

<b>TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES</b>
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<b>LAWS AND REGULATIONS ON TELEMEDICINE</b>
<b>1. Is telemedicine allowed in your country? If so, how is it defined?</b>
Telemedicine is allowed in Poland. There is no legal definition of telemedicine in Polish law. However, under the Medical Activity Act of 15 April 2011 (the 'MAA'), medical activity entails the provision of healthcare services. These services may be provided via IT or communication systems. A health service is understood as any action designed to preserve, save, restore or improve health and other medical activities resulting from treatment or from separate provisions regulating treatment or separate provisions regulating its performance.
<b>2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.</b>
<p>The legal basis for health services provided in the form of telemedicine is the MAA and laws regulating medical professions (Physician and Dentist Professions Act of 5 December 1996, Nurse and Midwife Professions Act of 15 July 2011 and Pharmacy Chambers Act of 19 April 1991), from which the admissibility of telemedicine is derived.</p> <p>The provision of health services in the form of teleconsultation within the framework of primary healthcare is laid down in the Ruling of the Minister of Health of 12 August 2020 on the organisational standard of teleconsultation within primary healthcare (the 'RMH').</p> <p>As an aside, the e-health sector in Poland has developed rapidly, including:</p> <ul style="list-style-type: none"><li>• use of information and telecommunication technology to support healthcare activities;</li><li>• implementation of electronic medical records (EMRs); and</li><li>• implementation of e-prescription, e-referral and e-medical leave.</li></ul> <p>Healthcare IT networks in Poland include both state patient-facing systems (Online Patient Account or Internetowe Konto Pacjenta) and registers operating in the healthcare system with, inter alia, the ability to search and apply for entries/authorisations, for example, the Register of Pharmacies and Register of Medicinal Products.</p>
<b>3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.</b>
<p>Before acting as a treatment entity, it is necessary to apply for and obtain entry in the Register of Healthcare Providers (Rejestr Podmiotów Wykonujących Działalność Leczniczą).</p> <p>The authorities maintaining the register, as indicated in Article 106 of the MAA, are:</p> <ul style="list-style-type: none"><li>• the provincial speaker competent for the seat or place of residence of the medical entity,</li><li>• a district medical board competent for the place of practising medicine,</li><li>• a district council of nurses and midwives competent for the place of the professional practice of a nurse; and</li><li>• National Council of Physiotherapists.</li></ul>

The body in charge of the register shall, once the applicant meets certain conditions, make an entry in the register.

The conditions to be met before registration are:

- adequate premises and equipment conforming to general space, sanitary and installation requirements, adapted to the type of conducted activity;
- medical devices used in medical activities must meet the general requirements for safety;
- health services may be provided only by persons who practise a medical profession and fulfil health requirements; and
- conclusion of a civil liability insurance contract.

#### **4. Was telemedicine authorised during the Covid-19 pandemic?**

During the Covid-19 pandemic, telemedicine was authorised in the Act of 2 March 2020 on specific solutions related to the prevention, prevention and eradication of Covid-19, other communicable diseases and emergencies caused by them, which introduced the institution of teleconsultation into the legal order, the organisational standards of which are defined in the regulation of the RMH.

#### **5. Is there any possibility of the regulatory landscape being changed in the post-pandemic scenario or has there already been a change in regulation in the post-pandemic scenario?**

In the post-pandemic scenario, teleconsultation was introduced into the legal order as a basic form of healthcare services in primary healthcare.

#### **6. What types of teleservices are allowed (eg, second opinion, teleconsultation, tediagnosis and telesurgery)?**

Telemedicine is considered as one of the standards of medical practice in providing patient primary care. The provision of services and physician responsibilities are the same, regardless of the form in which the healthcare service is provided.

The main form of telemedicine in Poland is teleconsultation, which, according to the RMH, is understood as health services provided at a distance using IT or communication systems. Such health services can take several forms, including a telephone or video call, or even electronic correspondence. As part of such a service, a doctor may take a medical history, perform certain tests, give recommendations, or issue an e-prescription or e-referral.

#### **7. Who can use telemedicine services? Please indicate whether only doctor-doctor or also patient-doctor remote medical services are allowed.**

In the absence of specific regulations, telemedicine should be assumed to be directed at patients as a form of medical practice in providing patient care.

Teleconsultation can take place if:

- infection with the virus SARS-CoV-2 is suspected;
- a patient needs a prescription for medication to continue treatment and the doctor has medical records;
- a patient needs a prescription for medical devices as a continuation of a previous order and the doctor has medical records;
- a patient needs a health certificate; and
- a child under six years of age receives follow-up advice that the doctor arranged during a face-to-face visit and does not involve a physical examination.

However, the law does not restrict the form of consultation between doctors, including teleconsultation, for example, services involving consultation between a specialist and primary care physician.
<b>8. Please outline the funding model for telemedicine. Is it available in your jurisdiction's public health system? Is telemedicine under mandatory insurance coverage? Please indicate what legislation applies.</b>
Telemedicine services are publicly funded on the same basis as stationary services under the Act of 15 July 2020 on healthcare services financed from public funds. Telemedicine is settled under an agreement with the National Health Fund, which also allows the settlement of teletreatment in outpatient specialist care and includes consultation provided as part of drug programmes, psychiatric care or addiction treatment. Telemedicine falls under mandatory insurance coverage under general rules.
<b>9. Please indicate whether any insurance requirements are applicable to telemedicine service providers.</b>
There are currently no insurance requirements applicable to telemedicine service providers.
<b>REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS</b>
<b>10. Who can practise telemedicine in your country? Please indicate whether other healthcare professionals are authorised to provide remote health services under the applicable rules (eg, nurses, psychologists, nutritionists and alternative health therapy providers).</b>
Under the MAA, the range of entities that can provide telemedicine services is analogous to that for standard health services, thus, these services may be provided by: <ul style="list-style-type: none"> <li>• medical entities, which are, inter alia, entrepreneurs within the meaning of the Entrepreneurs' Law Act of 6 March 2018; and</li> <li>• professional practices (individual or group) of doctors, and professional practices of nurses, midwives and physiotherapists.</li> </ul> Each of the above medical professions is regulated or supervised by its professional self-government that defines the standards of professional practice and supervises professional ethics.
<b>11. Are there any specific education requirements or training that healthcare professionals need to meet or attend to provide telemedicine services?</b>
No, there are no specific education requirements or training that healthcare professionals need to meet or attend to provide telemedicine services.
<b>12. Is there any registration requirement applicable to physicians that provide telemedicine services?</b>
No, there is no registration requirement applicable to physicians providing telemedicine services. Only an entry in the Register of Healthcare Providers is required. In the case of healthcare services rendered via telemedicine, principles governing the provision of services and physician responsibilities are the same for every form of provision.
<b>13. Please indicate whether special licenses or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.</b>
There are no special licenses or authorisations for institutional healthcare providers engaged in telemedicine services other than general rules that they must observe.

## REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES

### 14. Are there specific requirements applicable to the telemedicine platform?

No, there are no specific regulations governing the telemedicine platform. This matter is partially specified by medical self-government in Supreme Medical Council Guidelines for the provision of telemedicine services (the 'Guidelines'). The Supreme Medical Council recommends using its own account of the system providing cybersecurity, including free contact between a patient-doctor.

Pursuant to the Guidelines, telemedicine services are allowed by telephone, with the use of common telephones and telephone lines, or online through a secured telemedicine platform, application or other communication system, all of which must meet the conditions of a secure connection. All communication measures must provide the ability to verify a patient's identity and appropriate connection quality.

Using communicators not optimised for the provision of medical services is not recommended due to a high level of risk of failure to provide security of medical advice (eg, Messenger and WhatsApp). Moreover, professionals should not use open email, or contact a patient through a private email account or private telephone number.

The choice of a particular medium depends on the independent decision of the telemedicine provider.

### 15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?

In Poland, there are no legal requirements concerning electronic equipment or internet speed for telemedicine services. However, a healthcare provider should ensure the security of IT connections used for telemedicine purposes.

For more details about using equipment in telemedicine practice, please see item 14.

### 16. Does legislation provide for specific rules concerning patients' medical records?

Polish legislation does not impose specific regulations on patient medical records for telemedicine services. General rules governing treatment apply.

Primarily, pursuant to Article 24 section 1 of the Act of 6 November 2008 on patient rights and the Patient Rights Ombudsman (the 'APR') a healthcare provider shall keep, maintain and make medical records available. In principle, a medical record is maintained in electronic form. For this purpose, Article 10 of the Act of 28 April 2011 on information systems in health protection constitutes the Medical Information System (System Informacji Medycznej or SIM). Regardless of the form in which treatment is provided, all medical events constituting healthcare services, including telemedicine services, shall be reported through the SIM by the healthcare provider to enable another provider to download medical data in medical records. A SIM includes e-prescriptions, e-referrals and data on their realisation.

### 17. Are there geographic location requirements applicable to the provision of telemedicine services?

Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patient rights in cross-border healthcare applies to telemedicine services, according to which the member state of treatment means 'the Member State on whose territory

healthcare is actually provided to the patient. In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established'. The same is regulated in Article 24 section 1 point 5 of the MAA, pursuant to which the place of providing long-distance medical services is the place of residence of the medical professional. This is also confirmed in the Guidelines. There is no obstacle to providing telemedicine services to a patient residing outside Poland by a doctor residing in Poland, but rules specified in the Polish system shall apply to such treatment and healthcare. A practical result of this regulation may be, for example, a requirement to draft a medical record in the Polish language.

**18. Does the healthcare professional need to obtain the patient's consent to engage in telehealth?**

Pursuant to Article 32 of the Act of 5 December 1996 on the profession of physician and dentist, healthcare services may be provided upon patient consent or consent of the patient's legal representative if the patient is a minor (ie, under the age of 18) or incapable of giving conscious consent. After a patient turns 16, patient consent is also required.

Nevertheless, Polish legislation has not yet separately regulated the matter of consent requirement to engage in telehealth. This is specified in the Guidelines, pursuant to which a doctor should receive the conscious consent of the patient to provide telemedicine services. Moreover, such consent does not need to be in writing. It may be presumed through patient use of telemedicine services.

**19. Is there any other important requirement that should be highlighted?**

Due to the lack of specific requirements to provide telemedicine services in Poland, we do not observe other requirements that would apply.

**DATA PRIVACY ASPECTS**

**20. Are there data privacy issues that should be considered for the exploitation of such a market? If your answer is yes, please provide a short description.**

Yes, there are data privacy issues that should be considered for the exploitation of the telemedicine market. Patient personal data must be preserved with observance of privacy and professional secrecy of information set forth in the applicable legal framework (in particular, the GDPR<sup>1</sup> and APR, as well as the Medical Ethics Code).<sup>2</sup>

Because there are no data protection regulations specifically relating to telemedicine, general rules set forth in the GDPR apply.

Under the GDPR, patient data is data concerning health, which pertains to special categories of personal data. Therefore, its processing requires a higher level of protection. Such data can be processed only if there is a lawful basis for processing (in both Articles 6(1) and 9(2)), data subject rights are preserved, data processing operations are in line with principles of transparency, data minimisation, accuracy, purpose and storage limitation, integrity and confidentiality, and accountability (Article 5), and appropriate technical and organisational measures to ensure a level of security appropriate to risk are implemented (Articles 24 and 32).

<sup>1</sup> Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (the General Data Protection Regulation).

<sup>2</sup> See [https://nil.org.pl/uploaded\\_images/1574857770\\_kodeks-etyki-lekarskiej.pdf](https://nil.org.pl/uploaded_images/1574857770_kodeks-etyki-lekarskiej.pdf) accessed 16 May 2023.

Prior to processing, a controller may also need to carry out a data protection impact assessment (DPIA), which is especially required when processing special categories of data on a large scale (Article 35).

A useful guide on the fulfilment of obligations imposed by the GDPR on entities performing medical activity is provided in the Healthcare Sector Code of conduct approved by the Polish supervisory authority.<sup>3</sup>

**21. Does the applicable regulation provide for criteria and requirements for security systems to protect the patient's information?**

Yes, the applicable regulation provides criteria and requirements for security systems to protect patient information.

They particularly arise from: (1) specific regulations on medical records; (2) the GDPR; and (3) the National Cybersecurity System Act (implementing Directive (EU) 2016/1148 on security of network and information systems).

The minimum standard of the organisational and technical security of medical records is set forth in a Regulation of the Minister of Health on the types, scope and templates of medical records and method of their processing.

In general, telemedicine services shall be provided using reliable equipment and software that meets technical and information security requirements. The RMH sets certain requirements as regards security and confidentiality of teleconsultation and the method of verifying patient identity, but are not specific. Therefore, general rules in the GDPR and National Cybersecurity System Act shall apply.

Under the GDPR, the processing of personal data collected during the provision of telemedicine services must comply with rules set forth in the GDPR. As regards the security of systems, the GDPR adopts a risk-based approach and requires that a controller and processor implement appropriate technical and organisational measures to ensure a level of security appropriate to the identified risk (eg, pseudonymisation and encryption of personal data; and ability to ensure ongoing confidentiality, integrity, availability and resilience of processing systems) (Article 32).

Second, because healthcare services provided by a medical entity qualify as essential services under the National Cybersecurity System Act, such entities can be classified as Operators of Essential Services. Consequently, they must comply with specific obligations, such as information and communications technology (ICT) risk management (including risk assessment), collect information on cybersecurity threats and vulnerabilities to incidents, and report major incidents to the appropriate Computer Security Incident Response Team (CSIRT).

**22. Does the applicable regulation provide for requirements for the transfer of information abroad?**

Yes, the GDPR sets rules for the transfer of information (personal data) abroad. Within the European Economic Area (EEA), personal data can be transferred freely, that is, no additional requirements must be met. If personal data is to be transferred from the EEA to recipients in third countries (ie, outside the EEA), specific requirements and conditions must be met (under chapter V of the GDPR).

<sup>3</sup> See <http://rodowzdrowiu.pl/wp-content/uploads/2021/02/Projekt-kodeksu-ochrona-zdrowia-23.11.2020.pdf> accessed 17 May 2023.

- First, if a third country is declared as offering an adequate level of protection through an European Commission decision (so-called adequacy decision), it means that personal data can be transferred to a recipient in that third country without the data exporter being required to provide further safeguards or being subject to additional conditions (Article 45 of the GDPR).
- Second, if a third country is not covered by an adequacy decision, the transfer can take place with appropriate safeguards (eg, binding corporate rules (BCR) or standard contractual clauses approved by the European Commission) and on the condition that enforceable rights and effective legal remedies are available for individuals (Article 46 of the GDPR).
- Third, data can be transferred to a recipient in a third country based on a number of derogations for specific situations listed in Article 49 of the GDPR.

Following a Court of Justice of the European Union (CJEU) ruling in the Schrems II case (C-311/18), transfers outside the EEA based on standard contractual clauses (SCCs) require a transfer impact assessment (TIA). A TIA may reveal that using an SCC is insufficient and that additional safeguards (technical, organisational or contractual) are necessary.

**23. Is there any registration of databases requirement that companies must observe? Are there requirements regarding the recording of data in the patient's medical records?**

There is no database registration requirement in Poland.

An entity providing health services must keep, store and share medical records in the manner specified in the APR (Articles 23–30a), the Healthcare Information System Act (in particular, Article 11) and respective regulations, as well as ensure the protection of data in this documentation. As a rule, an entity providing health services shall keep medical records for a period of 20 years.

Principles governing the keeping of medical records are the same for health services provided in direct and telemedical form. Medical records shall, as a rule, be kept in electronic form. The types, scope and templates of medical records, as well as the minimum standard of their organisational and technical security are set in a Regulation of the Minister of Health on types, scope and templates of medical records, and method of their processing.

Moreover, entities providing healthcare services are required to keep EMRs in formats set in the Public Information Bulletin of the Minister for Health. The scope and types of EMRs arise from a Regulation of the Minister of Health on types of EMRs.

**LIABILITIES**

**24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.**

There are no specific rules on the liability of healthcare professionals involved in telemedicine practice. Liability for providing telemedicine services is the same as for traditional healthcare services. This includes civil, criminal and professional liability.

**Civil liability**

In order to find a professional civilly liable, it is necessary to prove damage, the professional's fault, and a causal link between the damage and the professional's action. It is also possible to prove contractual liability of the professional as regards damage arising from non-performance

or improper performance of contractual obligations toward the patient.

### **Criminal liability**

A professional may be criminally liable for, for example, causing harm to health or providing health services without authority.

### **Professional liability**

Pursuant to the Guidelines, a doctor is professionally liable for failure to abide by principles of medical ethics and provisions related to medical practice. The provision of telemedicine services in itself does not constitute circumstances justifying liability, but a doctor may be liable for not using available treatment methods if telemedicine solutions could have been used, but were not and a health service was not rendered.

## **TELEMEDICINE NUMBERS AND TRENDS**

### **25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?**

According to the Central Statistical Office, in 2021, 48.6 million medical consultations in primary care and 14.6 million in specialised care took place via telemedicine. In dental care, 714,000 consultations took place remotely.

### **26. What are the perspectives and trends in relation to the matter for the next few years? Please outline any unresolved issues, proposed changes or trends for the telemedicine sector and briefly indicate how these may foreseeably affect medical practice in the near future.**

The telemedicine sector will be affected by: (1) the proposed European Health Data Space (EDHS) regulation – draft regulation put forward by the European Commission in May 2022; and (2) the NIS2 Directive,<sup>4</sup> which is currently in the legislative process. The EDHS draft regulation will be one of the pillars of a European Health Union. By establishing a framework for the primary<sup>5</sup> and secondary use of electronic health data,<sup>6</sup> it may influence telemedicine services within the EU, including in Poland. Under the proposal, telemedicine is defined as the provision of healthcare services, including remote care and online pharmacies, through the use of information and communication technologies, in situations where the health professional and patient (or several health professionals) are not in the same location.

Telemedicine gained popularity during the pandemic, the first prescription apps are being reimbursed and data collected by modern gadgets is providing access to increasingly complete knowledge of patient health.

Medical startups in Poland, however, face many difficulties. Securing funding for growth and day-to-day operations, relieving bureaucracy and redefining the role of doctors in their relationship with patients, while reducing administrative barriers, are all current challenges that need to be addressed.

<sup>4</sup> Directive of the European Parliament and of the Council on measures for a high common level of cybersecurity across the Union, repealing Directive (EU) 2016/1148.

<sup>5</sup> 'Primary use of electronic health data' means the processing of personal electronic health data for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates.

<sup>6</sup> 'Secondary use of electronic health data' means the processing of electronic health data for purposes set out in c IV, ie, research, innovation, policy-making and regulatory activities.