

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/telehealth is permitted and regulated by Booklet 10 (General Ethical Guidelines for Good Practice in Telehealth (December 2021)) (Telehealth Guidelines) of the 'Ethical Guidelines for Good Practice in the Health Care Professions' (Ethical Guidelines). The Telehealth Guidelines define the term 'telehealth' as 'the application of electronic telecommunications, information technology or other electronic means to administer healthcare services in two geographically separated locations for the purpose of facilitating, improving, and enhancing clinical, educational and research, particularly to the under serviced areas in [South Africa]. Telehealth is a blanket term that covers all components and activities of healthcare and the healthcare system[s] that are conducted through telecommunications technology.'</p> <p>The objective of the telehealth system in South Africa is to deliver healthcare services at a distance particularly to South Africans residing in underserved areas where telehealth 'involves secure videoconferencing or similar forms of technology which enable healthcare practitioners to replicate, as far as practical, the interaction of traditional face-to-face consultations between healthcare practitioners and patients.'</p>
2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.
<p>The Health Professions Council of South Africa (HPCSA) has, in terms of its powers under the Health Professions Act 56 of 1974 (Health Professions Act), issued the Telehealth Guidelines, with which healthcare practitioners must comply when providing telehealth services.</p>
3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.
<p>The HPCSA is a statutory body established under the Health Professions Act. Its objectives include, among others, protecting the public in matters involving the rendering of health services by persons practising a health profession, upholding professional and ethical standards within the health professions and investigating complaints concerning persons registered in terms of the Health Professions Act, as well as ensuring that appropriate disciplinary action is taken against such persons in order to protect the interest of the public.</p> <p>The HPCSA is mandated to regulate the health professions in South Africa in aspects pertaining to education, training and registration, professional conduct and ethical behaviour, ensuring continuing professional development, and fostering compliance with healthcare standards.</p>
4. Was telemedicine authorized during the Covid-19 pandemic?
<p>During the Covid-19 pandemic, Booklet 10 (General Ethical Guidelines for Good Practice in Telemedicine (August 2014)) (Telemedicine Guidelines), which preceded the Telehealth Guidelines, was in force.</p> <p>Telemedicine, according to the definition in the Telemedicine Guideline, only recognised the use of electronic mechanisms for consulting or delivering medical services in the limited context of two or more healthcare practitioners consulting in respect of a patient (ie, to connect consulting healthcare practitioners with specialists).</p>

<p>However, during the pandemic, the HPCSA recognised that the pandemic constituted a public health emergency and risk to practitioners, patients and more broadly, the wellbeing of the South African community.</p> <p>In March and April 2020, the HPCSA announced that, for the duration of the pandemic, it would permit the use of telehealth defined as ‘remote consultations with patients using telephonic or virtual platforms of consultation’, and provided that healthcare practitioners were permitted to charge a fee for services rendered through a telehealth platform. Therefore, for the duration of the pandemic, healthcare practitioners were permitted to conduct telephonic and virtual consultations with their patients and charge a fee in respect of such telehealth services.</p>
<p>5. Is there any possibility of the regulatory landscape being changed in the post-pandemic scenario? Or has there been already a change in the regulation in the post-pandemic scenario?</p>
<p>In December 2021, the Telehealth Guidelines replaced the Telemedicine Guidelines and further replaced the term ‘telemedicine’ with ‘telehealth’.</p>
<p>6. What types of teleservices are allowed? (e.g. second opinion, teleconsultation, telediagnosis, telesurgery, among others)</p>
<p>Section 4.1 of the Telehealth Guidelines provides that routine telehealth may be used (preferably if there is an established practitioner-patient relationship) to supplement normal medical practice and only replaces face-to-face services where the quality and safety of patient care is not compromised.</p> <p>Section 4.3 provides that emergency instructions should be in writing and appropriate to the services being rendered via telehealth platforms where the practitioner must provide acute treatment and refer the patient to an emergency facility (where necessary).</p> <p>The types of telehealth services set out in the Telehealth Guidelines include: (1) routine telehealth (either by a patient or used by practitioner to obtain second opinion from other practitioners); (2) specialist telehealth consultations; and (3) emergency telehealth.</p>
<p>7. Who can use telemedicine services? Please indicate if whether only doctor-doctor or also patient-doctor remote medical services are allowed.</p>
<p>The Telehealth Guidelines provide for patient-doctor remote medical services as well as between healthcare practitioners. The Telehealth Guidelines expressly provide that:</p> <p>‘telehealth is intended to be utilised to replicate physical consultations as far as possible, but not as a substitute. It is desirable that the practitioner shall have established a professional relationship with their patient before telehealth services can be considered, although, this is not a compulsory requirement, depending on existing conditions. No practitioner may exclusively render professional services through telehealth.’</p>
<p>8. Please outline the funding model for telemedicine. Is it available in your jurisdiction public health system? Is telemedicine under mandatory insurance coverage? Please indicate what legislation applies.</p>
<p>The Telehealth Guidelines currently provide that a healthcare practitioner may charge consultation fees for services undertaken through telehealth platforms.</p> <p>In the public sector, telehealth has predominately been used between healthcare practitioners as a tool in the delivery of healthcare as well as enhancing the knowledge of those working in the medical field. The ‘South African Government: Strengthening the South African health system towards an integrated and unified health system, Presidential Health Summit Compact, 25 July 2019’ (Health Compact) identified nine pillars in relation to which the existing healthcare system needs to be improved or strengthened, before South Africa can move towards a unified healthcare system through the implementation of the National Health Insurance Bill.</p>

Pillar 9 of the Health Compact provides for developing an information system that will guide the health system policies, strategies and investments. Regarding Pillar 9, the Health Compact provides that the implementation of digital technologies in South African's health sector requires several interventions including improving the healthcare technology infrastructure and architecture platform.

In this regard, the Health Compact envisages various interventions including improving accessibility to health information systems by patients and healthcare practitioners through implementing health innovative technologies, such as patient care portals with a point of care devices as part of a telemedicine platform and use of mobile technologies.

To date, patient's making use of telehealth services remain liable for telehealth services received.

We note that there is currently no mandatory insurance coverage required in respect of telehealth services in South Africa. However, all private health establishments in South Africa are, in terms of section 46 of the National Health Act 61 of 2003 (National Health Act) required to maintain insurance cover sufficient to indemnify a user for damages that such user might suffer as a consequence of a wrongful act by any member of its staff or by any of its employees.

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

In October 2010, the Minister of Health in consultation with the HPCSA repealed the Regulations Relating to Indemnity Cover for Registered Health Practitioners, requiring registered healthcare practitioners with independent practices to obtain and maintain indemnity cover.

However, regulation 2 of the Regulations relating to Indemnity Cover for Psychologists requires a practising psychologist, registered in the category of independent practice, to obtain and maintain professional indemnity cover at all times. Psychologists are required to provide the Professional Board for Psychology on an annual basis with documentary proof and details of the required professional indemnity cover.

Although not mandated by the Health Professions Act, we note that health professionals (other than psychologist) generally have comprehensive indemnity protection.

Accordingly, although indemnity cover is not required for healthcare practitioners who are not psychologists, it is still advisable for all healthcare practitioners to obtain professional indemnity cover and ensure that such cover includes claims made in respect of telehealth services.

REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS

10. Who can practice telemedicine in your country? Please indicate whether other healthcare professionals are authorized to provide remote health services under the applicable rules (e.g. nurses, psychologists, nutritionists, alternative health therapies providers, etc.)

The definition of healthcare practitioners in the Telehealth Guidelines is very wide and includes a person providing health services, registered in terms of the Health Professions Act. It also includes any other appropriate disciplines as defined in the National Health Act.

Registration with the HPCSA is a prerequisite for practising a profession in terms of which a professional board has been established, where such practice is for gain within South Africa, or for any other health profession scope which has been defined by the Minister of Health in terms of the Health Professions Act.

Accordingly, only healthcare practitioners registered with the HPCSA are authorised to participate in telehealth practice in South Africa. In the case of telehealth across South Africa's

<p>borders, healthcare practitioners serving South African patients should be registered with the regulating bodies in their original countries as well as with the HPCSA.</p>
<p>11. Are there any specific education requirements or trainings that healthcare professionals need to meet or attend to provide telemedicine services?</p>
<p>Although there are no specific education requirements or trainings that healthcare practitioners need to meet or attend to provide telehealth services, we note that the Telehealth Guidelines hold healthcare practitioners (in charge of patient and consulting) to the same standards of professional practice as healthcare practitioners who conduct face-to-face consultations. Furthermore, healthcare practitioners collaborating in telehealth are required to ensure that they are duly registered as healthcare practitioners, before embarking on the clinical consultation.</p>
<p>12. Is there any registration requirement applicable to physicians that provide telemedicine services?</p>
<p>As set out in the response to Question 10, healthcare practitioners must generally be registered with the regulating bodies in their original countries (in respect of telehealth across South Africa's borders) and the HPCSA to participate in telehealth practice in South Africa and when serving South African patients.</p>
<p>13. Please indicate whether special licenses or authorizations are mandatory for institutional healthcare providers engaged in telemedicine services.</p>
<p>Other than healthcare practitioners being required to register with the HPCSA, there are no additional mandatory licences or approvals required from institutional healthcare practitioners engaged in telehealth services.</p>
<p>REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES</p>
<p>14. Are there specific requirements applicable to the telemedicine platform?</p>
<p>Telehealth services may be delivered through any suitable Information and Communication Technology (ICT) platforms, such as mobile phones, telephones, Skype, Teams, Google Meet or any similar virtual technology, to exchange information for the diagnosis and treatment of diseases and injuries, research, and evaluation, and for the continuing education of health professionals.</p> <p>The Telehealth Guidelines provide that the use of social media platforms for the purpose of telehealth is not desirable where healthcare practitioners are advised not to interact with patients via social media platforms as a failure to maintain strictly professional relationships with patients may result in ethical dilemmas and the acquisition of data about an individual's personal information, including health, outside a healthcare setting.</p>
<p>15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?</p>
<p>Telehealth information may be exchanged electronically, either synchronously or asynchronously (ie, on- or off-line), and formally, informally or in response to a need for remote support from a consulting practitioner.</p>
<p>16. Does the legislation provide for specific rules concerning patients' medical records?</p>
<p>Practitioners are required to keep detailed records of the patient's condition and information transmitted; and keep detailed records, online or otherwise, of the professional services delivered as well as the information received and on which the advice is based. Prior informed consent for the use of telehealth can be obtained in writing or recorded orally and must be kept with patient's records and a duplicate given to the patient, when required. All patient information and records should consist of copies of all patient-related electronic communications.</p> <p>The Telehealth Guidelines provide that the principles of good practice in relation to patient consent, confidentiality, and good record keeping still apply in respect of telehealth.</p>

17. Are there geographic location requirements applicable to the provision of telemedicine services?
There are no geographic location requirements applicable to the provision of telehealth in South Africa, except for those described in Question 10, above.
18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?
Healthcare practitioners are prohibited from providing medical advice or treatment using telehealth without obtaining proper prior informed consent (either orally recorded or written) from the patient both in respect of the treatment to be given and the use of telehealth technology.
19. Is there any other important requirement that should be highlighted?
<p>The General Regulations published in terms of the Medicines and Related Substances Act 101 of 1965 (Medicines Act), read with rule 17(1) of the Ethical Rules of Conduct for Practitioners registered under the Health Professions Act, 1974 (Ethical Rules) published in terms of the Health Professions Act permit the issuing of an electronic prescription for medicine scheduled in Schedules 1, 2, 3 and 4 provided that the prescription contains the information required in section 33(3) of the General Regulations. Furthermore, healthcare practitioners should ensure that in respect of any electronic prescription issued:</p> <ol style="list-style-type: none"> 1. an advanced electronic signature, has been used by the authorised prescriber to sign the electronic prescription; 2. the advanced electronic signature has been effected by the authorised prescriber personally, without delegating this duty to another person; and 3. the electronic prescription is only in respect of a prescription for Schedules 1, 2, 3 and 4 Medicines.
DATA PRIVACY ASPECTS
20. Are there data privacy issues should be considered for the exploitation of such market? If your answer is positive, please provide a short description.
<p>Healthcare practitioners are still required to act in the best interest and wellbeing of the patient as required by the National Health Act. The Telehealth Guidelines provide that patient confidentiality should be maintained in line with the National Health Act and the Protection of Personal Information Act 4 of 2013 (POPIA).</p> <p>Booklet 5 of the Ethical Guidelines also provides a guideline on confidentiality in respect of protecting and providing information, where patients have a right to expect that information about them will be held in confidence by their healthcare practitioners.</p>
21. Does the applicable regulation provide for criteria and requirements for the security systems to protect the patient's information?
<p>The Telehealth Guidelines provide that patient information should only be transmitted between sites, with the full knowledge and approval of the patient and only information that is relevant to the patient's clinical history should be transmitted electronically. To protect the identity of the patient when information is transmitted between sites, it is essential that personal identification should be removed, and the transmitted information is encrypted. All personal computers of the Telehealth service should be accessed by authorised personnel only through the use of a login password. Access to information by other healthcare practitioners, patients or third parties should be authorised by the healthcare provider in charge of the patient and be carried out according to the rules and regulations as outlined in POPIA.</p> <p>Healthcare practitioners using telehealth are required to:</p> <ol style="list-style-type: none"> 1. avoid accidental damage and loss of patient information;

<ol style="list-style-type: none"> 2. provide safe procedures to avoid any alteration or elimination of patient data; 3. ensure that patient information obtained electronically is kept in line with the HPCSA's guidelines on the keeping of patients' records in Booklet 9; and 4. comply with the legal requirements for data messages in the Electronic Communications and Transactions Act No 25 of 2002 and the protection of personal information in POPIA. <p>Additionally, healthcare practitioners must ensure that:</p> <ol style="list-style-type: none"> 1. adequate safety mechanisms are in place in respect of the processing of a patient's personal information by public and private bodies; 2. the minimum requirements for the processing of personal information are established; 3. the code of conduct for the management of patient data is provided for; and 4. they are cognisant of rights of persons regarding unsolicited electronic communications.
<p>22. Does the applicable regulation provide for requirements for the transfer of information abroad?</p>
<p>Yes, POPIA regulates the requirements for the transfer of personal information about a data subject (ie, the patient) to a third party in a foreign country.</p>
<p>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?</p>
<p>The requirements for the recording of data in a patient's medical records are set out in Question 16. They primarily require patient information and records to consist of copies of all patient-related electronic communications, including: (1) patient-practitioners communications; (2) prescriptions; (3) laboratory and test results; (4) evaluations and consultations; (5) records of past care; (6) instructions obtained or produced in connection to telehealth technologies; and (7) records of informed consents to treatment and use of telehealth.</p> <p>The patient's health records, data and platform bandwidth, established during the session of telehealth must be accessible, online, or physically, and documented for both the healthcare practitioners involved and their patients.</p> <p>The registered healthcare practitioner must ensure that the confidentiality mechanisms employed to ensure confidentiality are available when required and is further responsible for ensuring that non-registered personnel who may be offering auxiliary or technical services, are aware of and adhere to the guidelines in respect of the quality, security, and safety of patient information and records.</p>
<p>LIABILITIES</p>
<p>24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.</p>
<p>Failure by a healthcare practitioner to comply with the Telehealth Guidelines shall constitute an act or omission in respect of which disciplinary steps in terms of Chapter IV of the Health Professions Act may be taken.</p> <p>We note that a liability for professional medical negligence in respect of a normal delictual claim for damages will still be applicable in respect of telehealth services. Therefore, healthcare practitioners should keep in mind that the South African law of delict (tort) and its principles are still applicable in respect of telehealth services.</p>
<p>TELEMEDICINE NUMBERS AND TRENDS</p>
<p>25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?</p>

While there is no official publicly disclosed data indicating the use and acceptance of telehealth in South Africa, over the past two years South Africa has seen an accelerated increase in the uptake of telehealth services between patients and practitioners in the private sector which, similar to global trends, was largely driven by the pandemic.

In the HPCSA's 2020/2021 Annual Report, the HPCSA confirmed that 'more doctors, health systems and medical specialties are providing telehealth services. As insurers move to offer reimbursements for telehealth and the scope of telehealth coverage for Medicare Advantage enrollees expands the benefits and will continue to be more evident.'

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 HPCSA's 2020/2021 Annual Report notes the following trends, among others, in the technological environment in respect of telehealth:

1. telehealth will widen its reach and scope of services;
2. the arrival of Fifth Generation (5G) Networks will provide faster network speeds and is regarded as being crucial for transmitting large medical images, and for supporting telehealth initiatives and remote patient monitoring tools as well as complex uses of artificial intelligence (AI), augmented reality (AR), and virtual reality (VR);
3. VR will play a greater role in patient care; and
4. the potential for robots in healthcare to expand beyond surgical uses such as helping doctors examine and treat patients in rural areas via 'telepresence', transporting medical supplies, disinfecting hospital rooms, helping patients with rehabilitation or with prosthetics and automating labs and packaging medical devices.