

## TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES

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### **LAWS AND REGULATIONS ON TELEMEDICINE**

#### **1. Is telemedicine allowed in your country? If so, how is it defined?**

The provision of telemedicine services is permitted in Ireland. While telemedicine is not defined in legislation, the Medical Council in Ireland recently provided the following definition in its Guide to Professional Conduct and Ethics: 'Telemedicine describes the delivery of healthcare services through information and communication technologies to promote the health of individuals and their communities. It involves the exchange of information between doctors and patients, or between doctors and professional colleagues, for the diagnosis, treatment and prevention of disease and injuries, and for research, evaluation and continuing education.'

#### **2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.**

There is no specific legislation addressing the provision of telemedicine services in Ireland. However, health service providers must still comply with a range of applicable legislation, regulation and guidance. For example, the Medical Council Guide to Professional Conduct and Ethics states that telemedicine services can be provided by doctors, subject to:

- strong security measures;
- patients providing their consent to consultation being conducted through telemedicine and consent to any treatment provided;
- information policies being clear to patients;
- services being safe and suitable for patients;
- the patient's general practitioner being fully informed of the consultation;
- ensuring that all notes made during consultations being placed in patients' medical records; and
- intrajurisdictional transfers of personal patient information complying with data protection principles.

Furthermore, under Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, doctors providing telemedicine services are considered to be providing services in the European Union Member State in which they are established. Such doctors are required to comply with the legislation and regulatory requirements of that Member State only. If doctors based in Ireland are providing telemedicine services in Ireland or in any Member State, they must be registered with the Medical Council. While the Medical Council Guide is not legally binding, non-compliance with this requirement may constitute a breach of professional duty by medical doctors.

#### **3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.**

While there is no authority primarily responsible for regulating telemedicine in Ireland, the following statutory bodies are responsible for regulating different areas of the healthcare sector and may therefore have regulatory oversight on the provision of telemedicine services:

- the Health Information and Quality Authority (HIQA) is responsible for regulating and accrediting public hospitals, implementing quality assurance programmes, and evaluating the clinical and cost effectiveness of health technologies;

- the Health Products Regulatory Authority (HPRA) is responsible for the regulation of health products, including medicines, medical devices and cosmetics;
- the Competition and Consumer Protection Commission (CCPC) is responsible for enforcing consumer protection and general product safety legislation;
- the Data Protection Commission (DPC) is the Irish supervisory authority for the purposes of the General Data Protection Regulation (GDPR);
- the Medical Council is the regulatory body of medical doctors in Ireland and maintains the Register of Medical Practitioners;
- the National Standards Authority of Ireland (NSAI) creates, maintains, promotes and issues accredited certification of products, services and organisations with recognised standards; and
- the Department of Health is the government department tasked with the delivery of policies in the healthcare sector.

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

The provision of telemedicine services was authorised during the Covid-19 pandemic under pre-existing legislation and guidance relating to the provision of healthcare services generally.

However, regarding prescription medication, further legislation was enacted to permit the electronic transfer of prescriptions by doctors to a pharmacy via an approved electronic system: the HSE's Healthmail system.

#### **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?**

It is not currently envisaged that there will be a material change to the regulatory landscape following the pandemic. However, legislation introduced to permit the electronic transfer of prescriptions, while initially intended to be a temporary measure, remains in force and there is no apparent legislative intention to revoke it at this stage.

The Medical Council has also issued regular guidance on the provision of telemedicine services in Ireland and will continue to provide updates in this regard.

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

Telemedicine is defined broadly as 'the delivery of healthcare services through information and communication technologies' and would therefore include services such as opinions, consultations and diagnosis.

However, it is important to note that the provision of these services, whether through telemedicine or traditional means, must comply with all legislation and guidance applicable to the provision of healthcare services generally and the specific service being provided.

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

As noted above, the Medical Council states in its guidance that telemedicine 'involves the exchange of information between doctors and patients, or between doctors and professional colleagues, for the diagnosis, treatment and prevention of disease and injuries, and for research, evaluation and continuing education'.

Therefore, doctor-doctor and patient-doctor services are covered by the definition of telemedicine services in Ireland.

#### **8. Please outline the funding model for telemedicine. Is it available in your jurisdiction's**

<p><b>public health system? Is telemedicine under mandatory insurance coverage? Please indicate what legislation applies.</b></p>
<p>There is no specific funding model or mandatory insurance coverage applicable to the provision of telemedicine services in Ireland.</p>
<p><b>9. Please indicate whether any insurance requirements are applicable to telemedicine service providers.</b></p>
<p>There are no specific insurance requirements applicable to the provision of telemedicine services in Ireland.</p> <p>However, pursuant to the Medical Practitioners (Amendment) Act) 2007, all medical practitioners must have professional medical indemnity up to a specified level which varies for different specialties. For example, general practitioners must have cover up to €10m.</p> <p>Furthermore, pursuant to the European Union (Application of Patients' Rights in Cross-Border Healthcare) (Amendment) Regulations 2015, all healthcare professionals who are providing cross-border healthcare must have professional liability insurance.</p>
<p><b>REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS</b></p>
<p><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></p>
<p>As noted above, telemedicine involves the exchange of information between doctors and patients or doctors and professional colleagues. On this basis, only doctors registered with the Medical Council are permitted to provide telemedicine services to patients in Ireland.</p> <p>Professional colleagues such as nurses and other healthcare providers may engage with a doctor in his/her provision of telemedicine services, but cannot provide these services independently and directly to a patient.</p> <p>Other healthcare professionals are permitted to provide remote health services to patients, but these services should not fall within the definition of telemedicine services as provided by the Medical Council.</p>
<p><b>11. Are there any specific education requirements or training that healthcare professionals need to meet or attend to provide telemedicine services?</b></p>
<p>Excluding the requirement to be registered with the Medical Council, there are no other specific education requirements or training that healthcare professionals need to meet in order to provide telemedicine services in Ireland.</p> <p>General education and training requirements for medical practitioners engaging in traditional consultations are equally applicable in the provision of telemedicine services.</p>
<p><b>12. Is there any registration requirement applicable to physicians that provide telemedicine services?</b></p>
<p>There is no such registration requirement in Ireland specific to the telemedicine sector. All medical practitioners must be registered in Ireland with the Medical Council and this includes practitioners providing telemedicine services.</p> <p>Similarly, regarding the provision of other telehealth services:</p> <ul style="list-style-type: none"> <li>nurses and midwives must be registered with the Nursing and Midwifery Board of Ireland (NMBI);</li> </ul>

<ul style="list-style-type: none"> <li>• dentists must be registered with the Dental Council of Ireland; and</li> <li>• pharmacists must be registered with the Pharmaceutical Society of Ireland (PSI).</li> </ul>
<b>13. Please indicate whether special licenses or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.</b>
There are no such mandatory licenses or authorisations in Ireland.
<b>REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES</b>
<b>14. Are there specific requirements applicable to the telemedicine platform?</b>
There are no specific requirements applicable to the telemedicine platform in Ireland. However, telemedicine platforms are required to comply with applicable laws, including, for example, data protection legislation.
<b>15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?</b>
There are no specific requirements regarding electronic equipment or internet speed. However, it is essential that adequate means are in place to ensure compliance with other professional requirements, such as obtaining fully informed consent, communicating clear information policies and providing suitable services to patients.
<b>16. Does legislation provide for specific rules concerning patients' medical records?</b>
<p>Although there is no specific legislation concerning patients' medical records, the Medical Council Guide to Professional Conduct and Ethics states that doctors working in telemedicine should make every effort to ensure that notes taken about a patient are placed in the patient's medical record with his/her general practitioner as soon as possible.</p> <p>Furthermore, the same principles that apply in the context of traditional consultations apply equally to the provision of telemedicine services. This includes the requirement to protect a patient's privacy by keeping records and other information about patients securely. This is a particularly important consideration in the provision of telemedicine services and strong security measures should be taken to protect confidentiality inherent in the doctor-patient relationship.</p>
<b>17. Are there geographic location requirements applicable to the provision of telemedicine services?</b>
<p>As noted above, if doctors based in Ireland are providing telemedicine services in Ireland or any Member State, they must be registered with the Irish Medical Council.</p> <p>Doctors based in the EU or European Economic Area (EEA) can also provide telemedicine services to patients in Ireland, provided they are appropriately qualified and registered with a professional body in their jurisdiction.</p>
<b>18. Does the healthcare professional need to obtain the patient's consent to engage in telehealth?</b>
<p>Medical practitioners must ensure that patients have given their consent to conduct the consultation through telemedicine and consent to any treatment provided.</p> <p>As with traditional consultations, medical practitioners must ensure that:</p> <ul style="list-style-type: none"> <li>• patients' consent is sought and obtained before providing treatment;</li> <li>• patients have the capacity to consent;</li> <li>• patients have been provided with sufficient information to enable them to make informed</li> </ul>

<p>decisions about their care; and</p> <ul style="list-style-type: none"> <li>patients are updated on changes to their condition, treatments or investigations proposed and that consent is continuously sought on this basis.</li> </ul>
<p><b>19. Is there any other important requirement that should be highlighted?</b></p>
<p>N/A</p>
<p><b>DATA PRIVACY ASPECTS</b></p>
<p><b>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.</b></p>
<p>There are data privacy issues in Ireland that should be considered for the exploitation of the telemedicine market. As telemedicine involves the use of technology to transmit and store sensitive patient data, such as medical history, diagnoses and treatments, a telemedicine provider would be considered to be processing personal data relating to those patients. The processing of personal data in Ireland is subject to Regulation (EU) No 2016/679 (the 'GDPR') and the Data Protection Acts 1988 to 2018.</p> <p><b>General principles</b></p> <p>The GDPR is an extensive, principles-based regulation; however, the key principles that must be complied with are:</p> <ul style="list-style-type: none"> <li>lawfulness, fairness and transparency: processing must have a lawful basis (as listed in Article 6(1) of the GDPR), be fair to data subjects and be transparent; this typically requires companies, at a minimum, having privacy and data protection policies in place;</li> <li>purpose limitation: processing must be for clear, express and legitimate purposes, and not further processed in a manner that is incompatible with, or goes beyond the purpose of, those purposes;</li> <li>data minimisation: processing must be adequate, relevant and limited to what is necessary in relation to the purposes for which data is processed;</li> <li>accuracy: data should be accurate and, where necessary, kept up to date; as a corollary, all reasonable steps should be taken to delete or rectify inaccurate data;</li> <li>storage limitation: data should be kept in a form that permits the identification of data subjects for no longer than is necessary for the purposes for which the personal data is processed;</li> <li>integrity and confidentiality: data must be processed in a manner that ensures the appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures; this is particularly important where the telemedicine provider will be relying on videoconferencing to contact patients; and</li> <li>accountability: the controller of the personal data needs to be responsible, and demonstrate responsibility for, the personal data.</li> </ul> <p><b>Role of the provider</b></p> <p>Telemedicine providers need to consider the types of data that they are processing and the role that they have in relation to it. Where they determine the purpose and means of processing, they function as a controller of personal data, which carries significant responsibilities, including the provision of information about processing activities to data subjects and facilitating data subject rights requests. Where a telemedicine provider carries out instructions on behalf of another entity, they may be acting as a processor and they need to ensure that their contract with the other entity complies with Article 28 of the GDPR.</p> <p><b>Health data</b></p> <p>Information relating to a person's health is considered to be a special category of personal data under the GDPR and subject to additional protection. Article 9(1) of the GDPR prohibits the</p>

processing of special category personal data unless an exception in Article 9(2) of the GDPR can be satisfied. These exceptions should be carefully considered by a telemedicine provider. One option is the explicit consent of the data subject; however, consent under the GDPR is a high standard and requires the provision of clear information to the data subject, as well as the right for them to withdraw that consent at any time.

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

Applicable law provides criteria for security systems to protect patient information.

Under Article 32 of the GDPR, controllers must implement appropriate technical and organisational measures to ensure a level of security appropriate to the risks to personal data. The standard set by the GDPR does, however, allow controllers to consider the state of the art and the costs of implementation, alongside the scope, context and purposes of processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons. Examples of technical and organisational measures can include the pseudonymisation and encryption of personal data, processes for regular testing, and evaluation of the effectiveness of technical and organisational measures. Where telemedicine providers rely on videoconferencing and electronic health records as part of the delivery of their services to patients, they need to ensure appropriate security measures are in place to comply with this responsibility.

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

Yes, under the GDPR, there are rules on how data can be transferred outside the EEA. The GDPR requires that these types of international transfers of personal data are subject to 'appropriate safeguards', which are set out in Chapter V of the GDPR. The aim is ensuring that personal data receives the same level of protection as provided by the GDPR, even if it is transferred outside the EEA.

**Safeguards**

For the transfer of data to the third countries, common safeguards that are relied on are: (1) the adequacy decision of the European Commission, which is a formal finding that the protection of personal data in that country is of an adequate level; and (2) the standard contractual clauses (SCCs). The SCCs are standard-form clauses published by the European Commission, which parties enter into to set out how personal data will be protected.

**Assessment**

As well as putting in place an appropriate safeguard, there is a requirement to conduct a 'transfer impact assessment' (TIA). The TIA considers that any impacts on personal data of local laws in the jurisdiction to which data is transferred are considered, for example, whether law enforcement would have greater access to the personal data. Where the TIA identifies risks arising from local laws, the parties must consider whether there are any supplementary measures or additional protections that they can put in place to mitigate risks arising from local laws and bring the level of protection for personal data up to a level that is equivalent to the GDPR.

**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 are currently no database registration requirements in Ireland for electronic health records. Recording of data in the patient's medical records is subject to the general principles contained in Article 5 of the GDPR.

**LIABILITIES**

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

Healthcare professionals and institutions may be subject to liability for medical negligence under common law in Ireland. This can occur where a medical practitioner provides treatment, whether through traditional means or telemedicine, that falls below an acceptable standard of care and directly causes harm to a patient. The current legal standard of care is that a medical practitioner must not fall below the ordinary skill of an ordinary practitioner exercising and professing to have the particular skill at issue. The burden of proof lies on the patient bringing the action and the award for harm caused is compensation in damages.

**TELEMEDICINE NUMBERS AND TRENDS**

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

Although there is no specific regulatory framework in Ireland governing the practice of telemedicine, the provision of these services and growth of this sector is widely recognised in Ireland.

As noted above, the Medical Council has published specific guidance for doctors on the provision of telemedicine services.

Furthermore, eHealth Ireland, a division of Ireland's Health Service Executive (HSE), is responsible for the delivery of technology to support healthcare across the Irish health service. eHealth Ireland published a study in March 2021 finding that, since the beginning of the Covid-19 pandemic, telemedicine had increased fivefold and more than one in five people in Ireland had experienced telemedicine services.

**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.**

There are several state initiatives relevant to the telehealth sector in Ireland. For example, eHealth Ireland has recently commenced the National Telehealth Programme, which aims, inter alia, to improve population health outcomes through facilitating increased accessibility to and quality of digital health supports and services. The programme is focused on four key workstreams:

1. video enabled care;
2. remote health monitoring;
3. online support and therapies; and
4. engagement, research and evaluation.

The introduction of electronic prescriptions in Ireland also represents a significant development in the provision of telemedicine services in this jurisdiction.

Furthermore, the HSE's National Service Plan 2022 highlighted its objective to build on work accelerated by the pandemic, including telehealth, to roll out new models of care focused on the individual and fundamental to addressing the demand/capacity gap in the Irish healthcare sector. The plan identified maximising the potential use of telehealth as a priority area of action.

Information and communications technology (ICT) and eHealth capital funding available in 2022 was €130m, as allocated by the Department of Health in Ireland, which reflects the growing influence of telemedicine on the health sector.