

# Indonesia: Revisiting telehealth/telemedicine post-Health Omnibus Law

### In brief

The newly enacted Law No. 17 of 2023 on Health ("Health Omnibus Law"), which came into effect on 8 August 2023, regulates on new issues concerning health services made through information communication technology, including telemedicine. Moreover, the Health Omnibus Law also introduces new terms on digital health tech, i.e., telehealth.

Telemedicine and telehealth are areas that are not yet fully developed in Indonesia. More detailed rulings on telehealth/telemedicine are to be regulated under government and Ministry of Health ("MOH") regulations as the implementing regulations of the Health Omnibus Law. They have not been issued yet.

In this client alert, we will provide a brief update on how telemedicine and telehealth are regulated post-Health Omnibus Law, and how these sectors are going to be regulated under the upcoming government regulation that is currently being drafted as the implementing regulation of the Health Omnibus Law ("**Draft GR**").

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## Key takeaways

During the COVID-19 pandemic, regular hospital visits (with physical interaction between doctors and patients) became risky due to the risk of infection. People preferred to use remote clinical services, via real-time two-way communication between patients and healthcare providers. This practice, continued after the pandemic. App-based consultations are becoming popular, in part due to Indonesia's vast archipelagic geography and the uneven distribution of healthcare facilities within Indonesian territory.

To accommodate this situation, the MOH and the Indonesian Medical Council issued several interim regulations that provide an interim legal basis for the existence of telemedicine services as well as to provide guidance on the scope of permitted medical activity that can be discharged through electronic communication means. However, those interim regulations were only valid during the COVID-19 emergency situation. This means that they are technically no longer valid, since the government revoked the national COVID-19 health emergency status on 4 August 2023.

The newly enacted Health Omnibus Law intends to provide a legal basis for the remote provision of health services through communication and digital communication technology.

The term 'communication' and 'digital communication technology' are not clearly defined under the Health Omnibus Law, and therefore can be widely interpreted as any provision of any healthcare services via technological means (including but not limited to internet-based video, telephone, video conference, email, and similar electronic-based communications) where the service provider and the patient are not physically in the same location.

Under the Health Omnibus Law, the provision of health services through communication and digital communication technology can be provided through either "telemedicine" or "telehealth": :

- All healthcare facilities (i.e., including hospitals, public health centers, clinics, health laboratories, pharmacies and independent practitioners) are allowed to provide telehealth and/or telemedicine services.
- All healthcare facilities are also given the opportunity to cooperate with registered third-party electronic system operators in providing the telehealth and telemedicine services.

The system used for telehealth and telemedicine must be integrated with the National Healthcare Information System, i.e., Satu Sehat.

## 1. Telemedicine/telehealth: what's what?

Below are the definitions of "telehealth" and "telemedicine" under the Health Omnibus Law:

Telehealth	Telemedicine
Provision and facilitation of health services, including public health, health information services, and self-service, through communication and digital communication technology.	Provision and facilitation of clinical services through telecommunications and digital communication technology.

Essentially, telehealth deals with both clinical and non-clinical online healthcare services, whereas telemedicine is the specialized version of telehealth that only relates to clinical services, and other non-clinical healthcare related services are categorized as ordinary telehealth.

Since there are no specific benchmarks on what constitutes "clinical" or "non-clinical" services, and what falls under "telemedicine" or "telehealth", there is a risk that these two terms will often be used interchangeably.

Based on our reading of the Health Omnibus Law and Draft GR, a platform (including application programming interface) would be categorized as telemedicine where there is two-way communication between patients and medical personnel to exchange medical information. On the contrary, a platform offering one-way communication regarding providing public health awareness to the public, certain groups of people or individual would consequently be categorized as telehealth.

Below are more detailed differences between telemedicine and telehealth based on our reading of the Health Omnibus Law and Draft GR:

	Telemedicine	Telehealth (Non-Clinical)
The providers' licenses	Article 172 (4) of the Health Law states that telemedicine providers must be duly licensed as medical/health personnel to practice in Indonesia.	No such requirement for telehealth is mentioned under the Health Omnibus Law and the Draft GR.
Services	The elucidation of Article 25 (4) of the Health Omnibus Law states that forms of health services via telemedicine include medical/clinical care and/or clinical health consultation services.  Under Article 548 (1) of the GR Draft, the types of services that can be provided by telemedicine providers include the following:  (a) Teleconsultations (i.e., remote clinical consultations to help establish a diagnosis and/or provide management considerations/suggestions)  (b) Teleradiology (i.e., expertise services for supporting examination results)  (c) Telepharmacy (i.e., a remote pharmaceutical service)  (d) Other telemedicine services that are in line with developments in science and technology	The Health Omnibus Law provides several examples of non-clinical telehealth:  (a) Article 68 of the Health Omnibus Law – public knowledge and awareness of the importance of nutrition and its influence on improving nutritional status can be obtained through telehealth services.  (b) Article 546 of GR Draft – the provision of nonclinical telehealth services can take the form of promotive, preventive, curative, rehabilitative and/or palliative services, as well as health information and administration systems.



	Telemedicine	Telehealth (Non-Clinical)
Scope	Under Article 172 (3) of the Health Omnibus Law, telemedicine services can be provided between the following:	No clear scope of service.
	<ul> <li>(a) Healthcare facilities in the form of consultations to establish a diagnosis, therapy and/or disease prevention</li> </ul>	
	(b) Healthcare facilities and individuals in the form of exchanging information for a diagnosis, therapy and/or prevention of disease and injury	
Payment	The Draft GR specifically mentions that fees related to telemedicine services can be paid for through (i) national health insurance, (ii) private insurance, or (iii) individual/independent payment.	No similar provision concerning payment that relates to non-clinical telehealth.
Electronic medical records	Article 4 of MOH Regulation 24 of 2022 specifically requires healthcare facilities that provide telemedicine services to keep electronic medical records.	No such obligations since they only relate to nonclinical types of health services.
Licensing obligations  Note: Since the detailed regulations on telemedicine/telehealth have not been issued, it remains to be seen whether telehealth would also be a licensable service.	Under Article 551 (3) of the Draft GR, telemedicine platform developed independently by business actors are subject to registration requirement with the MOH.  The MOH has also issued MOH Decree No. HK.01.07/Menkes/1280/2023 ("MOH Decree No. HK 01/07"), which stipulates the registration procedures and requirements for any "digital health tech innovation solutions," including telemedicine, to the MOH. The registration procedures under MOH Decree No. HK 01/07 adopt the Regulatory Sandbox concept (as defined below).  Nevertheless, under MOH Decree No. HK 01/07, the registration is still voluntary. The regulation only encourages telemedicine providers to register themselves with the MOH. We will discuss the Regulatory Sandbox further in the next section.	There is no specific licensing requirement for non-clinical telehealth under the Omnibus Health Law or Draft GR.  However, MOH Decree No. HK 01/07 also considers telehealth service as one of the digital health tech innovations that are encouraged to be registered with the MOH, but registration is voluntary in nature.  Notwithstanding, it does not clearly mention which forms of telehealth (clinical or non-clinical) subject to MOH Decree HK 01/07.  Nevertheless, as of the date this client alert is prepared, we have only seen telemedicine (clinical telehealth) platform providers being registered with the MOH through the Regulatory Sandbox.

# 2. Regulatory sandbox registration

"Regulatory Sandbox" is a registration concept that aims to promote innovation where the registration procedures will mostly be related to consultation and testing. By first testing a product or service in a Regulatory Sandbox, the relevant government authority (in this case, the MOH) can directly judge the viability of innovative products and services on a case-by-case basis. The government can use the experiences throughout the testing phase to formulate new supervisory rules or new regulations. This registration is still voluntary in nature.

Business actors that are registered with the Regulatory Sandbox will be given one of the following statuses:

- Registered/Tercatat: given to business actors that have passed verification and validation of the Regulatory Sandbox
- Supervised/Diawasi: given to business actors selected to take part in the Regulatory Sandbox
- Coached/Dibina: given to business actors that receive recommendations during the coaching stage of the Regulatory Sandbox



Those who have received the "supervised" and "coached" status must display the MOH logo with the indication of "Being Supervised by the MOH" or "Coached by the MOH," as follows. However, those with the "registered" status are not allowed to display any MOH-related logo on their digital health services platform.



According to several news reports, the MOH has granted the "coached" status to 15 telemedicine providers, including Halodoc, Alodoc, Medic+, Lifepack, SehatQ, etc. The MOH announces the status given to telemedicine providers through its website (link).

Telemedicine providers that have received the "supervised" or "coached" status from the MOH should be less likely to be noncompliant with the prevailing regulations since they will always be supervised and guided by the MOH while there is a lack of regulation regarding telemedicine services.

It remains to be seen, however, whether the MOH will continue to implement the Regulatory Sandbox registration approach, and make the Regulatory Sandbox registration obligatory. Further, considering the fast-paced health tech innovation, it also remains to be seen how the MOH will enforce the regulatory requirements applicable to telemedicine/telehealth, including licensing oblig ations, in practice.

## 3. Liability

Another key potential issue sorrounding this digital health tech is regarding the liability of the medical personnel providing the telemedicine (clinical telehealth) services. In essence, given that each doctor offering teleconsultations through a platform must hold their own medical practice licenses (i.e., STR and SIP), it can be deemed that if there is a wrong assessment by a doctor, the liability should still fall on the doctor since each medical healthcare professional bears professional responsibility for ensuring the proper assessment and treatment of the patient. Therefore, although done online, doctors and other medical personnels still need to comply with the ethical directions of the associations and may be suspended from practice if the associations deem that they have conducted any actions that are contrary to the prevailing medical ethics.

In light of the above, the legal liabilities of the medical personnel cannot be automatically averted to electronic system op erators (ESOs). Nevertheless, the ESOs are still required to implement robust screening and reporting protocols, and immediately take down any suspected illegal contents and/or advertising materials.

However, it remains to be seen how the the telemedicine regulations can cover the telemedicine services provided by foreign medical personnel through online platform media from overseas.

### Conclusion

Overall, the Health Omnibus Law aims to provide a clear strong and permanent legal basis for the development of digital health technology, especially telehealth and telemedicine. As the implementing regulation of the Health Omnibus Law has been issued, it is important for businesses in the healthcare sector to keep themselves updated on the development of regulations and identify the compliance actions that are applicable to them.

It remains to be seen what changes or new provisions the government will issue through the implementing regulations, e.g., whether the Draft GR or specific MOH regulations will further limit the provision of telemedicine and telehealth services to patients.



It also remains to be seen what obligations, licensing requirements and possible sanctions will be imposed on  $telehealth/telemedicine\ providers.$ 



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