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Legal Framework for Telemedicine in Georgia: Doctrinal and Comparative Legal Analysis of International Standards and National Practices

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Abstract

Based on national and international practice, this article discusses telemedicine as a set of legal, technological, and ethical decisions that are an inevitable result of the modern healthcare system. This article aims to assess the adequacy of Georgia's regulatory framework for telemedicine through a comparative analysis of international standards and national legislation, and to identify existing legal gaps.

From the perspective of international law, the right to health is recognized as a fundamental human right, obligating states to ensure the accessibility, quality, and continuity of medical services for all citizens. Accordingly, the study focuses on the possibilities of telemedicine, which is an effective mechanism for providing continuous and high-quality medical services, especially in geographically remote, rural, and politically/strategically challenging regions.

The research is based on doctrinal legal analysis, comparative examination of international and Georgian normative acts, and analysis of relevant case law. International instruments and standards examined include World Health Organization (WHO) recommendations, ISO 13131:2021, the EU General Data Protection Regulation (GDPR), and the U.S. Health Insurance Portability and Accountability Act (HIPAA), and relevant

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jurisprudence of European and U.S. courts. Georgian healthcare, medical practice, and data protection legislation were analyzed to assess regulatory compatibility and implementation practice. Taking into account the realities of Georgia, the article analyzes national legislation and the existing practice of developing telemedicine. Special attention is paid to the possibilities of implementing telemedicine in politically and strategically difficult regions as one of the effective mechanisms for ensuring continuous and high-quality medical services for the population.

Based on the results of the study, which is based on the analysis of international practice and regulatory standards, the article presents recommendations for strengthening the legal framework of telemedicine in Georgia, which takes into account the protection of patient rights, strengthening professional responsibility standards, and improving access to medical services in politically and strategically difficult regions.

The study reveals that although Georgian legislation allows telemedicine within the framework of general medical regulation, it lacks: a unified legal definition of telemedicine; specific binding standards for remote informed consent procedures; detailed regulation of cross-border and regional licensing issues; explicit clinical quality assurance mechanisms tailored to remote healthcare services; and specialized liability rules adapted to digital medical practice. International standards demonstrate a trend toward harmonization based on patient rights protection, data security, professional accountability, and technological interoperability, while Georgia's framework remains fragmented and indirectly regulated.

To strengthen the legal framework for telemedicine in Georgia, the study recommends: adopting a comprehensive legal definition and regulatory act dedicated to telemedicine; establishing mandatory digital informed consent standards; introducing telemedicine-specific certification and liability provisions; strengthening state supervision and quality control mechanisms; and improving legal guarantees for safe telemedicine practice in politically and geographically complex regions. The development of a coherent telemedicine regulatory model would contribute to the effective realization of the right to health, enhance access to quality medical services, and align Georgian practice with evolving international standards.

Keywords: Medical institutions, medical services, patient rights, regional healthcare, telemedicine

Introduction

The right to health is internationally recognized as an integral and fundamental part of human rights, obliging the state to ensure the accessibility, quality, and effectiveness of health care for the population. This principle is

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confirmed by Article 25 of the Universal Declaration of Human Rights (1948), according to which "everyone has the right to a standard of living adequate for the health and well-being of the population" (Universal Declaration of Human Rights, 1948, Art. 25). This obligation is further reinforced in the International Covenant on Economic, Social and Cultural Rights,1966), whose Article 12 obliges states to ensure equal access, reliability and quality of health care for all, without discrimination (International Covenant on Economic, Social and Cultural Rights, 1966, Art. 12).

The article provides assessments of legal, ethical, and professional standards that set the rules for the provision of remote medical services, including informed consent, personal data protection, quality control of medical services, and professional liability. The article also discusses international regulations and recommendations, including the recommendations of the World Health Organization (WHO), the ISO 13131:2021 standard, the European General Data Protection Regulation (GDPR) and the United States Health Insurance Portability and Privacy Act (HIPAA), the case law of the European Court of Human Rights and the US courts, which makes it possible to assess the balance between patient rights, professional obligations and state control.

The synthesis of the obtained results serves to assess the legal mechanisms and develop doctrinal recommendations for improving the regulation of telemedicine. Healthcare in Georgia is significantly conditioned by regional differentiation and infrastructural limitations, which are especially noticeable in politically/strategically difficult regions. In an environment where the provision of healthcare services is limited, telemedicine is a legal instrument for protecting patient rights, which contributes to the protection of patient health and equal and safe access to medical services.

Methods

The research methodology is based on doctrinal analysis, a comparative study of international and national normative frameworks, as well as a substantive analysis of case law and political-legal documents. However, beyond descriptive examination, the study applies a structured analytical framework that evaluates telemedicine regulation through predefined legal indicators. The analysis proceeds in three stages: 1) Identification of core regulatory components of telemedicine; 2) Comparative assessment of international and selected foreign standards; 3) Evaluation of the Georgian legal framework against identified benchmarks. The methodological approach combines deductive and inductive methods, which ensure both the transition from general principles to specific cases and the formation of general conclusions based on practical material. Deductive reasoning is used to derive

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evaluation criteria from international human rights standards, while inductive analysis is applied in assessing national legislative practice and case law.

The study uses a comparative analysis of international and national normative frameworks, which makes it possible to identify similarities and differences in legal instruments for telemedicine in different jurisdictions. The selection of international instruments and foreign jurisdictions was based on the following criteria: Normative authority and global influence (e.g., WHO recommendations, ISO standards); Advanced regulatory maturity in telemedicine governance (European Union, United States, Germany); Relevance to data protection and digital healthcare regulation; Applicability to Georgia's legal system and international obligations (particularly under the International Covenant on Economic, Social and Cultural Rights and the European human rights framework). The European Union was selected due to its comprehensive regulatory model (GDPR, Cross-Border Healthcare Directive, European Health Data Space Regulation). The United States was included as a model of decentralized but highly developed telemedicine practice and liability regulation. Germany was chosen as a representative civil law jurisdiction that recently transitioned from restrictive to regulated telemedicine practice, offering a useful evolutionary comparison.

The work is also based on comparative and historical-chronological analysis, which allows assessing the evolution and development trends of telemedicine regulation. The comparative assessment is structured around five core regulatory dimensions: Legal definition and normative recognition of telemedicine; Patient rights protection mechanisms (including informed consent standards); Personal data protection and cybersecurity safeguards; Clinical quality standards and professional certification requirements; Professional liability and regulatory oversight mechanisms; Each jurisdiction is examined across these dimensions to identify similarities, divergences, and levels of regulatory sophistication.

To ensure systematic evaluation, the study applies the following legal indicators: Compliance level with international human rights obligations (right to health; Article 12 ICESCR; Article 8 ECHR); Level of patient rights protection (clarity of informed consent rules, enforceability, remedies); Regulatory maturity (existence of telemedicine-specific legislation vs. indirect regulation); Institutional oversight mechanisms (supervisory authorities, licensing systems); Normative coherence and clarity (presence of unified regulatory model vs. fragmented framework). These indicators are used to assess both international regulatory models and the Georgian legal system.

Judicial decisions of the European Court of Human Rights, the Court of Justice of the European Union, and U.S. courts were analyzed to identify interpretative trends regarding: medical data confidentiality, cross-border telemedicine services, licensing and state regulatory authority, and balancing

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professional freedom and public interest. The case law analysis serves as a functional test of how telemedicine norms operate in practice.

The Georgian legal framework was evaluated against the comparative benchmark model developed in this study. Normative acts governing healthcare, medical activity, personal data protection, electronic health records, and digital prescriptions were examined to determine whether telemedicine is formally recognized, whether remote-specific procedural safeguards exist, whether professional responsibility is adapted to digital healthcare, and whether regional accessibility obligations are adequately addressed. By operationalizing legal comparison through defined indicators and structured regulatory dimensions, the study moves beyond descriptive doctrinal analysis and provides a systematic evaluation of the strengths, gaps, and developmental stage of telemedicine regulation in Georgia.

Results

1. Legal Essence of Telemedicine

Telemedicine is an important mechanism for implementing the state's positive obligation to improve access to healthcare across the country, especially in regions where geographical, infrastructural, or political barriers limit the provision of medical services (World Health Organization [WHO], 2016).

Telemedicine refers to the remote provision of medical services using information and communication technologies, including remote consultations, electronic data transmission, and patient monitoring. The purpose of these services is to improve healthcare delivery throughout the country, including in the regions, increase the efficiency of medical services and reduce waiting times, and ensure the active involvement of the population in managing their own health. Legally, telemedicine includes a complex of relationships related to medical activities that are carried out through remote communication, between a doctor and a patient, or between doctors, using digital platforms and technological means (WHO, 2010).

Understanding the legal nature of telemedicine is based on two main principles:

First, international obligations related to the realization of the right to health, and second, ensuring patient data protection and informed consent in a remote environment. Telemedicine requires regulating the issues of patient identification, informed consent, data protection, confirmation of diagnosis, and professional liability in a way that does not create the risk of violating patient rights or violating professional ethics (Health Insurance Portability and Accountability Act, 1996).

Telemedicine disease management promotes active patient engagement in self-care, continuous monitoring, and rapid response by

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healthcare providers. However, technological progress cannot replace the core of medical responsibility, and the physician remains responsible for the consequences of his or her professional conduct, even when medical care is provided in a remote, digital environment (Bashshur et.al., 2014).

As a result, even in the context of remote medical care, the center of responsibility is still focused on the doctor's professional judgment, which emphasizes the need to strengthen the legal framework.

2. International standards and regulations

As can be seen from the analysis of international practice, telemedicine is regulated by various legal acts and professional standards that ensure the protection of patient rights, the quality of clinical services, and technological safety.

The “Global Standard for Accessibility of Telemedicine Services”, published in 2022 by the World Health Organization and the International Telecommunication Union (ITU), defines the technical requirements for the accessibility of telemedicine platforms, which are intended to be taken into account in national regulations in member states (WHO & International Telecommunication Union [ITU], 2022).

The International Organization for Standardization (ISO)'s "Health informatics - Telehealth services - Quality planning guidelines" is a comprehensive telemedicine standard, ISO 13131:2021, that focuses on quality, risk, and resource management. It improves data security and patient care (International Organization for Standardization [ISO], 2021).

In the United States, the Health Insurance Portability and Accountability Act establishes fundamental principles for the confidentiality and security of patient health information. The law sets out rules governing the storage, transfer, and protection of personal health information by healthcare providers, and ensures the patient’s right to control the use of their information. This mechanism directly affects the security and trustworthiness of telemedicine services (Health Insurance Portability and Accountability Act, 1996).

Regulation (EU) 2016/679 of the European Parliament and of the Council - General Data Protection Regulation [GDPR], 2016/679, 2018, is a fundamental document in data protection legislation that regulates the collection, processing, storage, transfer of personal data and promotes the protection, accountability and control of personal data (Council Regulation (EU) 2016/679).

In the European Union, eHealth ensures efficiency, equitable access, and citizen engagement in health management (European Commission, 2012). This integrated approach creates a legal framework for eHealth to operate in a safe, standardized, and ethical manner. This multidisciplinary field brings

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together healthcare professionals, researchers, policymakers, and technologists, who collaborate to harness innovation for better health outcomes and more sustainable healthcare systems.

The Cross-Border Healthcare Directive (2011/24/EU), adopted in 2011, establishes the right of EU citizens to receive healthcare in other Member States under the same conditions as in their own country, thereby facilitating the continuity of healthcare and the secure exchange of data (Directive 2011/24/EU, 2011). However, access to health data varies across EU Member States, due to data formats, standards, and technological infrastructure. In response to the regulatory fragmentation in the field of health data management, the EU institutions adopted Regulation (EU)2025/327 – the European Health Data Space Regulation (EHDS), which guarantees the harmonisation of data protection, accessibility, and interoperability standards across Member States (European Commission, n.d.).

The German Professional Code for Doctors (Muster-Berufsordnung für Ärzte, or MBO-Ä) explicitly prohibited remote treatment until 2018 and required direct personal contact with the patient (unmittelbarer persönlicher Kontakt). However, in 2020, in light of technological progress and practical needs, the German Medical Association (Bundesärztekammer) updated the existing rules and established a framework within the framework of the federal guideline ("Telemedizinische Versorgung/ Fernbehandlung"), according to which remote consultations (by telephone or video) are only permitted if professional standards are met and the patient's informed consent is obtained (Professional Code for Physicians in Germany, 1997).

An analysis of international standards and regulations reveals that the legal framework for telemedicine is evolving dynamically. Although a universal normative model does not yet exist, states are gradually harmonizing based on patient rights, data security, and medical ethics.

A review of international standards and regulations reveals that telemedicine regulatory models are based on different, yet interconnected, principles. The EU model, particularly within the framework of the GDPR, is built on the principle of accountability and preventive regulation, which implies not only the existence of general data protection norms, but also specific requirements for technical and organizational security, a prior assessment of risks, and a clear definition of legal liability. The US model (HIPAA) is based on strict confidentiality and data protection regulations, where special attention is paid to security standards for the processing of electronic health information and practical enforcement of liability. The German model is a professional-ethical regulatory model that considers remote treatment permissible only under strict professional standards and clearly defines the boundaries of the doctor's liability. The analysis of these models shows that in international practice, the regulation of telemedicine is

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based on a combination of three main elements: first, the specification of technical and legal standards for data protection; second, specialized regulation of professional responsibility; third, quality and safety oversight mechanisms.

In the case of Georgia, the current legal framework contains general norms on patient rights and data protection; however, the specific technical, professional, and institutional regulation of telemedicine is not systematically formalized. Accordingly, the Georgian model is more general-normative, while the EU and US models are characterized by more detailed and instrumental regulation.

3. Professional Standards, Clinical Quality, and Legal Framework in Telemedicine

Professional Standards

Adherence to professional standards in telemedicine practice is a key guarantee in terms of medical ethics, data security, and patient rights. Professional standards are the cornerstone of the legal framework for remote medical services, as they define not only clinical and technical requirements, but also criteria for accountability, informed consent, and ethical control (American Telemedicine Association, 2022). Standardization helps ensure that remote consultations fully comply with professional obligations and clinical quality standards (European Commission, 2012).

Informed Consent

The requirement for informed consent of the patient within the framework of telemedicine services is based on Article 8 of the European Convention on Human Rights (ECHR), which guarantees the right to respect for private and family life (European Convention on Human Rights, 1950, Art. 8) and is based on the Convention on Human Rights and Biomedicine (Oviedo Convention), which defines ethical standards for medical practice (Convention on Human Rights and Biomedicine, 1997).

International standards emphasize the importance of patient information and consent in telemedicine. The patient must be provided with full information about the technologies used, medical procedures, possible risks, and data processing rules (Wootton, 1998). Informed consent is an ethical and legally binding requirement that guarantees patient autonomy and legal protection.

Data Protection and Confidentiality

Protecting a patient's personal and medical data is a key element of telemedicine. Different jurisdictions regulate the issue differently, but the

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main principles are common: protection of confidentiality, secure storage of data, and transparency of processing.

The Health Insurance Portability and Accountability Act in the USA sets strict standards for the storage and transfer of medical information (HIPAA, 1996).

The General Data Protection Regulation of the European Union establishes enhanced standards for the processing, storage, and transfer of data, including for remote healthcare services. Data protection requirements are a legal obligation, the violation of which entails not only civil, but also administrative and criminal liability (GDPR, Regulation (EU) 2016/679).

The "Telemediengesetz" and "Sozialgesetzbuch V (SGB V)" in force in Germany include special articles that define informed patient consent, data security measures, and the legal basis for e-health services (Grau et al., 2025).

Clinical standards

The clinical quality of telemedicine is regulated by international protocols and guidelines, the purpose of which is to maintain the quality of remote healthcare services. Remote diagnostics and monitoring should be carried out with the same clinical accuracy as traditional consultations (Kruse et al., 2017). The patient should have the opportunity to request a face-to-face consultation if necessary, which contributes to the observance of the full cycle of medical care (World Health Organization. (2022). The international quality guideline - ISO 13131:2021 standard defines the criteria for planning the quality of telemedicine services, which ensures the accuracy and standardized methodology of remote diagnostics (International Organization for Standardization, 2021).

Liability and certification issues

The provision of telemedicine services requires a clear legal framework that defines the responsibilities of the doctor and the conditions for certification (Bashshur et al., 2014). Professional liability should cover cases where medical errors, data breaches, or ethical breaches occur. At the same time, certification of the doctor is necessary for remote healthcare services as a quality guarantee and a safety tool (American Medical Association. (n.d.).

The Telemedizinische Versorgung guidelines approved by the German Medical Association establish a clear boundary between the doctor's liability and the patient's obligation to inform, which ensures a legal balance in remote treatment (Professional Code for Physicians in Germany, 1997).

The legal framework for telemedicine is based on a set of professional standards, ethical principles, and data protection, which determine both the quality of service, the limits of the doctor's liability, and the protection of the patient's rights. International practice shows that the legal framework is

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dynamically developing, and harmonization based on patient rights, data security, and medical ethics is one of the main conditions for the development of a modern digital healthcare system.

4. Case law

The article discusses court decisions that have had a significant impact on the development of the legal framework for telemedicine.

In the case of Biriuk v. Lithuania - the European Court of Human Rights confirmed that the confidentiality of a patient's medical data is a right protected by Article 8 of the European Convention on Human Rights (respect for private and family life). The Court noted that the state is obliged to ensure that the processing of medical information is carried out within a clear legal framework that protects both data security and the patient's identity. The decision is particularly important in the context of digital healthcare and telemedicine, where data exchange and processing require a high level of legal control (Biriuk v. Lithuania, 2018).

In case C-115/24, the European Court of Justice explained that “telemedicine” is a medical service that is based entirely on information and communication technologies, and the patient and the service provider are not in the same place. The Court ruled that the countries of the service provider can apply their own legislation, as long as quality and safety standards are met. National licensing requirements must comply with EU principles, such as the freedom to provide services in the EU internal market, and can be assessed in the context of the public interest (UJ v Österreichische Zahnärztekammer, 2025).

MacDonald v. Sabando - The New Jersey District Court upheld the constitutionality of New Jersey's telemedicine licensing law and dismissed a lawsuit by doctors from other states who sought to provide services from outside the state's borders. The decision strongly affirmed that states have the authority to regulate the practice of telemedicine within their jurisdiction, thereby underscoring the importance of a state-based licensing system in the field of telemedicine (MacDonald v. Sabando, 2025).

International case law confirms that telemedicine is recognized as a form of medical care that requires a balance between state regulation and professional freedom.

Georgian Legislation and Practical Experience in the Field of Telemedicine

The Georgian legal framework for the provision of healthcare and medical services is based on several key acts that define both the fundamentals of medical services and patient rights, informed consent, and data protection.

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Legal Framework

The Law of Georgia "On Healthcare" establishes the state's obligation to create accessible and safe healthcare services for all citizens. Thus, the state is obliged to create a legal and organizational framework that ensures the efficiency, equality, and protection of citizens' health in the healthcare system (Law of Georgia On Health Protection, 1997).

The Law of Georgia "On Medical Activity" establishes the legal basis for regulating the practice of telemedicine, which includes the rules for providing medical consultations, standards of patient rights and data protection, as well as legal norms determining liability. The law provides that telemedicine consultations should be carried out only by an independent medical entity, which is fully responsible for the results of the consultation and the recommendations issued. Confidentiality of patient information is mandatory by law: all data that is examined, processed, or stored in the process of telemedicine must be properly protected. Technical personnel involved in telemedicine are obliged to adhere to confidentiality standards and not disclose information about the patient's health condition or details of the consultation. These legal regulations ensure the safety, quality of remote medical services, and the protection of patient rights (Law of Georgia On Medical Practice, 2001).

The Law of Georgia on Personal Data Protection defines the principles, rights, and obligations of data processing, which is especially important in the field of telemedicine. The law sets strict requirements regarding the lawfulness, purposefulness, and data security of data processing. Taking into account the principles of confidentiality and informed consent, the law is a guarantee of the protection of patient data (Law of Georgia on Personal Data Protection, 2023).

Normative acts regulate the rules for the functioning and production of the Electronic Health Record (EHR) system (Order No. 01-1/N on Determining the Procedure for the Functioning and Production of the Electronic Health Records System, 2019), the rules for the circulation of electronic prescriptions (Order No. 01-29/N on Approval of the Rules for Circulation of Form No. 3 Electronic Prescription for Pharmaceutical Products (Medicinal Products) Belonging to the Second Group, 2016) and the rules for the functioning and production of the electronic system of the register of persons with disabilities (Order No. 7/N on Approval of the Rules for the Operation and Maintenance of the Electronic System of the Register of Persons with Disabilities, 2024), which play an important role in the process of developing and legalizing telemedicine.

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Patient rights in the context of telemedicine

Georgian legislation establishes the basic rights and guarantees of the patient that fully apply to all forms of medical services, including telemedicine. These rights include the principle of informed consent, the confidentiality of personal data, and the protection of service quality standards (Law of Georgia On Health Protection, 1997, Art. 4).

The principle of informed consent implies the patient's right to receive complete and understandable information about the goals and content of the medical service, the expected benefits and risks, as well as the available alternatives, to be able to make a reasoned and voluntary decision (Law of Georgia on Medical Practice, 2001, Art. 91).

Protection of personal data - data collected, processed, and stored in the process of telemedicine must be protected in accordance with the law. The medical institution is obliged to take technical and organizational measures to ensure data security (Law of Georgia on Personal Data Protection, 2023, Art. 6).

Quality of service - medical consultations must comply with professional standards, and specialists are obliged to establish a complete and reliable diagnosis, if necessary, with the recommendation of additional studies or a personal visit (Law of Georgia on Medical Practice, 2001, Art. 90).

Specificity and regional significance of telemedicine

Telemedicine services are not formalized as an independent legal institution in the Georgian legal system at this stage, although the current normative framework allows it to be implemented within the framework of general medical activities and patient rights regulations. Telemedicine acquires particular importance in politically and strategically difficult regions of Georgia, where the infrastructural capabilities for providing medical services are limited, while the personnel are insufficiently represented and the geographical location significantly limits the population's access to medical services. In such conditions, remote consultations are an important legal and practical mechanism for the state, which guarantees the realization of citizens' right to health and the continuity of medical services.

For Georgia, as a State Party to the International Covenant on Economic, Social and Cultural Rights, the right to health implies the State's obligation to ensure accessible, quality, and equitable health care for all citizens, including in areas where the provision of services is geographically or politically restricted. This international obligation is also reflected at the national level, within which telemedicine is considered as one of the legal and organizational tools that combines the principles of medical ethics, data protection, and quality of service (International Covenant on Economic, Social and Cultural Rights, 1966).

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The normative acts of the Ministry of Health of Georgia regulate the rules for the production, storage and protection of electronic health records, as well as the legal framework for the issuance and use of electronic prescriptions, which creates both a legal and technical basis for the development of telemedicine. These regulations aim to ensure the security, confidentiality and reliability of remote communication, which is directly related to the constitutional principles of protecting patient rights.

The importance of the development of telemedicine has especially intensified after the COVID-19 pandemic, when the provision of medical services in regional and high-mountainous settlements was seriously limited. A three-year telemedicine initiative was launched in September 2021 with funding from the European Union and the involvement of four UN agencies (WHO, UNFPA, UNICEF, UNOPS). The aim of the initiative was to mitigate the impact of COVID-19 through digital health tools and take initial steps towards a long-term transformation of the healthcare system (World Health Organization, 2025). Within the framework of the joint initiative, the implementation of the telemedicine model began, as a result of which more than 60 primary healthcare facilities were equipped with digital technologies, and specialized trainings were held for medical personnel in order to provide qualified remote healthcare services. The support of UNICEF and the European Union is important, within the framework of which UNICEF and the European Union have begun the integration of digital healthcare systems in rural clinics of Georgia. The initiative includes organizing online meetings for parents on issues of child care and development. The main goal is the long-term transformation of the healthcare system and wider access to medical services (UNICEF for every child, 2023).

Thus, telemedicine in the Georgian legal space can be assessed as a modern healthcare tool that ensures the decentralization of medical services, the realization of citizens' right to health, and the full fulfillment of the state's obligations in the field of healthcare, and represents a legal mechanism for the effective implementation of the state's obligations in the context of protecting the right to health.

Assessment of Georgian regulation based on analytical indicators

The assessment of the current legal framework in Georgia was carried out on the basis of the analytical indicators of the study, which makes it possible to determine its relevance in terms of the safe and rights-based implementation of telemedicine.

Level of protection of patient rights - Georgian legislation provides for the general principle of informed consent and recognition of patient autonomy. However, the specific conditions of telemedicine - including remote identification, electronic consent format, and extended information about

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technological risks - are not specifically regulated and do not contain a detailed standard adapted for telemedicine.

Data protection regime - The Law "On Personal Data Protection" creates a general legal basis for the processing of medical data. Nevertheless, the minimum technical requirements for the security of telemedicine platforms are not specifically defined at the normative level, which may create a lack of legal clarity in practice.

Professional liability and access regime - The current regulation does not distinguish telemedicine as an independent professional category. The liability of a doctor is determined by the rules of general medical activity, which provide a legal basis, but do not establish specific professional standards for remote diagnostics and consultation. Thus, the liability model is formally valid, but not specialized.

Regulatory enforcement and quality control mechanisms - A special monitoring or supervision mechanism for telemedicine is not institutionally established. The existing control system is based on general medical supervision and does not take into account the specific technological and cybersecurity risks of remote healthcare services.

The above assessment indicates that the implementation of telemedicine in Georgia is legally possible; however, regulation requires structural refinement and detailing tailored to the specifics of telemedicine to ensure effective protection of rights and uniform enforcement of quality standards.

6. Recommendations for Georgia to Strengthen the Legal Framework for Telemedicine

Protection of Patient Rights

Identified Legal Gap: The current legislation provides for the general principle of informed consent; however, in the specific conditions of telemedicine (remote identification, electronic consent, extended information about technological risks), a specialized standard is not defined. Accordingly, it is advisable to establish a special standard for informed consent, which determines the patient's right to receive full information about the technologies used, medical interventions, possible risks, and alternative treatments. This standard should be approved and controlled by an independent body.

Strengthening professional responsibility and clinical standards

Identified Legal Gap: In telemedicine, the boundaries of a doctor's professional responsibility and specific certification requirements are not separately established by law, and international clinical standards are not systematically integrated into the national framework. Accordingly, it is advisable to clearly define the professional obligations of a doctor,

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certification rules, and liability limits in the legal framework of telemedicine, as well as to gradually implement international standards (ISO 13131:2021). It is necessary to systematically retrain medical personnel in ethics, use of technologies, and data protection. 6.3. Improving access to medical services in hard-to-reach regions

Identified legal gap: Despite the use of telemedicine, institutional support for remote healthcare services and legal mechanisms for service continuity are not fully structured, especially in crises. Accordingly, it is advisable to promote the development of technological infrastructure and the availability of remote healthcare services within the framework of state policy. Special protocols should be defined by legislation to ensure the continuity of medical services in crises.

The above recommendations stem from the legal gaps identified in subsection 5.4 and represent a logical continuation of the evaluative analysis, which ensures a direct link to the findings of the recommendations.

The analytical assessment of the study showed that telemedicine is an effective tool for improving the accessibility and quality of medical services, especially in regions with limited healthcare infrastructure. A comparative analysis of international standards and national regulations revealed that modern telemedicine models are based on detailed data protection mechanisms, a specialized definition of professional liability, and institutional oversight systems.

The assessment of the Georgian legal framework according to four analytical indicators revealed that the implementation of telemedicine is formally possible within the framework of the current legislation; however, the regulation is not fully adapted to the specific risks of remote medical services. In particular, there is no specialized standard for remote informed consent; technical requirements for data protection in the context of telemedicine are not detailed; the boundaries of professional liability are not specifically defined for remote healthcare services; And the oversight mechanisms are based on general medical control and do not take into account technological risks.

As a result, the study concludes that the successful and safe development of telemedicine in Georgia depends on the systematic refinement of the legal framework and regulation tailored to the specifics of telemedicine, which ensures effective protection of patient rights, data security, and uniform enforcement of quality standards, including in a regional and politically complex environment.

Discussion

The article proposes recommendations for strengthening the legal framework for telemedicine in Georgia:

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Protection of patient rights - It is advisable to establish a standard for informed consent, which determines the patient's right to receive full information about the technologies used, medical interventions, risks, and alternative treatments. The standard should be monitored by an independent body.

Strengthening professional responsibility and clinical standards - The legal framework for telemedicine should define the professional obligations of a doctor, certification rules, and limits of responsibility, and include the implementation of international standards (ISO 13131:2021). It is necessary to systematically retrain medical personnel in the direction of ethics, use of technology, and data protection.

Improving access to medical services in hard-to-reach regions - The state is obliged to promote the development of technological infrastructure and the availability of remote healthcare services. In crises, it is necessary to have protocols defined by legislation for the continuity of medical services.

This table presents a systematic grouping of recommendations, identifying the parties implementing each recommendation and the corresponding key actions. This format provides a clear understanding of the components of the recommendations and the possibility of visual analysis of the distribution of responsibilities, which creates an important basis for the transparency of scientific analysis and the effectiveness of policy development (Table 1).

Table 1: Recommendations, implementing parties and key actions/activities

№	Recommendation	Implementing Parties	Key Actions/Activities
1	Creating an informed consent standard	Ministry	Develop a standard defined by legislation that ensures full patient information about the medical technologies used, interventions performed, possible risks and alternative treatments.
2	Medical data protection	Medical institutions, Ministry	Define requirements for the processes of collecting, storing, processing and transferring personal data.
3	Monitoring and control	Ministry, Ministry agencies	Develop mechanisms for monitoring informed consent, data confidentiality and compliance with medical ethical norms. In case of detection of violations of the law, appropriate response should be taken.
4	Professional obligations of a doctor	Ministry, professional associations	Define medical certification procedures. Clarify the boundaries of a doctor's professional responsibility within the framework of telemedicine.
5	Implementation of international standards	Medical institutions, Ministry	Implement the ISO 13131:2021 standard in remote diagnostics and monitoring processes.

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6	Professional retraining	Ministry, professional associations	Systematic retraining of medical personnel in the ethics of telemedicine, the use of modern technologies, and data protection.
7	Technological infrastructure in difficult regions	Local self-government bodies, governments of autonomous republics	Large-scale implementation of electronic health records, remote consultations and electronic prescription records, with the aim of ensuring continuity of services.
8	Public-private partnership	Ministry, private sector	Strengthening cooperation to ensure maximum participation of the population in the implementation of innovative technologies.
9	Protocols	Ministry	Development of special protocols to ensure the continuity and safety of medical services.

Conclusions

The study found that telemedicine is an effective tool for improving access to and quality of medical services, especially in regions where healthcare services are limited. However, its practice is associated with significant legal challenges, including patient confidentiality, data security, professional liability, compliance with medical licensing rules, as well as special challenges in occupied/conflict territories, where legal regulations are associated with a complex political environment.

Based on the results of the study, the development of telemedicine in Georgia is advisable. Therefore, it is better to:

- Develop binding legal norms on informed consent of the patient, data protection and professional responsibility;
- Establish state supervision that ensures quality control and accountability of the entities involved;
- Promote the implementation of legal and technical training of doctors and healthcare professionals in the practice of telemedicine;
- Define legal mechanisms to ensure the safe and effective implementation of telemedicine practice in conflict regions.

Telemedicine can become an important tool in the field of health care; however, its success is associated with the full regulation of the legal framework, quality monitoring and safe operation, especially in regional, rural and politically and strategically complex areas.

The comparative analysis conducted in this study demonstrates that, unlike the regulatory models of the European Union and the United States, Georgian legislation does not yet establish a telemedicine-specific normative framework. While general healthcare and data protection laws provide a legal basis for remote healthcare services, the absence of a unified legal definition, standardized digital informed consent procedures, telemedicine-adapted licensing rules, and explicit liability allocation mechanisms indicates a fragmented level of regulatory maturity.

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In contrast, international standards such as ISO 13131:2021 and regulatory instruments such as the GDPR and HIPAA provide detailed quality assurance, accountability, and data governance mechanisms tailored specifically to digital healthcare environments. The analysis of case law further confirms that contemporary legal systems increasingly treat telemedicine as an autonomous modality of medical practice requiring explicit regulatory safeguards.

The identified gaps in Georgian legislation - particularly regarding remote-specific consent standards, cross-border service provision, certification requirements, and structured supervisory oversight - demonstrate that telemedicine is currently regulated indirectly rather than systematically. This regulatory fragmentation may create legal uncertainty for medical professionals and insufficient procedural guarantees for patients.

Therefore, the recommendations proposed in this study are not merely normative policy suggestions, but are directly derived from the comparative evaluation of regulatory maturity, patient rights protection standards, and compliance with international obligations concerning the right to health. Strengthening the telemedicine framework in Georgia would enhance legal certainty, reinforce data security guarantees, and ensure more effective realization of healthcare accessibility, especially in geographically remote and politically sensitive regions.

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