative documents employ the term "electronic health services" to refer to health services provided electronically using information and communication technologies. We argue that these services can also be referred to as "digital services" since they rely on electronic technology operating based on binary code, a form that can be processed by computers, one of the most prevalent information and communication technologies. Consequently, in the subsequent sections of this paper, we will use these terms interchangeably depending on the context, but they will always pertain

Provision § 2 par. 1 of the Act on ITVS.

<sup>&</sup>lt;sup>8</sup> Provision § 2 par. 2 of the Act on ITVS.

<sup>&</sup>lt;sup>9</sup> Provision § 3 letter a) of the Act on ITVS.

to services within the realm of electronic healthcare, commonly referred to as e-Health. The term "e-Health" conceptually includes all aspects of health, not only health care or healthcare, for example, individual health promotion measures, perhaps in homes, medical facilities or schools. <sup>10</sup>

The development and implementation of digital healthcare services represent a prominent trend in the contemporary world. However, certain prerequisites must be met to enable the development and utilization of digital services. These prerequisites include political will for their introduction, the provision of electronic identification and authentication capabilities for users and service providers, the necessary hardware and software infrastructure, access to the Internet, an online portal encompassing essential information, forms, and service access, and, importantly, information systems from which data is derived to support individual electronic services.<sup>11</sup>

Based on an examination of national strategic documents, legislation, and other sources, including European Union programs and non-legislative legal information available on professional websites<sup>12</sup>, we present the following overview of digital healthcare services in the Slovak Republic:

- **E-health** National health portal,
- Electronic health book,
- Patient summary,
- E-ordering electronic appointment booking with healthcare professionals,
- E-prescription electronic prescriptions for medicines, medical devices, and dietetic foods,
- E-examination electronic recording of medical examinations.
- **E-vaccination** electronic vaccination records,
- **E-lab** electronic records of laboratory examination results,
- E-PN electronic confirmation of temporary incapacity for work,
- **E-birth** electronic notification of child births.

<sup>&</sup>lt;sup>10</sup> STŘEDA, L., HÁNA, K. eHealth a telemedicine. Prague: Grada Publishing, 2016, p. 14.

ANDRAŠKO, J. et al. Regulatory challenges of e-Government in the Slovak Republic in the context of European Union law. Prague: Wolters Kluwer CR, 2022, p. 286.

<sup>&</sup>lt;sup>12</sup> For example, the eHealth portal operated by the National Center for Health Information.

- My Health application,
- eAlerts application<sup>13</sup>.

These services are provided to natural persons, including citizens of the Slovak Republic and foreigners who are part of the national social and health system. They also offer advantages to healthcare providers and professionals. The mentioned services are administered by the state in accordance with legislation.

In addition to these services, the private sector also provides other electronic services in the healthcare sector. These services primarily include:

- Online appointment booking with healthcare professionals,
- Virtual consultations with healthcare professionals,
- Provision of professional articles,
- Healthcare professional's evaluation.

## 1.1 Scope of the Digital Services Aut

The scope of the Digital Services Act is defined in Article 2, paragraph 1, with the modification that it applies to intermediary services offered to recipients of services residing in or located within the European Union, regardless of the location of the service providers. 14 The Digital Services Act imposes several obligations on providers of intermediary services, subject to the harmonization rules of the European Union concerning its member states. The objective is to "ensure a safe, predictable, and trustworthy online environment, combat the dissemination of illegal content on the Internet, mitigate societal risks associated with disinformation or other content, and effectively safeguard fundamental rights enshrined in the charter while fostering innovation."<sup>15</sup> Consequently, the regulation establishes conditions conducive to the development of innovative digital services and their expansion within the internal market. However, it is important to acknowledge that the increased usage of these services, even for legitimate and beneficial purposes, has also led to a rise in the dissemination of illegal or harmful information and activities.

More information about digital healthcare services in the Slovak Republic: SOPÚCHOVÁ, S. Electronic healthcare in the Slovak Republic. E-Health and telemedicine. Bratislava: Wolters Kluwer 2022

<sup>&</sup>lt;sup>14</sup> Article 2, paragraph 1 of the Digital Services Act.

<sup>&</sup>lt;sup>15</sup> Recital (9) of the Digital Services Act.

It is evident that the Digital Services Act introduces a new term into legal usage, namely "**intermediary service**," which it defines within its glossary of terms. An integral part of this definition is the concept of an "**information society service**." Therefore, we conclude that the Digital Services Act applies exclusively to providers of specific information society services, specifically intermediary services. Our analysis suggests that it is necessary to first clarify the concept of "information society services" and subsequently delve into the definition of "intermediary services." While the original definition of information society services can be found in another legislative act of the European Union, the term "intermediary services" is primarily used within the context of the Digital Services Act. <sup>16</sup>

Information society service constitute a significant segment of the European Union's economy and the daily lives of its citizens. All services provided within the realm of the information society can be categorized as such, encompassing services typically offered for a fee, delivered remotely, electronically, and in response to individual requests from service recipients.<sup>17</sup> This definition is further enriched by specific defining characteristics that merit reproduction:

- "remotely" signifies that the service is provided without both parties being physically present at the same location,
- "by electronic means" indicates that the service is transmitted from the point of origin to the destination using electronic equipment designed for data processing (including digital compression) and storage, with the entire transmission occurring via wire, radio waves, optical means, or other electromagnetic methods,
- "based on the individual request of the recipient of the services" implies that the service is provided through data transfer initiated by the individual recipient's request.<sup>18</sup>

In addition to the positive definition of information society services, Directive 2015/1535 of the European Parliament and the Council of the European Union, which establishes the procedure for providing

<sup>16</sup> The Digital Markets Act defines the term "online intermediary services", which it includes among basic platform services.

Article 1, paragraph 1, letter b) Directive 2015/1535of the European Parliament and the Council of the European Union, which establishes the procedure for providing information in the field of technical regulations and rules relating to information society services.

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information related to technical regulations and rules governing information society services, includes an indicative list of services that do not fall under this term.

Returning to the concept of intermediary services, which we categorize broadly as information society services, the second part of their definition is found within the Digital Services Act itself. Intermediary services, as a subset of information society services, encompass services that:

- a) transmit information provided by the service recipient through a communication network or provide access to a communication network, which constitutes "ordinary transmission" services.
- transfer information provided by the service recipient through a communication network, temporarily and automatically storing it solely to facilitate its subsequent transmission to other recipients upon their request, constituting "caching" services.
- c) store information provided by the service recipient upon their request, in which case they are referred to as "**hosting**" services.<sup>19</sup>

All three categories of intermediary services involve the transmission or storage of information provided by the service recipient. Consequently, they are subject to the liability of providers for foreign content. The Digital Services Act delineates provider liability by specifying under what circumstances they are not liable. Furthermore, the act imposes various obligations on these providers, including duties of due care to foster a transparent and safe online environment. It is worth noting that Directive 2000/31/EC of the European Parliament and the Council on certain legal aspects of information society services in the internal market, particularly regarding electronic commerce, addresses the liability of intermediaries and service providers. This directive, established in 2000, was transposed into Slovak law by Act no. 22/2004 Coll. on electronic commerce and amendments and additions to Act no. 128/2002 Coll. on state control of the internal market concerning consumer protection and amendments and supplements to various laws, as amended by Act no. 284/2002 Coll.

<sup>&</sup>lt;sup>19</sup> Article 3, letter g) Digital Services Act.

## 1.2 Digital healthcare services and the Digital Services Act

The effective operation of state digital healthcare services and e-Health applications necessitates several technical and legal instruments, primarily established by Act no. 153/2013 Coll. on the National Health Information System and on amendments and additions to certain laws (hereinafter referred to as the "NHIS Act"). These services are further supported by other legally binding regulations and by-laws. Key tools for digital healthcare services include the National Healthcare Information System, the citizen's electronic identity card, electronic proof of residence for foreigners, electronic ID cards for healthcare professionals, and health informatics standards.

The primary research objective stated in the introduction of this paper is to determine whether the Digital Services Act is applicable to the existing digital healthcare services in the Slovak Republic or if the regulation represents a new framework for governing these services.

The initial question we must address is whether the digital healthcare services qualify as services of the information society. Subsequently, we need to assess whether they fall under the category of intermediary services. This evaluation is conducted in connection with both the positive and negative definitions of information society services.

As previously mentioned, information society services, according to the positive definition, encompass all services provided by an information society, typically offered for a fee, delivered remotely, electronically, and in response to the individual request of the service recipient. The negative definition, found in Annex I of Directive 2015/1535, specifies certain services that do not exhibit all the defining characteristics of an information society service. The issue at hand pertains to examples like a medical examination or treatment in a healthcare clinic, which, despite the potential use of electronic equipment, involve the physical presence of the patient and thus do not qualify as services provided at a distance. Furthermore, services such as consultations with a doctor via telephone are not considered services electronically. Consequently, medical examinations. treatments, and phone consultations with a doctor do not constitute information society services due to the absence of some defining features.

It is important to note that the list of services that do not qualify as information society services is merely indicative. Digital healthcare services provided in the Slovak Republic do not appear on this list,

necessitating an assessment based on the positive definition of an information society service. Despite being offered remotely and electronically, these services are not typically fee-based and may not always align with individual requests from service recipients. Therefore, we assert that none of the digital healthcare services provided by the state qualify as information society services. Consequently, considering the above, they also do not qualify as intermediary services since they fail to meet the fundamental requirement of being an information society service.

## 1.2.1 Digital healthcare services provided by private sector

Within the realm of electronic healthcare provision, especially in fields like telemedicine and robotics, dynamic developments are underway, driven significantly by the widespread adoption of artificial intelligence. These innovations are making significant inroads in the healthcare sector, not excluding the direct provision of healthcare services.

In addition to digital services covered by the state and constituting the e-Health initiative in Slovakia, the private sector offers supplementary healthcare services. These services lack official recognition, names, or inclusion in the e-Health project. Upon analyzing the online landscape, these services can be categorized into several levels:

- Online appointment booking with healthcare professionals,
- Virtual consultations with healthcare professionals,
- Provision of professional articles,
- Healthcare professional's evaluation.

Since many of these services are typically provided through a single website, we will examine them collectively as a package of services. The services are notably diverse, encompassing online healthcare consultations (akin to telemedicine), appointment booking for precise doctor visits, and doctor evaluation services with attributes of an information society service. In the following section, we delve into an analysis of these digital services.

## Online appointment booking with healthcare professionals

Private portals within the healthcare sector (hereinafter referred to as "private healthcare portals") offer the option of booking appointments with healthcare professionals for a fee. Considering the additional attributes of information society services, we assert that the service constitutes an information society service. This classification is based on several factors, including the service's fee-based nature, remote delivery through electronic means, and its provision upon individual request by the recipient.

This service does not involve the mere transmission of information provided by the service recipient via communication networks or providing access to such networks. It also does not entail the automatic, temporary storage of recipient-provided information for streamlining further transmission to other recipients upon their request. Moreover, it does not encompass the storage of information provided by the service recipient upon their request. From these considerations, it becomes evident that booking patient appointments with specific healthcare professionals via the Internet does not fall within the scope of an intermediary service as defined in the Digital Services Act.

Nevertheless, a pertinent question remains for further research: What is the legal basis for this type of appointment booking service? This inquiry arises because Act no. 576/2004 Coll. on healthcare, services related to healthcare provision, and the amendment of certain laws (hereafter referred to as the "Health Care Act") governs the legal framework for booking appointments. The Health Care Act allows for the possibility of booking free appointments with healthcare professionals from a waiting list during regular office hours or, alternatively, the option of booking appointments during extended office hours for a fee, with a maximum charge of EUR 30.<sup>20</sup> This service is delivered through a state-provided digital E-ordering system.<sup>21</sup>

## Virtual consultations with healthcare professionals

Virtual, or online, consultations with doctors are offered by private healthcare portals primarily for informative and advisory purposes. These portals explicitly state that their services do not serve as a substitute for personal medical examinations and diagnostics conducted through conventional medical procedures. Similar to appointment booking, virtual consultations involve fees and align with the characteristics of an information society service. However, they do

<sup>&</sup>lt;sup>20</sup> Provisions of § 2a of the Health Care Act.

Additional analysis of E-ordering system provided by state: SOPÚCHOVÁ, S. Electronic healthcare in the Slovak Republic. E-Health and telemedicine. Bratislava: Wolters Kluwer, 2022.

not meet the criteria for an intermediary service. It is worth noting that virtual consultations as a form of telemedicine are also supported by the state, especially during crisis situations, pursuant to amendments to the Health Care Act.<sup>22</sup> In this case, the Slovak legislator had in mind outpatient care, because experience has shown that the provision of consultations by telephone or e-mail is common, but these have not yet been supported by law (e.g. verification of results by telephone, health consultation, etc.).<sup>23</sup>

## Healthcare professional's evaluation

Healthcare professional's evaluation service represent a relatively recent addition to private-sector healthcare services, lacking state-provided alternatives. These services enable users to provide voluntary feedback about specific doctors. However, such ratings are typically contingent on having personally consulted with the doctor. Providers of these services typically disclaim responsibility for the accuracy and truthfulness of the ratings. They reserve the right to remove usergenerated content if it conflicts with the doctor's right to protect their personal reputation.<sup>24</sup> Notably, these services, although free for users (service recipients), can be a source of revenue for providers through advertising-related compensation or other means. This makes them an economic activity.

Healthcare professional's evaluation services exhibit characteristics of an information society service, as they are provided remotely through electronic means, based on individual service requests. While they are offered free of charge to users (service recipients), providers may earn compensation from third parties, contributing to their status as an economic activity. Healthcare professional's evaluation service also fall within the scope of intermediary services, particularly as "hosting" services. Operators of these private healthcare portals, functioning as service providers, store user-generated information at the recipient's request.

<sup>&</sup>lt;sup>22</sup> The provisions of § 49k par. 1 of the Health Care Act.

<sup>23</sup> SOPÚCHOVÁ, S. Artificial intelligence and its use in the process of providing health care. In: Human rights. From reality to the virtual world. Josefow: Alcide De Gasperi University of Euroregional Economy in Józefów, 2021, p. 94.

<sup>&</sup>lt;sup>24</sup> Internet portal TopDoktor. Business conditions. Available online: https://www.topdoktor.sk/p/ obchodne-podmienky

ANDRAŠKO, J. et al. Law of Information and Communication Technologies 2. Bratislava: TINCT, 2021, p. 63.

The Digital Services Act establishes that hosting service providers bear no responsibility for stored information unless specific conditions are met. These conditions encompass a lack of actual knowledge regarding illegal activity or content and a lack of awareness of facts or circumstances indicating obvious illegality. If such knowledge or awareness arises, hosting service providers must promptly remove or disable access to the unlawful content.<sup>26</sup>

In practice, situations may arise where user-generated content on healthcare professional's evaluation may exhibit signs of illegal activity or unlawful content.<sup>27</sup> While portal operators may provide doctors with the ability to delete ratings from their profiles, the legal obligation remains with the portal operator, not the doctor, to remove illegal content. This raises legal questions about the doctor's authority to assess what constitutes a violation of their personal rights and what qualifies as legitimate criticism - a form of freedom of speech. This situation presents two legal issues: determining who is obligated to remove illegal content (as clarified by the Act on Digital Services) and the subjective nature of content removal decisions, which could potentially infringe on freedom of speech.

## Conclusion

Digital services have become increasingly prevalent across various sectors of society, including healthcare, which is undergoing a transformation driven by information and communication technologies. However, healthcare services, including medical examinations, do not always fit neatly within the framework of the Digital Services Act, and this holds true for other areas such as autonomous vehicles and education. In this discussion, we have assessed whether digital healthcare services can be categorized under the Digital Services Act, a European Union regulation. Our examination led to several conclusions and raised some pertinent issues:

<sup>&</sup>lt;sup>26</sup> Article 6 par. 1 of the Digital Services Act.

According to Article 1 letter h) of the Digital Services Act is illegal content "any information that, by itself or by referring to any activity, including the sale of products or the provision of services, is not in accordance with the legal regulations of the Union or any member state, regardless of the precise subject matter or nature of such legislation.

## Public vs. private sector digital healthcare services

We divided digital healthcare services into those provided by the state (public sector) and those offered by private companies (private sector). This distinction reflects the current situation in the Slovak Republic, shaped by the state's inability to provide comprehensive digital healthcare services.

Our research revealed that the Digital Services Act primarily applies to electronic healthcare services in the private sector, while public sector services do not fall under its purview. The fundamental reason for this differentiation is that public sector services do not meet the criteria of information society services or intermediary services as defined by the Act.

## Private sector intermediary services

Within the private sector, certain services could be considered intermediary services. Notably, healthcare professional's evaluation services and platforms for publishing professional articles stand out in this regard. These services involve the storage of user-generated content, which is an essential characteristic of intermediary services under the Digital Services Act.

#### Content moderation and removal

The issue of content moderation and removal becomes significant in the context of healthcare professional's evaluation services. It raises questions about balancing freedom of speech with the protection of individual personality rights. The Digital Services Act places the responsibility for content removal on service providers, creating a potential tension between these two fundamental rights.

## **Duplication of services**

A peculiar situation has arisen in Slovakia concerning the duplication of digital healthcare services. For instance, the state offers a service for making appointments with doctors called E-ordering, while private health portals also facilitate online appointment booking with healthcare professionals for varying fees. The legal basis for such private services differs, and the market pricing for these services varies significantly.

## Virtual consultations and non-standard approaches

Virtual consultations with doctors are another point of contrast between public and private sector offerings. The state regulates electronic consultations quite restrictively, allowing them only during crisis situations. In contrast, private healthcare portals offer consultations with doctors for a fee but emphasize that these consultations are not a replacement for traditional healthcare. This approach raises concerns about cybersecurity, personal data protection, and liability for damages, which remain inadequately addressed.

In summary, our research confirmed initial hypothesis that digital healthcare services cannot be neatly categorized and subjected to the Digital Services Act's provisions. The complex landscape arises from the coexistence of services provided by both the state and private entities in Slovakia. This situation underscores the need for comprehensive legal frameworks to govern digital healthcare services and ensure they meet the highest standards of safety, security, and quality.

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