

## TELEMEDICINE AS A NEW FORM OF MEDICAL SERVICES – LEGAL ASPECT\*

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**Abstract.** Telemedicine, a rapidly evolving field enabled by telecommunications technology, is transforming healthcare on a global scale. It offers new avenues for accessing medical services and redefines the patient-physician relationship, encompassing diagnosis, treatment, and health condition monitoring. However, this transformative force in healthcare is accompanied by intricate legal and regulatory complexities that warrant profound exploration. This article delves into the legal facets of telemedicine, examining its regulation, patient data protection, physician liability, and global variations. It also underscores the paramount importance of safeguarding patient privacy in the digital age of healthcare. This comprehensive analysis illustrates the profound influence of legal considerations on healthcare quality and patient safety, and how they shape the course of technology-driven healthcare.

**Keywords:** healthcare; medicine; patient safety; telemedicine

### 1. BACKGROUND

Telemedicine has surged to the forefront of healthcare, fundamentally reshaping the way we access medical services and interact with healthcare providers. As this innovative field continues to evolve, it brings to the fore an array of legal and regulatory challenges that have far-reaching implications for patient care and safety. In this article, we embark on an insightful

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journey into the legal intricacies surrounding telemedicine, shedding light on how legal regulations govern its practice, ensure patient data protection, and define physician accountability. We also delve into the global variations in telemedicine regulations and explore the impact of technology on the ever-evolving landscape of healthcare law. Emphasizing the paramount importance of safeguarding patient privacy in the digital era, this article serves as a valuable resource for healthcare professionals and patients navigating the dynamic realm of telemedicine.

### **1.1. The Significance of Telemedicine in Healthcare**

Telemedicine, as a rapidly evolving field based on telecommunications technology, plays a crucial role in transforming healthcare worldwide. It opens up new possibilities for accessing medical services and changes the way patients and healthcare providers communicate, diagnose, treat, and monitor health conditions.

The significance of telemedicine extends to several key areas: 1) accessibility: telemedicine provides an innovative way for patients, particularly those in remote or underserved areas, to access healthcare services. It breaks down geographical barriers, enabling individuals to connect with healthcare professionals without the need for travel; 2) convenience: telemedicine offers a convenient option for patients who may have difficulty attending in-person appointments due to work, family commitments, or transportation issues. Patients can receive care from the comfort of their homes; 3) efficiency: telemedicine can streamline healthcare delivery by reducing waiting time and enabling quicker access to care. It also facilitates follow-up appointments and monitoring, improving overall healthcare efficiency; 4) cost-effectiveness: telemedicine can potentially reduce healthcare costs for both patients and providers. It can limit the need for physical infrastructure and staffing associated with traditional healthcare settings; 5) healthcare professional collaboration: telemedicine fosters collaboration among healthcare professionals, allowing specialists to consult on complex cases and share expertise with their peers; 6) remote monitoring: telemedicine supports the remote monitoring of patients with chronic conditions, enabling healthcare providers to track health indicators and intervene when necessary; 7) emergency care: in emergency situations, telemedicine can be a lifeline, connecting patients with emergency medical specialists for immediate assistance; 8) global health: telemedicine has applications in global health initiatives, such as teleconsultations for disease management and healthcare capacity-building in underserved regions.

As telemedicine continues to evolve, it plays a significant role in improving healthcare accessibility, efficiency, and patient outcomes. However, as it

becomes more integrated into healthcare systems, important legal and regulatory challenges must be addressed to ensure its safe and effective implementation.

Preventive examinations of workers, like any other medical examinations, should be conducted in accordance with existing regulations, professional ethics, and the guidelines of current medical knowledge.<sup>1</sup> What's more, Article 1 of the Act on Occupational Medicine<sup>2</sup> emphasizes that as part of health monitoring, workers receive medical information and medical recommendations regarding ways to prevent adverse changes in their health. Article 18 of this Act underscores the importance of the quality of preventive examinations, identifying this element as one of the main areas of control for the basic unit of occupational medicine conducted by the regional center of occupational medicine.

### **1.2. Legal and Regulatory Challenges in Telemedicine**

As telemedicine continues to play an increasingly vital role in healthcare, it faces important legal and regulatory challenges that impact its development and application. The use of telecommunications technology to deliver medical services raises numerous legal and ethical questions that require careful consideration.

Key legal and regulatory challenges in telemedicine include issues related to licensure and practice across state or national borders, patient data protection, physician liability, reimbursement policies, and the overall standard of care. For instance, when healthcare providers offer telemedicine services to patients located in different states or countries, questions arise regarding which laws and regulations apply and how healthcare professionals can practice within the confines of legal and ethical boundaries.

Data privacy and security are paramount concerns in telemedicine. Safeguarding patient information in digital formats is critical, and healthcare providers must comply with data protection regulations and standards. This entails addressing issues related to data transmission, storage, and access while ensuring the confidentiality and integrity of patient data.

Physician liability is another significant challenge. When providing remote healthcare services, healthcare professionals must adhere to the same standards of care and ethical guidelines as in traditional clinical settings.

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<sup>1</sup> Announcement of the Marshal of the Sejm of the Republic of Poland of January 13, 2022 on the announcement of the uniform text of the Act on the Occupational Health Service, Journal of Laws item 437.

<sup>2</sup> Regulation of the Minister of Health and Social Welfare of May 30, 1996 on medical examinations of employees, the scope of preventive health care for employees and medical certificates issued for the purposes provided for in the Labor Code, Journal of Laws No. 69, item 332.

This necessitates clear protocols for informed consent, documentation of telemedicine encounters, and the ability to provide a comparable quality of care to that of in-person visits.

Reimbursement policies present their own complexities in the telemedicine landscape. The billing and reimbursement framework for telemedicine services varies between regions and healthcare systems. These policies have a direct impact on the financial viability of telemedicine practices and the accessibility of care for patients.

The overall standard of care is a critical consideration in telemedicine. Ensuring that the quality of care provided through telemedicine is consistent with in-person care is of paramount importance. Medical boards and regulatory bodies must establish guidelines and best practices to maintain a high standard of care in the evolving field of telemedicine.

In this article, we delve deeper into these legal and regulatory challenges, offering insights into how they impact the telemedicine sector and the steps taken to address them. Understanding these challenges is essential for both healthcare professionals and patients who utilize telemedicine services to navigate this health care field in a safe and effective way.

## 2. UNDERSTANDING TELEMEDICINE

### 2.1. Defining Telemedicine

Telemedicine services, delivered over the internet, essentially consist of providing advice, lectures, guidelines for exercises, their assessment, monitoring, and consultations related to health education. These actions cannot be considered medical care. Medical care services require, at the very least, as inferred from the principles of experience, a thorough assessment to determine their necessity for achieving the intended goal. It is, therefore, necessary to evaluate the patient's health status to make a proper diagnosis and prescribe a suitable therapeutic course tailored to the specific individual [Pogorzelska, Marcinowicz, and Chlabicz 2023].

Services provided based on information received from clients may not always rely on credible, specific data that would enable proper medical care. The establishment of correct behavioral patterns cannot be equated with medical care. Telemedicine, while valuable, must grapple with the challenge of ensuring that remote consultations and recommendations are based on accurate and relevant health information, which can be especially complex in a virtual environment.

To understand what telemedicine is, an essential reference point is a judgment from the Administrative Court in Krakow: "Telemedicine

services provided via the internet essentially involve giving advice, lectures, providing guidance on exercise routines, their assessment and monitoring, as well as consultations regarding health education. These activities cannot be considered medical care. Medical care services require, at the very least, as inferred even from the principles of experience, a thorough determination that it is necessary to achieve the intended goal. It is therefore essential to assess the patient's health in order to make a proper diagnosis and prescribe an appropriate therapeutic course tailored to the specific individual. Services based on information provided by clients may not always rely on credible, specific data that enables proper medical care. Establishing correct behavioral patterns should not be equated with medical care.”<sup>3</sup>

It is crucial to distinguish between the guidance and information offered through telemedicine and the comprehensive medical care provided in a traditional clinical setting. Telemedicine, by its nature, often operates in a sphere that is more advisory and informative. It can offer guidance, share knowledge, and encourage healthy behaviors, but it may not be a direct substitute for a full medical examination and the development of precise medical treatment plans.

For many medical conditions, a hands-on evaluation is necessary to make an accurate diagnosis and develop a comprehensive treatment plan. Telemedicine can play a supportive and supplementary role in healthcare, providing a platform for remote discussions and initial assessments, but it might not replace the in-depth, in-person evaluations carried out in a traditional clinical setting.

The challenge, then, is to find a balance between the convenience and accessibility of telemedicine services and the necessity for comprehensive medical care that involves physical examinations and face-to-face interactions with healthcare professionals. Recognizing the strengths and limitations of each approach is crucial in optimizing patient care and ensuring that telemedicine complements, rather than replaces, traditional medical practices.

## **2.2. Telemedicine vs. Traditional Clinical Care**

The necessity of in-person evaluation and its differences from telemedicine are critical aspects to consider. In traditional clinical care, a patient visits a healthcare facility, and through a series of physical examinations, laboratory tests, and consultations, a healthcare professional can make a comprehensive assessment of the patient's health.

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<sup>3</sup> Judgment of the Provincial Administrative Court in Kraków of June 23, 2015, ref. no. I SA/Kr 721/15, Lex no. 1813436.

However, telemedicine operates differently. It relies on remote communication technologies to connect patients and healthcare providers. Telemedicine can provide valuable services like initial assessments, remote monitoring, and consultations. Still, it often lacks the ability to perform in-depth physical examinations that are fundamental in traditional clinical care.

In traditional clinical care, healthcare professionals can physically examine patients, utilizing various diagnostic tools and techniques. They can assess vital signs, inspect physical conditions, and conduct in-person tests and procedures. This hands-on approach is crucial for many medical conditions, especially those requiring precise diagnosis and tailored treatment plans.

Telemedicine, on the other hand, primarily functions in a virtual environment, making it more suitable for providing guidance, sharing information, and encouraging healthy behaviors. It is an invaluable tool for remote patient education, consultation for minor health concerns, and initial assessments. However, it may not fully substitute the in-person evaluations conducted in traditional clinical settings.

To provide the best possible care, it is essential to recognize the strengths and limitations of both telemedicine and traditional clinical care. Finding a balance between these two approaches is crucial to ensure that patients receive appropriate care, taking advantage of the convenience and accessibility of telemedicine while recognizing its constraints in cases where physical examinations are indispensable.

### 3. BALANCING TELEMEDICINE AND IN-PERSON CARE

#### **3.1. The Necessity of In-Person Evaluation**

For many medical conditions, a hands-on evaluation is necessary to make an accurate diagnosis and develop a comprehensive treatment plan. Telemedicine can play a supportive and supplementary role in healthcare, providing a platform for remote discussions and initial assessments, but it might not replace the in-depth, in-person evaluations carried out in a traditional clinical setting [Pogorzelska, Marcinowicz, and Chlabicz 2023].

#### **3.2. Finding a Balance for Optimal Patient Care**

The challenge, then, is to find a balance between the convenience and accessibility of telemedicine services and the necessity for comprehensive medical care that involves physical examinations and face-to-face interactions with healthcare professionals. Recognizing the strengths and limitations of each approach is crucial in optimizing patient care and ensuring

that telemedicine complements, rather than replaces, traditional medical practices.

### **3.3. The Committee on Medical Ethics**

The Committee on Medical Ethics underlines that it is the physician's responsibility to decide whether a teleconsultation is suitable in a given clinical context. If a teleconsultation is deemed appropriate, the patient must be informed about the extent to which the physician can provide assistance and the limitations associated with remote consultations.

Crucially, the feasibility of conducting teleconsultations is determined by medical criteria, not by the preferences or commercial interests involved. The Committee asserts that remote consultations should not be provided to patients who have not been previously examined and treated by the responsible physician or for patients presenting new health concerns.

For patients under a specific physician's care, teleconsultations can provide continuity of treatment, the opportunity for consultation, and a sense of security in therapy. It is essential to remember, however, that if the patient's reported symptoms necessitate a physical examination, an in-person visit to the physician is required. Issuing documents such as prescriptions or medical certificates without a physical examination may be considered a failure to meet the standard of due diligence [Nittari et al. 2020, 1436].

The professional, civil, and criminal responsibilities associated with telemedical services are no different from those for other medical services, and patients are entitled to all the rights they would have in any medical context.

The Committee on Medical Ethics of the National Medical Council, after a detailed examination of numerous instances of fee-based online prescription and certificate issuance, critically evaluates this phenomenon, especially in cases where: 1) minimal patient input, such as completing a survey that does not meet the criteria for a physical examination, is sufficient for prescription or certificate issuance; 2) the initiation of the process requires a payment; 3) there is no direct patient-physician interaction; 4) the offers for prescription and certificate issuance solely serve their commercial sale, bearing characteristics of advertising, and may, for example, offer special discounts for survey completion; 5) the service's finalization, as per the offer, is an extremely brief (3-5 minutes) process, suggesting a lack of due diligence; 6) the patient has not been previously examined and treated by the issuing physician for on-demand prescriptions or certificates.

Physicians issuing prescriptions and certificates in the described manner expose themselves to professional liability due to violations of various

articles of the Medical Code of Ethics:<sup>4</sup> a) Article 8 – Failing to exercise due diligence and dedicate adequate time to the patient; b) Article 9 – Failing to define exceptions when remote consultation is permissible; c) Article 10 – Exceeding one’s professional capabilities when issuing certificates outside of one’s medical specialty; d) Article 11 – Failing to ensure appropriate patient care quality; e) Article 40 – Issuing certificates without a physical examination and/or suitable documentation.

#### 4. MEDICAL ETHICS AND THE COMMERCIAL ISSUANCE OF CERTIFICATES

##### 4.1. Teleconsultations vs. Issuance of Certificates

The Medical Ethics Committee, in its critical stance toward the commercial issuance of medical certificates, highlights a misinterpretation of the principles governing telemedicine. This misinterpretation involves the commercial online issuance of medical certificates and prescriptions upon request. The National Medical Council’s Medical Ethics Committee expresses particular concern when situations arise where minimal patient input, such as completing a brief survey, triggers the process, and payment is required for the issuance of the document.

##### 4.2. Responsibilities and Rights of Physicians and Patients

To begin, the committee emphasizes the importance of distinguishing between teleconsultations and the sale of prescriptions and certificates on demand. According to the established definition, teleconsultation constitutes a healthcare service provided remotely through teleinformatic or communication systems. The responsibilities of a physician and the rights of a patient remain consistent, regardless of whether the medical consultation is conducted through telemedicine or in-person. Therefore, the principles governing teleconsultations using telemedical technology and face-to-face consultations are fundamentally the same.

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<sup>4</sup> Code of Medical Ethics.



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The professional, civil, and criminal responsibilities associated with telemedical services are no different from those for other medical services, and patients are entitled to all the rights they would have in any medical context.

## 5. LEGAL GUIDELINES FOR TELEMEDICINE IN THE EUROPEAN UNION

### 5.1. The Impact of COVID-19 on Telemedicine

The COVID-19 pandemic prompted an increased utilization of telemedicine visits, but the legal framework regarding their implementation and reporting standards remained relatively limited. The Act on Medical Activity grants the Minister of Health the authority to establish organizational standards for specific medical fields and services, as outlined in Article 22, Section 5 of the Act on Medical Activity,<sup>5</sup> which states that "the minister responsible for health matters can define healthcare organizational standards in selected medical fields or specific medical entities to ensure the quality of healthcare services." These standards, when issued as regulations, are legally binding and mandatory, requiring medical entities to adhere to them when providing healthcare services in the designated medical field or activity.

### 5.2. Privacy Concerns in Telemedicine

Historically, the regulations for telemedicine services were confined to the Minister of Health's organizational standards for radiology and diagnostic imaging performed through teleinformatics systems.<sup>6</sup> It wasn't until

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<sup>5</sup> Announcement of the Speaker of the Sejm of the Republic of Poland of March 16, 2021 on the announcement of the uniform text of the Act on medical activities, Journal of Laws item 711.

<sup>6</sup> Regulation of the Minister of Health of April 11, 2019 on organizational standards of health

August 29, 2020, that organizational standards for primary healthcare telemedicine visits came into effect.<sup>7</sup> However, no specific provisions addressing specialist healthcare teleconsultations were established under Article 22, Section 5 of the Act on Medical Activity.<sup>8</sup>

Given this absence of dedicated regulations for specialist healthcare teleconsultations, it is recommended to apply the regulations designed for primary healthcare telemedicine to specialist teleconsultations. These organizational standards encompass various formal aspects of telemedicine implementation that are common to both primary and specialist healthcare services. These shared elements encompass criteria for patient qualification for remote services, the mode of telemedicine visits, patient identity verification, appointment cancellations, and medical entity responsibility for service-related issues.

### **5.3. European Commission's Recommendations**

To ensure patient identity confirmation in compliance with the principles specified in Article 50, Sections 2-2b of the Act on Healthcare Benefits Financed from Public Funds, patients can use various methods such as presenting identification documents (e.g., ID card, passport, driving license), school cards, or electronic documents displayed on mobile device screens.<sup>9</sup> Alternatively, patients can verify their identity through electronic patient health accounts, created through personally confirmed identification or electronic identification means issued within the electronic identification system.

Regarding eligibility verification for healthcare services financed by public funds during telemedicine visits, patients can verbally confirm their eligibility by stating, "I am entitled to use healthcare services financed from public funds," as outlined in Article 50, Section 7 of the Act on Healthcare Services Financed from Public Funds.<sup>10</sup> The teleconsultation should also be documented in the individual medical record, including information on the use of teleinformatics systems or other communication systems,

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care in the field of radiology and imaging diagnostics performed via ICT systems, Journal of Laws item 834.

<sup>7</sup> Regulation of the Minister of Health of August 12, 2020 on the organizational standard of teleconsultation within primary health care, Journal of Laws item 1395.

<sup>8</sup> Announcement of the Speaker of the Sejm of the Republic of Poland of March 16, 2021 on the announcement of the uniform text of the Act on medical activities, Journal of Laws item 711.

<sup>9</sup> Act of August 27, 2004 on health care services financed from public funds, Journal of Laws No. 210, item 2135.

<sup>10</sup> Ibid.

patient awareness of teleconsultation limitations, and instructions for in-person visits in case of deteriorating health.

#### **5.4. Role of the European Data Protection Board**

Additional aspects addressed in the organizational standards include the postponement of certain examinations, informing patients about the need for in-person care if necessary, appointment cancellations due to connectivity issues, and guidance on using e-prescriptions and e-referral services. Notably, an adjustment in the organizational standards for primary healthcare telemedicine services limits remote services to children aged six and older, with exceptions for ongoing treatment. A similar approach is suggested for specialist care teleoncology services, extending these to patients aged six and older, except in cases involving treatment plan monitoring or routine procedures affecting treatment quality. In alignment with the March 5, 2021, regulation,<sup>11</sup> specialist care telemedicine services should not be provided when patients or their legal representatives decline remote services, when the visit is for certificate acquisition, or when patients with chronic conditions experience worsening or changing symptoms. Finally, the entity providing telemedicine services is obligated to maintain medical records in accordance with the regulations governing record type, scope, format, and processing methods,<sup>12</sup> storing them as stipulated in Article 29, Section 1, Points 1-4 of the Act on Patients' Rights and Patients' Spokesman Rights,<sup>13</sup> depending on the document type. It's crucial to note that recording audio and video during teleconsultations does not replace the comprehensive medical record, which has its own specific scope and management guidelines detailed in the referenced regulation.

The COVID-19 pandemic brought about significant legal and regulatory challenges for the European Union and its member states, impacting not only public health but also the realm of telemedicine. The Polish Society of Occupational Medicine, in its statement published on April 9, 2020, underscored the importance of physician discretion in providing healthcare services through teleinformatics.<sup>14</sup> Physicians were entrusted with the responsibility of assessing whether remote services were safe and suitable

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<sup>11</sup> Regulation of the Minister of Health of August 12, 2020 on the organizational standard of teleconsultation within primary health care, Journal of Laws item 1395.

<sup>12</sup> Regulation of the Minister of Health of April 6, 2020 on the types, scope and templates of medical documentation and the method of its processing, Journal of Laws item 666.

<sup>13</sup> Announcement of the Speaker of the Sejm of the Republic of Poland of May 4, 2020 on the announcement of the uniform text of the Act on Patient Rights and the Patient Ombudsman, Journal of Laws item 849.

<sup>14</sup> See <https://ptmp.org.pl/wp-content/uploads/2020/04/Badania-profilaktyczne-telemedycyna.pdf> [accessed: 04.12.2023].

for the patient in question.<sup>15</sup> They could conduct health assessments, offer medical advice, and issue certificates through digital means while being cautious of patient safety and their own liability.

Moreover, the Act of March 2, 2020, provided flexibility in terms of conducting periodic medical examinations, acknowledging the need to adapt to the unique circumstances of the pandemic.<sup>16</sup> The pandemic's impact on telemedicine also spurred the European Commission into action. On April 8, 2020, they issued a recommendation emphasizing the role of digital technologies in the fight against COVID-19, particularly mobile applications assisting health authorities. Ensuring the privacy and security of personal data while harnessing the potential of telemedicine was paramount. The Commission emphasized the necessity of user trust, compliance with fundamental rights, and data security in the development and use of telemedicine applications, establishing legal and regulatory standards for both member states and app developers. These standards highlighted the importance of respecting individual rights and privacy in the context of telemedicine. Telemedicine's role in the pandemic response was further validated by the European Data Protection Board (EDPB), which recognized the need to address privacy concerns in geolocation and contact tracing tools. In summary, the legal guidelines provide a framework for balancing telemedicine's essential role in the fight against COVID-19 with the critical need to protect data and individual privacy.<sup>17</sup>

## 6. THE EVOLUTION OF TELEMEDICINE IN POLISH HEALTHCARE

### 6.1. Pre-2015 Legal and Ethical Framework

Before the act dated 9th October 2015, amending the act on information systems in health care, was enforced on the 12th of December 2015,<sup>18</sup> the use of information and communication technology (ICT) in healthcare services was primarily guided by individual legal regulations and ethical principles. The Medical Code of Ethics, for instance, stipulated that a physician could initiate treatment only after a physical examination of the patient,

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<sup>15</sup> Act of December 5, 1996 on the professions of doctor and dentist, Journal of Laws of 1997 No. 28, item 152.

<sup>16</sup> Act of March 2, 2020 on special solutions related to the prevention, counteracting and combating of COVID-19, other infectious diseases and crisis situations caused by them, Journal of Laws item 374.

<sup>17</sup> Communication from the Commission Guidance on Apps supporting the fight against COVID 19 pandemic in relation to data protection 2020/C 124 I/01, Official Journal, C 124, 1-9.

<sup>18</sup> Act of October 9, 2015 amending the Act on the health care information system and certain other acts, Journal of Laws item 1991.

with exceptions for situations where remote medical advice was the only option [Król-Całkowska, Walczak and Szymański, 2022, 127].

## **6.2. The Act of December 2015<sup>19</sup>**

Although the Medical Code of Ethics was not a binding legal document, it was recognized that ethical norms could be incorporated into the legal system. The Act on Medical Chambers incorporated the norms from the Medical Code of Ethics, allowing its principles to guide healthcare practices. Consequently, the application of these ethical principles in providing healthcare services without personal contact with the patient was deemed acceptable in certain exceptional cases, subject to a physician's discretion [ibid.].

## **6.3. Use of ICT in Healthcare Services**

Telemedicine, which encompasses the use of ICT in healthcare, was an evolving field and had been discussed in literature for over a decade. It found application in various medical contexts, including teleconsultations for severe poisoning, cardiac rehabilitation, and monitoring the health status of diabetic patients.

## **6.4. Telemedicine During the COVID-19 Pandemic**

A significant change came with the revision of Article 42, Section 2 of the Act on the Profession of Doctor and Dentist on the 5th of December 1996.<sup>20</sup> This revision explicitly allowed physicians to assess a person's health either through an in-person examination or using teleinformatic systems or communication systems, broadening the scope of remote healthcare services [Rudowski, 2003, 219-21; Sołomacha et al. 2022, 115].

## **6.5. Regulations for Specific Medical Contexts**

When considering healthcare services provided remotely, it is vital to distinguish between "personal contact" and "direct contact." The use of ICT by a physician to interact with a patient does not prevent direct contact, but it does limit personal contact, which involves physical meetings. This differentiation has implications for matters like determining the eligibility for sickness benefits.

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<sup>19</sup> Ibid.

<sup>20</sup> Act of December 5, 1996 on the professions of doctor and dentist, Journal of Laws of 1997, No. 28, item 152.

Exceptions to the rule of personal examination were also outlined in the Mental Health Protection Act,<sup>21</sup> which mandated a personal examination before decisions regarding a patient's mental health could be made.

The Act on Medical Activity<sup>22</sup> recognized the general admissibility of using ICT in healthcare services, emphasizing that medical services could be provided through teleinformatic or communication systems. This definition encompassed a wide range of healthcare activities aimed at maintaining, restoring, improving health, and other medical activities, regardless of the specific services offered.

Telemedicine gained more prominence during the COVID-19 pandemic. However, it was worth noting that the legal framework for remote healthcare services was already in place before the pandemic. Telemedicine specifically referred to services provided through teleinformatic systems related to suspected or confirmed cases of COVID-19.

## 7. REGULATORY FRAMEWORK FOR TELEMEDICINE SERVICES

### 7.1. The Impact of COVID-19 on Telemedicine Utilization

The COVID-19 pandemic prompted an increased utilization of telemedicine visits, but the legal framework regarding their implementation and reporting standards remained relatively limited [Pogorzelska, Marciniowicz and Chlabicz, 2023].

### 7.2. Minister of Health's Authority to Establish Organizational Standards

The Act on Medical Activity grants the Minister of Health the authority to establish organizational standards for specific medical fields and services, as outlined in Article 22, Section 5 of the Act on Medical Activity,<sup>23</sup> which states that "the minister responsible for health matters can define healthcare organizational standards in selected medical fields or specific medical entities to ensure the quality of healthcare services." These standards, when issued as regulations, are legally binding and mandatory, requiring medical entities to adhere to them when providing healthcare services in the designated medical field or activity [Haleem et al. 2021; Furlepa et al. 2021, 1221].

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<sup>21</sup> Act of August 19, 1994 on mental health protection, Journal of Laws No. 111, item 535.

<sup>22</sup> Act of April 15, 2011 on medical activities, Journal of Laws No. 112, item 654.

<sup>23</sup> Announcement of the Speaker of the Sejm of the Republic of Poland of March 16, 2021 on the announcement of the uniform text of the Act on medical activities, Journal of Laws item 711.

### **7.3. Historical Regulations for Telemedicine Services**

Historically, the regulations for telemedicine services were confined to the Minister of Health's organizational standards for radiology and diagnostic imaging performed through teleinformatics systems.<sup>24</sup>

### **7.4. Organizational Standards for Primary Healthcare Telemedicine**

It wasn't until August 29, 2020, that organizational standards for primary healthcare telemedicine visits came into effect.<sup>25</sup> However, no specific provisions addressing specialist healthcare teleconsultations were established under Article 22, Section 5 of the Act on Medical Activity<sup>26</sup> [Furlepa et al. 2022, 1221].

### **7.5. Absence of Specific Regulations for Specialist Healthcare Teleconsultations**

Given this absence of dedicated regulations for specialist healthcare teleconsultations, it is recommended to apply the regulations designed for primary healthcare telemedicine to specialist teleconsultations. These organizational standards encompass various formal aspects of telemedicine implementation that are common to both primary and specialist healthcare services. These shared elements encompass criteria for patient qualification for remote services, the mode of telemedicine visits, patient identity verification, appointment cancellations, and medical entity responsibility for service-related issues [Furlepa et al. 2022; Rudowski 2003, 219-21; Sołomacha et al. 2022, 115].

### **7.6. Applying Primary Healthcare Standards to Specialist Teleconsultations**

To ensure patient identity confirmation in compliance with the principles specified in Article 50, Sections 2-2b of the Act on Healthcare Benefits Financed from Public Funds,<sup>27</sup> patients can use various methods such

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<sup>24</sup> Regulation of the Minister of Health of April 11, 2019 on organizational standards of health care in the field of radiology and imaging diagnostics performed via ICT systems, Journal of Laws item 834.

<sup>25</sup> Regulation of the Minister of Health of August 12, 2020 on the organizational standard of teleconsultation within primary health care, Journal of Laws item 1395.

<sup>26</sup> Announcement of the Speaker of the Sejm of the Republic of Poland of March 16, 2021 on the announcement of the uniform text of the Act on medical activities, Journal of Laws item 711.

<sup>27</sup> Act of August 27, 2004 on health care services financed from public funds, Journal of Laws No. 210, item 2135.

as presenting identification documents (e.g., ID card, passport, driving license), school cards, or electronic documents displayed on mobile device screens. Alternatively, patients can verify their identity through electronic patient health accounts, created through personally confirmed identification or electronic identification means issued within the electronic identification system.

### **7.7. Patient Identity Verification and Eligibility Confirmation**

Regarding eligibility verification for healthcare services financed by public funds during telemedicine visits, patients can verbally confirm their eligibility by stating, “I am entitled to use healthcare services financed from public funds,” as outlined in Article 50, Section 7 of the Act on Healthcare Services Financed from Public Funds.<sup>28</sup> The teleconsultation should also be documented in the individual medical record, including information on the use of teleinformatics systems or other communication systems, patient awareness of teleconsultation limitations, and instructions for in-person visits in case of deteriorating health.

### **7.8. Documentation Requirements for Teleconsultations**

Additional aspects addressed in the organizational standards include the postponement of certain examinations, informing patients about the need for in-person care if necessary, appointment cancellations due to connectivity issues, and guidance on using e-prescriptions and e-referral services.

### **7.9. Limitations on Specialist Care Telemedicine Services**

In alignment with the regulation<sup>29</sup> specialist care telemedicine services should not be provided when patients or their legal representatives decline remote services, when the visit is for certificate acquisition, or when patients with chronic conditions experience worsening or changing symptoms [Hal-eem et al. 2021; Król-Całkowska, Walczak and Szymański 2022; Sołomacha et al. 2022, 115].

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<sup>28</sup> Ibid.

<sup>29</sup> Regulation of the Minister of Health of August 12, 2020 on the organizational standard of teleconsultation within primary health care, Journal of Laws item 1395.



### 7.10. Maintenance of Medical Records in Telemedicine

Finally, the entity providing telemedicine services is obligated to maintain medical records in accordance with the regulations governing record type, scope, format, and processing methods,<sup>30</sup> storing them as stipulated in Article 29, Section 1, Points 1-4 of the Act on Patients' Rights and Patients' Spokesman Rights,<sup>31</sup> depending on the document type. It's crucial to note that recording audio and video during teleconsultations does not replace the comprehensive medical record, which has its own specific scope and management guidelines detailed in the referenced regulation [Sołomacha et al. 2022, 115].

## CONCLUSION

The dynamic realm of telemedicine has witnessed rapid growth and profound impacts on healthcare worldwide. Yet, this transformative field operates within the confines of complex legal and regulatory landscapes. As we conclude this exploration of telemedicine's legal dimensions, it is evident that these regulations not only safeguard patient rights but also shape the quality of healthcare, underscoring the importance of telemedicine in the future of healthcare. While telemedicine offers unprecedented convenience and accessibility, it is not a wholesale substitute for in-person evaluations, and its strengths and limitations must be understood and balanced. This article has provided a comprehensive view of the legal aspects of telemedicine, empowering healthcare professionals and patients to navigate the intricacies of this technology-driven healthcare revolution.

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<sup>30</sup> Regulation of the Minister of Health of April 6, 2020 on the types, scope and templates of medical documentation and the method of its processing, Journal of Laws item 666.

<sup>31</sup> Announcement of the Speaker of the Sejm of the Republic of Poland of July 22, 2022 on the announcement of the uniform text of the Act on Patient Rights and the Patient Ombudsman, Journal of Laws item 1876.

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