

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?

Yes. Under the Ministry of Health (MOH) Regulation No 20 of 2019 on The Organization of Telemedicine Services Among Health Service Facilities ('MOH Reg No 20/2019'), telemedicine is defined as the provision of healthcare services remotely by healthcare professionals using communication and information technology, including the exchange of information regarding diagnoses, medication, the prevention of illness and injury, research and evaluation, as well as sustainable education in healthcare services for the interest of the enhancement of the health of individuals and the public.

In addition, the Medical Council issued Regulation No 74 of 2020 on Clinical Authorities and Medical Treatment Through Telemedicine During the Covid-19 Pandemic ('Medical Council Reg No 74/2020'). Telemedicine is defined therein as the provision of remote medical services by doctors and dentists using information and communication technology, including the exchange of diagnostic information, treatment, the prevention of disease and injury, research and evaluation, and the sustainable education of health service providers for the purpose of improving individual and public health.

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

In general, medical services are governed under Law No 36 of 2009 on Health (the 'Health Law'). The Health Law has several implementing regulations, among others, MOH Reg No 20/2019; however, MOH Reg No 20/2019 only regulates the organisation of telemedicine services among health service facilities or *fasyankes* (*fasilitas pelayanan kesehatan*), for example, hospitals, pharmacies, clinics and health laboratories, whose purpose is to increase the accuracy and speed of medical diagnosis for health service facilities that have no certain healthcare professionals. MOH Reg No 20/2019 does not set out the implementation of telemedicine between health service facilities or healthcare professionals and telemedicine users.

The Indonesian Government, including the MOH, has not issued any specific and technical regulation on the implementation of telemedicine (specifically between health service facilities/healthcare professionals and their users), *although* telemedicine users and business actors in Indonesia keep increasing and the MOH has acknowledged telemedicine as one of the e-health strategies for resolving infrastructure, communication and human resources issues under its Regulation No 46 of 2017 on National E-Health Strategies.

However, as one of the measures to prevent the Covid-19 disease, the Medical Council issued Medical Council Reg No 74/2020, which allows telemedicine to be between healthcare professionals and patients. To date, in practice, some platforms provide services for health consultations for patients. However, according to Medical Council Reg No 74/2020, this regulation will only remain in effect until the Indonesian Government officially declares the end of the Covid-19 public health emergency.

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

The key licensing body for health services is the MOH. The MOH issues licensing for, among others, health service facilities that provide and/or request telemedicine services and practice permits for healthcare professionals.

The MOH's responsibilities are, among others, formulating, determining and implementing policies on public health; prevention and disease control; healthcare services; pharmacy; medical devices; and healthcare professionals – the functions include issuing regulations and policies related to telemedicine services and supervising the implementation of telemedicine (including supervising the system used to provide telemedicine services).

In addition to the MOH, for doctors (including dentists), there is an independent body called the Indonesian Medical Council (Konsil Kedokteran) that implements regulatory functions related to medical practice, including issuing some certificates and registrations related to the competency of doctors in providing medical services.

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

Yes, telemedicine is allowed during the Covid-19 pandemic as it is regulated, among others, under Medical Council Reg No 74/2020.

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, we are not aware of any law or regulations discussed by the representatives or MOH regarding telemedicine although, as mentioned above, telemedicine is acknowledged by MOH as one of the strategies to support the implementation of e-health.

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

According to MOH Reg No 20/2019, the following teleservices are allowed:

- teleradiology;
- tele-electrocardiography;
- tele-ultrasonography;
- teleconsultancy; and
- other telemedicine consultancy services according to developments in science and technology.

Based on Medical Council Reg No 74/2020, telemedicine constitutes consultancy services provided by doctors by implementing the confidentiality principle of patients.

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

MOH Reg No 20/2019

Telemedicine services are provided between health service facilities to support diagnoses, therapy and/or the prevention of diseases. Health service facilities include government and privately owned hospitals, and health service facilities that request consultations, which include frontline health service facilities, such as public health centres. As the regulation only applies to telemedicine services provided between healthcare facilities, it does not cover health consultancy services provided through websites and phone apps to patients. Further, the regulation requires telemedicine services to be provided by healthcare professionals who hold a licence to practise in

the organising health service facilities.

Medical Council Reg No 74/2020

Unlike MOH Reg No 20/2019, application-based health consultancy services and health consultancy services by phone for doctor-patients are covered by this regulation. However, the provision of consultancy services must be through or managed by the health service facilities. Telemedicine services may be provided in online writing, voice and/or videos directly to obtain information required to support diagnoses, as well as patient management and treatment in accordance with the prevailing laws and regulations. Doctors and dentists who provide medical services through telemedicine must be registered and have a licence to practise in the relevant health service facilities.

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.

There are no funding provisions or mandatory insurance cover for telemedicine under the laws and regulations. MOH Reg No 20/2019 only states that the telemedicine fee for the health insurance programme must be determined by the MOH. Further, the central and regional government may assist the funding of telemedicine services through the state budget, regional budget and/or other sources under the applicable laws and regulations.

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

There are no specific requirements on this. MOH Reg No 20/2019 only states that the telemedicine fee for the health insurance programme must be determined by the MOH. However, there is no further regulation from the MOH on this matter.

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).

MOH Reg No 20/2019

The regulation states that telemedicine services may be provided by healthcare professionals who hold a licence to practise in the organising health service facilities. Therefore, for the provision of telemedicine services among health service facilities, other healthcare professionals (not only doctors, but including, among others, nurses, pharmacists, nutritionists and alternative health therapy providers) are allowed to practise telemedicine, as long as they hold the required licence to practise in the relevant health service facilities.

Medical Council Reg No 74/2020

The regulation only sets out the telemedicine services provided by doctors and dentists who are registered and have a licence to practise in the relevant health service facilities. Doctors and dentists are collectively defined as doctors, specialists, sub-specialists, dentists and specialist dentists who have graduated from medical and dental schools, either within the country or abroad, that are recognised by the Government of the Republic of Indonesia in accordance with the

prevailing laws and regulations. Therefore, we believe that other healthcare professionals are allowed to practise telemedicine, as long as they meet these criteria.

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

There is no specific regulation or guidelines on this matter. There was a regulation in 2017 on the trial of telemedicine services by hospitals and public health centres, which set out, among others, the telemedicine procedures; however, this regulation is no longer valid.

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

There is no specific regulation on this matter. However, as required, they must be registered and obtain a licence to practise at the relevant health service facilities to provide telemedicine services.

13. Please indicate whether special licenses or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.

Under MOH Reg 20/2019, health service facilities must be registered with the MOH. These health service facilities must also comply with certain requirements, including requirements related to: (1) human resources (doctors, medical staff etc); (2) facilities, infrastructure and equipment; and (3) applications.

REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES

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

There is no specific requirement that applies to telemedicine platforms that directly connects healthcare professionals and patients (outside of the scope of MOH Reg No 20/2019).

However, for telemedicine platforms that are used to provide telemedicine services among health service facilities, the platform can be provided by the MOH, or any application developed by health service facilities, which must be integrated with the MOH's application. The regulation is silent on specific requirements for such telemedicine platforms, but it requires telemedicine electronic systems to comply with the laws and regulations on data security and safety.

For general requirements, all electronic systems in Indonesia must obtain an electronic system organiser (ESO) registration certificate from the Ministry of Communications and Informatics (MOCI). The relevant MOCI regulations require an application to be registered with the MOCI before Indonesian users can use it. Currently, the MOCI will block electronic systems provided to Indonesian users but not registered with it.

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

There is no specific requirement on these matters. MOH Reg No 20/2019 only generally requires telemedicine facilities, infrastructure and equipment to be sufficient for the telemedicine services, which at least includes sufficient room, electric power, an internet network, and medical and non-medical equipment that supports the provision of telemedicine services. All of them must comply with the relevant laws and regulations.

16. Does legislation provide for specific rules concerning patients' medical records?
<p>Yes, the medical record is regulated under MOH Regulation No 24 of 2022 on Medical Records ('MOH Reg 24/2022'). It is defined as a document containing data that includes the patient's identity, examination results, treatment, action and services provided to the patient. Meanwhile, an electronic medical record is defined as a medical record made using an electronic system that is intended for the administration of medical records. Under this regulation, health service facilities providing telemedicine services must provide, operate or manage electronic medical records. Further, under Medical Council Reg No 74/2020, doctors and dentists providing telemedicine services must maintain medical records, either manual medical records in written form or electronic medical records in the form of transcripts, for all patients and store them in the relevant health service facilities.</p>
17. Are there geographic location requirements applicable to the provision of telemedicine services?
<p>There are no specific requirements on the geographic location for telemedicine services.</p>
18. Does the healthcare professional need to obtain the patient's consent to engage in telehealth?
<p>Yes, under Medical Council Reg No 74/2020, patients obtaining telemedicine services must give their general or informed consent.</p>
19. Is there any other important requirement that should be highlighted?
<p>Electronic system</p> <p>Electronic systems in the organisation of electronic medical records may be in the form of one developed by the MOH, the health services facilities themselves or electronic system organisers through cooperation. If using the MOH's system, the health service facilities must submit a written application to the MOH. If it cooperates with electronic system organisers, the electronic system must be registered with the MOCI and the electronic system organisers must have data storage facilities in Indonesia.</p> <p>Medical record activities</p> <p>The activities of organising electronic medical records shall include, among others:</p> <ul style="list-style-type: none"> • registration of patients; • distribution of electronic medical record data; • filling out of clinical information; if there is more than one health personnel, the filing must be conducted in an integrated manner; • processing of electronic medical record information, which shall include coding according to International Statistical Classification of Disease and Related Health Problems, reporting (to internal and external parties) and analysis; health services facilities unavailable to organise this shall conduct indexing, namely a data grouping activity, at least in the form of the following indexes: name, address, type of diseases, measures/operations and death; • data input for financing claims; • storage of electronic medical records; if conducted digitally, a backup system is required, and the electronic medical records must also be connected/interoperable with a service

platform for health data interoperability and integration managed by the MOH;

- quality assurance of electronic medical records; and
- transfer of the content of electronic medical records, namely a transfer activity of medical records for the purpose of referrals of individual health services to health services facilities receiving referrals; this shall be conducted through a service platform for health data interoperability and integration managed by the MOH.

Ownership of medical records

Medical record documents shall belong to health services facilities, while the content (eg, identity and result of check-ups) of medical records shall belong to patients.

Health services facilities must open access to all the content of electronic medical records of patients to the MOH.

Retention period

The storage of electronic medical record data in health services facilities shall be conducted for at least 25 years from the date of the last visit of patients.

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.

The treatment of personal data that is processed either by health services facilities or any telemedicine platform is subject to provisions under Law No 27 of 2022 on Personal Data Protection (the 'PDP Law'). Personal data itself is defined as the data of an individual that is or can be identified specifically or in combination with other information, either directly or indirectly, through an electronic or non-electronic system.

Under the PDP Law, data subjects' (the patients') rights are, among others:

- to request information related to the clarity of their identity, the legal basis and the purpose and use of their personal data, as well the accountability of any party who requests the data;
- to complete, renew and amend mistakes or inaccuracies in their data according to the purpose of data processing;
- to access and obtain copies of their data;
- to terminate, erase and destroy their data;
- to withdraw any consent to the processing of their data;
- to object to any act or decision-making process that is based entirely on automatic processing, including profiling;
- to postpone or limit the processing of any data on a proportional basis according to the purpose of data processing;
- to file a civil lawsuit and receive indemnities in relation to any violation of the confidentiality of their data;
- to obtain and use their data provided by a controller, in commonly recognised forms and formats or in ways that can be read by electronic systems; and
- to use and submit their data to another controller provided that the relevant systems are capable of safely communicating with each other in accordance with the data protection principles as required under this law.

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

In general, under the PDP Law, data controllers must protect and ensure the security of the data they process, by creating and implementing operational technical measures to protect data from unlawful data processing interference and determining the data security level required according to the nature of and risk to the data.

In addition, the electronic system used to process the personal data in electronic systems (including patient's information in their medical records) must have compatibility and/or interoperability capabilities.

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

Under MOCI Regulation No 20 of 2016 on Personal Data Protection in Electronic Systems ('MOCI Regulation No 20/2016'), an electronic system organiser must obtain explicit consent to process personal data (processing includes the transfer of personal data). In addition, under MOCI Regulation No 20/2016, a cross-border data transfer had to be notified to MOCI (in the form of plan and realisation reports).

In addition, the PDP Law sets out different provisions on cross-border data transfer. According to the PDP Law, the senders of personal data must comply with the following requirements to transfer data outside Indonesia:

- Adequacy: personal data controllers as senders must ensure that the relevant recipient's state has an equal and/or higher level of data protection compared to Indonesia.
- Contractual obligation: if the data protection provisions of the recipient's state are not sufficient, the personal data controllers must ensure that sufficient and binding data protection provisions are implemented by the recipient.
- Consent: if neither of the above criteria can be met, consent from the personal data subject must be obtained.

Note that the PDP Law states that all laws and regulations (including MOCI Regulation No 20/2016) that govern personal data protection will still apply, as long as they do not conflict with the provisions under the PDP Law.

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?

Registrations that must be conducted are explained above, that is, registration of the electronic system with MOCI and MOH. The recording of data as medical records must comply with MOH Reg 24/2022 and the PDP Law, as explained above.

In addition, there is no specific requirement for private health services facilities or electronic system organisers who provide telemedicine services (other than in relation to medical record storage) to have a data centre in Indonesia, unless the data is set out as strategic data that will be subject to certain requirements.

LIABILITIES

24. Please provide a high-level overview of the liability of healthcare professionals and

<p>institutions involved in telemedicine practices.</p>
<p>In general, according to the Health Law, every person has the right to claim compensation for a person, health worker and/or organiser's health that results in losses due to errors or negligence in health services that they received.</p> <p>Further, health professionals are also subject to the Indonesian Medical Codes of Ethics, and therefore, liability in relation to the profession shall be determined through an ethics trial.</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>
<p>Under Article 57 of the Health Law, every person has the right to keep their personal health conditions confidential that have been disclosed to health services facilities. The provision on the right to confidentiality of personal health condition does not apply in the case of:</p> <ul style="list-style-type: none"> • a statutory order; • a court order; • the relevant licence; • public interest; or • the interest of the person. <p>In addition, under the PDP Law, the confidentiality rights of personal data are exempted from:</p> <ul style="list-style-type: none"> • the interests of national defence and security; • the interests of the law enforcement process; • public interest in the context of state administration; • the interests of the supervision of the sectors of financial services, and monetary, payment system and financial system stability carried out in the context of state administration; or • the interests of statistics and scientific research.
<p>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.</p>
<p>As to the date of this advice, both the government and Indonesian Medical Council are not discussing any amendment/implementing regulation. On the other hand, telemedicine services are becoming more popular and accessible, while the government also recognises the utilisation of telemedicine platforms considering needs and demands.</p> <p>Under MOH Regulation No 46 of 2017 on National E-Health Strategies, which also covers telemedicine practice, it is stated that MOH regulations in principle provide provisions on health data and information. Therefore, further implementing regulations must be issued to cover more detailed standards and guidelines for the e-health sector.</p> <p>Considering the above, the government is aware that current regulations may not accommodate the growth of telemedicine practice. Medical Council Reg No 74/2020, as the underlying basis for doctor-patient telemedicine services, was issued in accordance with the Covid-19 pandemic; thus, it will only remain in effect until the Covid-19 pandemic is no longer stated as a public health emergency.</p> <p>Given the above, the amendment of current regulations and/or issuance of implementing regulations covering more technical provisions on telemedicine should be expected, although the timeline is uncertain.</p>