

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?
<p>Telemedicine is allowed in Israel.</p> <p>In a Circular issued by the Israeli Ministry of Health (IMOH) titled Standards for Operating Remote Health Services (Telemedicine, Tele-Health), dated 26 May 2019 (the 'Circular'), Telemedicine is defined as: 'an encounter between [an] identified care provider and patient, not necessarily overlapping in place and time, performed using technological means via electronic communication for the provision of health services'.</p> <p>We note that the IMOH also issued specific standards regarding remote cardiac rehabilitation in a circular dated 15 November 2018.</p>
2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.
<p>The main Israeli law that governs the rights of patients and obligations of medical care providers is the Israeli Patient's Rights Law, 1996-5756 (the 'Patient Law').</p> <p>Telemedicine is regulated in Israel primarily through the Circular.</p> <p>The Circular contains provisions regarding the responsibilities of health organisations/institutes and standards regarding the operation of telemedicine services.</p> <p>When providing telemedicine services, the health institution must prepare a detailed and explained service protocol, which may be provided to the IMOH upon request, relating to several issues, for example, details regarding the services provided, categories of patients, alternative services applicable and details of the advantages/disadvantages of each service, data security measurements, and approval of the registration of every piece of medical equipment and technology (as required under the Medical Equipment Law, 5772-2012) used in the scope of telemedicine services.</p> <p>Health organisations/institutes are required, among other things, to determine specific working procedures, to comply with data security requirements and to provide designated training, as well as to appoint a professional manager for the telemedicine services (the 'Manager').</p> <p>The Manager is responsible for the overall provision of telemedicine services in all legal and professional aspects, including setting, implementing and monitoring updated working procedures, conducting professional reviews of care providers' work, and initiating procedures for the improvement of services' safety and quality.</p> <p>All care providers must hold a valid Israeli licence to practise medicine, or if there is no applicable licence, their occupation must be recognised and supervised by the IMOH.</p> <p>All care providers must undergo designated training for the provision of telemedicine services <i>prior</i> to the provision of such services and <i>throughout</i> their work (refreshing training).</p> <p>The care provider's responsibilities when providing medical services remain the same whether the services are provided by telemedicine or in person. In other words, the care provider is professionally responsible for the quality and safety of the treatment; is obligated to maintain medical records of the encounter; and must refer the patient to conduct a frontal examination or to a specialist (all to the extent required).</p>

Health organisations/institutes must be ISO 27799 and ISO 27001 certified with respect to data security standards.

Prior to the provision of telemedicine services, the patient must be identified and informed consent for providing telemedicine services must be obtained (the Circular contains an example notice for patient authentication, as well as an example form for the patient's informed consent).

To complete this overview, we note that in the prism of privacy law, the Israeli Protection of Privacy Authority (the 'PPA') addressed the field of remote medicine in a recent publication dated 2 August 2022 titled '*Protection of Patients' Privacy in the Provision of Telemedicine*' (the 'PPA Remote Medicine Publication'), under which it provided several clarifications and recommendations for healthcare providers (including any other bodies involved in the collection of medical information), dealing with potential violations of privacy with respect to patients' consent, data minimisation, outsourcing services, patients' identification and usage of connected medical devices/applications.

In addition, we draw your attention to the Israeli Medical Association's publication '*Telemedicine – ethical principles for the provision of remote medical care*', dated September 2019, which states that remote medical service is subject to all the ethical principles that apply to standard medical care.

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

The IMOH is the regulator in all matters concerning healthcare in Israel and serves as the licensing authority for all medical practices.

The IMOH clearly states in the Circular that telemedicine services must be rendered solely by care providers who hold a valid Israeli licence to practise medicine, or if there is no applicable licence, their occupation must be recognised and supervised by the IMOH.

The Regularization of Practice in Health Professions Law, 5768-2008 (the 'Practice Law') states that the IMOH is authorised to provide certifications in health professions in accordance with specific criteria set forth under the Practice Law.

The IMOH is responsible for managing a registry that is open to the public and contains all practitioners in health professions certified by the IMOH.

The Practice Law provides the IMOH with monitoring authorities regarding certified healthcare practitioners, which include the authority to apply professional instructions and directives for the assurance of the services provided by certified healthcare practitioners

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

Telemedicine was authorised during the Covid-19 pandemic.

We note that the pandemic has increased the use of telemedicine in Israel exponentially, as several companies in the field of remote medicine broke out during the pandemic, when such a service was indispensable (the most well-known company is 'TytoCare', who invented a connected medical device).

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?

To date, the IMOH has not issued any updates to the Circular (which was published in 2019, prior to the pandemic).

We note that, as remote medicine has many forms (other than the virtual doctor-patient encounter), the PPA addressed this issue in August 2022, as stated above.

In addition, in a recent draft published by the PPA for public comments titled '*Protection of*

Patients' Privacy when Transferring Medical Information via Digital Devices and Undesignated Software, dated 6 November 2022, the PPA relates to the trend of transferring medical information using software that is not designed to manage medical information, such as WhatsApp, Gmail and Telegram, and the potential risks of the violation of patients' privacy as a result.

Although this is merely a draft, it is safe to assume that the PPA will formally issue guidelines or directives regarding the transfer of medical information via different software and personal devices, which may also affect telemedicine services (especially in the private sector, which is not formally regulated, as mentioned herein).

To conclude, because telemedicine is an evolving practice, we can only assume there may be additional guidelines and directives issued by the IMOH and/or PPA.

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

Under the Circular, determining the types of services that can be performed remotely is in the authority of the management of every health organisation, and therefore, may vary from one institute to another. It is advised that the service will be provided as a mix of both remote and frontal services, subject to the patient's preference and in accordance with the applicable medical requirements.

As stated above, the IMOH also issued specific standards regarding remote cardiac rehabilitation in a circular dated 15 November 2018.

We note that according to the Circular, medicines or diagnostics can be prescribed after a telemedicine session, in accordance with the standards of the respective field of treatment and in accordance with the method of transferring information agreed with the patient.

Under the Medical Doctors (Issuance of Prescription) Regulation 1981-5741, a prescription can be issued by a medical doctor in an online/e-Prescription format.

We add that a care provider may also refer a patient to the emergency room while indicating the level of urgency.

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

Under the Circular, telemedicine is defined as a doctor-patient service.

As to doctor-doctor communication via telemedicine, such communication takes place in the private sector. To the best of our knowledge, this type of service is not officially regulated by the IMOH.

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.

Under the Israel National Health Insurance Law, 5755-1995, all Israeli residents are entitled to basic healthcare as a fundamental right. As a result, all Israeli residents are obligated to join one of four official health insurance organisations, known as 'Kupat Holim' ('Sick Funds'), which operate as non-profit organisations and are prohibited by law from declining membership by Israeli residents.

It is possible to expand medical coverage, thus improving one's health insurance, by purchasing private health insurance in addition.

According to the Circular, Sick Funds cannot impose a deductible amount exceeding the amount imposed for a similar service provided in a frontal encounter. In the event the telemedicine service is deductible, the Sick Fund must inform the patient prior to the provision of the service.

We note that private telemedicine services (ie, services not provided through a Sick Fund) may also be reimbursed. Although such a sector is not regulated under the Circular, it may be

applicable under the Patient Law, the Doctor's oath and the Israeli Medical Association's publication '*Telemedicine – ethical principles for the provision of remote medical care*' (as stated above).

9. Please indicate whether any insurance requirements are applicable to telemedicine service providers.

Care providers (specifically physicians) obtain professional liability insurance as best practice; however, this field is not broadly regulated. There are certain medical services that require professional insurance coverage under law (eg, dental clinics or health institutes that are required to obtain insurance for care providers who are not certified doctors and practice medicine (eg, nurses)).

REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS

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).

According to the Circular, telemedicine can be rendered by care providers.

Under the Patient Law, *care providers* are as follows: physician, dentist, intern, nurse, midwife, psychologist, occupational therapist, physiotherapist, speech therapist, nutritionist-dietitian, clinical criminologist, podiatrist, surgical podiatrist, chiropractor and any other occupation that the IMOH's director has recognised as a care provider.

11. Are there any specific education requirements or training that healthcare professionals need to meet or attend to provide telemedicine services?

As previously stated, all care providers who render telemedicine services must hold a valid Israeli licence to practise medicine or, if there is no applicable licence, their occupation must be recognised and supervised by the IMOH.

In addition, all care providers must complete designated training in telemedicine services *prior* to the provision of such services, as well as *throughout* their work (refreshing training).

The Circular sets forth the subjects on which the training must focus, as follows:

- professionalism: categorising the situations that allow for remote medical care and those that require face-to-face sessions, based on safety principles;
- technology: introducing care providers to technology operated in remote medicine, including training for practising different technologies;
- care provider-patient relations: communication via technological means and aspects of confidentiality; and
- ethical and legal aspects: care provider's medical responsibility, documentation practices and privacy issues.

12. Is there any registration requirement applicable to physicians that provide telemedicine services?

All physicians must be registered with the IMOH, regardless of the type of services they provide.

According to the Israeli Medical Association's publication '*Telemedicine – ethical principles for the provision of remote medical care*', a physician is not obligated to render telemedicine services and has sole discretion regarding whether to engage in such services.

13. Please indicate whether special licenses or authorisations are mandatory for

institutional healthcare providers engaged in telemedicine services.
<p>As stated above, under the Circular, health institutions must prepare a detailed and explained service protocol, which <i>may be provided to the IMOH upon request</i>, relating to several issues, for example, details regarding the services provided, categories of patients, alternative services applicable and details of the advantages/disadvantages of each service, data security measurements, and approval of the registration of every piece of medical equipment and technology (as required under the Medical Equipment Law, 5772-2012) used in the scope of telemedicine services.</p> <p>The IMOH is authorised to request additional information from health institutions.</p>
REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES
14. Are there specific requirements applicable to the telemedicine platform?
<p>As mentioned above, practising telemedicine requires:</p> <ul style="list-style-type: none"> • professional and certified care providers for the provision of services; • detailed service protocols prepared and implemented by health institutions; • using registered medical equipment under the law, to the extent applicable, for the rendering of telemedicine services; • designated training in telemedicine completed by care providers; • establishment of work procedures by health institutions; • appointment of a professional manager by health institutions, responsible for telemedicine services at the applicable institute; • data security obligations; • patient authentication requirements; • obtaining patient's informed consent; and • managing medical records in accordance with the law.
15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?
<p>As stated above, under the Circular, rendering telemedicine services via medical equipment (including software) is subject to the registration thereof under the Medical Equipment Law, 5772-2012, to the extent applicable.</p> <p>We are not aware of any requirements regarding internet speed in the scope of telemedicine services; however, we do specify that the PPA advises using a private and secured network when conducting a virtual medical session rather than public Wi-Fi.</p>
16. Does legislation provide for specific rules concerning patients' medical records?
<p>Under the Patient Law, medical care must be recorded and indicate the following: the patient's and care provider's identified details, the medical care provided to the patient, medical history as provided by the patient during the session, the diagnosis provided and instructions of treatment. Personal notes conducted by the care provider with respect to a session with a patient are <i>not</i> part of the medical records.</p> <p>The Patient Law also determines provisions regarding storing medical records, patient's right for information and more.</p> <p>The IMOH also issued a circular titled Standards for Managing Patients Records in the Health System, dated 15 December 2019, which provides a broad and detailed guideline with respect to medical records.</p> <p>On this note, the PPA clarified in the PPA Remote Medicine Publication that medical information collected in the scope of telemedicine services may be considered as a computerised medical</p>

record under the Patient Law; and is therefore not only subject to data security regulations but also IMOH's directives regarding medical records.

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

Telemedicine services can be provided from abroad only to the extent that the care provider holds a valid Israeli licence to practise medicine or, if there is no applicable licence, his/her occupation must be recognised and supervised by the IMOH.

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

First and foremost, the Patient Law regulates the requirement to obtain the patient's informed consent as a condition for providing medical care.

As the provision of medical care using telemedicine is no different than face-to-face medical care, the requirement to obtain the patient's informed consent is also mandatory for the provision of telemedicine services.

This fundamental requirement is regulated under the Circular, as well as in the PPA Remote Medicine Publication and the Israeli Medical Association's publication '*Telemedicine – ethical principles for the provision of remote medical care*'.

A health institute that provides telemedicine services is the controller of the data collected in the provision of such services and is therefore obligated to obtain patients' consent after informing them of the data that will be collected, the use and purpose thereof, whether there will be any transfer of data to third parties and the patients' right to access the data.

When providing telemedicine services, it is also required to inform patients of the potential risks involved in this service in the prism of data security (as stated above, the Circular contains an example form regarding patient's informed consent).

When health institutes are engaged with third-party suppliers, it is the third party's obligation to obtain the patient's specific consent to use his/her data, in addition to consent obtained for the provision of the telemedicine service itself (the PPA gives great importance to this matter specifically when using artificial intelligence (AI)-based medical services).

The Israeli Medical Association's position, as manifested in its publication '*Telemedicine – ethical principles for the provision of remote medical care*', is that informed consent must refer to the actual medical care provided, as well as to how it is provided, that is, via telemedicine.

On a final note, we state that under the Patient Law, care providers can exchange medical information for the purpose of medical care provided to a specific patient without the need to obtain the patient's consent.

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

All major requirements are detailed herein.

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.

Telemedicine, by nature, entails many aspects of data privacy. It is a popular feature of modern digital life that became more and more common during the Covid-19 pandemic and thereafter.

Because medical information is considered sensitive and personal information, there is high

value in protecting it and preventing its exposure (this also the Israeli Supreme Court's position).
Remote medicine, when rendered in an unsecured manner, might result in data exposure that directly affects a patient's life.

In addition, medical information is of high financial value and as such may be targeted by harmful parties.

Therefore, and as the PPA clearly recommends in the PPA Remote Medicine Publication, it is crucial to maintain high data security measurements, to obtain consent legally, and to maintain and manage the medical information collected and processed in compliance with applicable law.

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

The Circular clearly states that health organisations/institutes must be ISO 27799 and ISO 27001 certified with respect to data security standards.

In addition, prior to the provision of telemedicine services, the patient must be identified and informed consent for providing telemedicine services must be obtained (the Circular contains an example notice for patient authentication, as well as an example form for patient's informed consent).

As noted above, the PPA clarifies in the PPA Remote Medicine Publication that medical information collected in the scope of telemedicine services may be considered as a computerised medical record under the Patient Law and is therefore not only subject to data security regulations but also IMOH's directives regarding medical records.

In that respect, we refer back to the IMOH's circular titled Standards for Managing Patients Records in the Health System, which provides a broad and detailed guideline with respect to medical records.

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

The transfer of data (kept in a database under the Protection of Privacy Law 5741-1981 (the 'Privacy Law')) is regulated under the Protection of Privacy Regulations (Transfer of Data to Database Outside of the Country) 5761-2001 (the 'Transfer Regulations').

The transfer of data outside Israel is permitted, provided that the applicable law of the country to which the data is transferred provides a level of data protection that is no less than that provided under Israeli law.

Nevertheless, for certain events, the Transfer Regulations allow for data transfer, for example, in the event that the data subject has agreed to the transfer of his/her data.

In any event, the data recipient must provide a written undertaking stating that all adequate means are implemented for the protection of the data subject's privacy and that the data will not be transferred to any third party in the recipient's country or in a different country.

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?

The Privacy Law states that databases containing 'sensitive information' (eg, medical information) must be registered with the PPA's registrar; 'sensitive information' means: (1) data on the personality, intimate affairs, state of health, economic position, opinions and beliefs of a person; and (2) information that the Minister of Justice determined by order, with the approval of the Constitution, Law and Justice Committee of the Knesset, is sensitive information.

Under the Privacy Law, no person shall manage or possess a database that requires

registration, unless it has been registered.

In addition, as noted above, the PPA clarified in the PPA Remote Medicine Publication that medical information collected in the scope of telemedicine services may be considered as a computerised medical record under the Patient Law and is therefore not only subject to data security regulations but also IMOH's directives regarding medical records.

LIABILITIES

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

The liability of healthcare professionals and institutions involved in telemedicine practice is based on general legal principles of malpractice and negligence. One would assume that the criteria implemented in order to determine such liability should take into account a higher standard of practice to reflect the fact that the services are provided remotely.

TELEMEDICINE NUMBERS AND TRENDS

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

All publications of the IMOH, as well as the PPA, are available to the public.

In that respect, both the Circular and PPA Remote Medicine Publication are disclosed to the public.

In addition, the IMOH's registry containing all certified care providers is open to the public.

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.

We believe that following the PPA Remote Medicine Publication, and as the field of telemedicine will keep growing and improving, we will witness the formation of specific legislation in that respect, regulating data security obligations, patient's awareness and rights, and various requirements for care providers.

In our opinion the field of telemedicine has several unresolved issues, as follows:

- Telemedicine is not known or accessible to all. Older, disabled and low socio-economic populations are most likely to be unaware of the possibilities offered through telemedicine because they do not have any internet or due to the fact that such services are not always offered/accessible in certain areas of Israel.
- The field of AI-based medical services is still in progress and allows for better and more advanced ways for providing medical care. As in all AI matters, legal questions arise regarding the potential bias of an algorithm or 'black box AI', which have yet to be resolved.
- Telemedicine has great advantages, yet it can, on the other hand, lead to diminishing the patient-doctor trust relationship, which is an integral part of medical care.
- When using technological appliances in the scope of telemedicine, there may be potential defects or bugs that could result in damages, thus requiring regulating the liability scopes of each relevant party.