

TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES
Authors: Vu Thi Thu Hien and Duong Yen Nhi, Tilleke & Gibbins Date of completion: 31 January 2023
LAWS AND REGULATIONS ON TELEMEDICINE
1. Is telemedicine allowed in your country? If so, how is it defined?
Telemedicine is permitted in Vietnam. According to Circular No 49/2017/TT-BYT of the Ministry of Health (MoH) dated 28 December 2017 on Telemedicine, telemedicine is defined as exchange of information related to a patient's health between such patient and a healthcare professional or among healthcare professionals in distant sites, through the use of information technology (IT) and telecommunication.
2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.
<p>In Vietnam, telemedicine is directly regulated by:</p> <ul style="list-style-type: none">• Circular No 53/2014/TT-BYT of the MoH, dated 29 December 2014 on provision of online healthcare services;• Circular No 49/2017/TT-BYT of the MoH, dated 28 December 2017 on telemedicine (Circular 49);• Circular No 46/2018/TT-BYT of the MoH, dated 28 December 2018 on electronic medical records;• Decision No 2628/QĐ-BYT of the MoH, dated 22 June 2020 on approving scheme for remote medical examination and treatment for 2020–2025;• Decision No 4054/QĐ-BYT of the MoH, dated 22 September 2020 on promulgating interim guidelines and regulations for organisation of remote medical examination and treatment consultations and advising;• Decision No 5237/QĐ-BYT of the MoH, dated 16 December 2020 on the issuance of the list of services temporarily applicable in telemedicine;• Decision No 4152/QĐ-BYT of the MoH, dated 28 August 2021 on the issuance of temporary guidelines for 'Telemedicine for severe Covid-19 patients between treatment facilities'; and• Official Letter No 2416/BYT-CNTT of the MoH, dated 30 April 2020 on the implementation of remote medical examination and treatment consultation activities. <p>Telemedicine is further subject to compliance with the broader regulatory framework concerning the medical profession in general, such as the Law on Medical Examination and Treatment No 40/2009/QH12 adopted by the National Assembly of Vietnam on 23 November 2009, which provides for the exercise of the medical profession; and Decree No 87/2011/ND-CP of the Government, dated 27 September 2011 on detailing and guiding a number of articles of the Law on Medical Examination and Treatment.</p> <p>Furthermore, as information security in telemedicine is also a concern in Vietnam, telemedicine is also regulated by:</p> <ul style="list-style-type: none">• Law on Information Technology No 67/2006/QH11 adopted by the National Assembly of Vietnam on 29 June 2006;• Law on Network Information Security No 86/2015/QH13 adopted by the National Assembly of Vietnam on 19 November 2015; and• Law on Cybersecurity No 24/2018/QH14 adopted by the National Assembly of Vietnam on 12 June 2018.

3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.
In Vietnam, there is no licensing for telemedicine. Therefore, there are no key telemedicine licensing bodies. However, heads of health facilities in Vietnam need to report the decision on providing telemedicine to superior health authorities. The superior health authorities are normally the Ministry of Health or provincial health departments.
4. Was telemedicine authorized during the Covid-19 pandemic?
Telemedicine was authorised during the Covid-19 pandemic, particularly through Official Letter No 2416/BYT-CNTT of the MoH, dated 30 April 2020 on the implementation of remote medical examination and treatment consultation activities.
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?
Post-pandemic, telemedicine continues to be regulated by the previous legislation and has been encouraged to be implemented in detail on a definitive basis by Decision No 4054/QĐ-BYT of the MoH, dated 22 September 2020. This Decision provide guidelines and regulations for the organisation of remote medical examination and treatment consultations and advising.
6. What types of teleservices are allowed? (e.g. second opinion, teleconsultation, telediagnosis, telesurgery, among others)
According to Decision No 5237/QĐ-BYT of the MoH, dated 16 December 2020 on the issuance of the list of services temporarily applicable in telemedicine, teleservices permitted in Vietnam are: <ul style="list-style-type: none"> • teleconsultation; • telediagnosis; • teleradiology; • telehematology; • telesurgery; and • teleoperation.
7. Who can use telemedicine services? Please indicate if whether only doctor-doctor or also patient-doctor remote medical services are allowed.
Telemedicine shall be provided on the principle of voluntary cooperation between participants. Both doctor-doctor and patient-doctor telemedicine services are allowed.
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.
There is no specific regulation of the funding model for telemedicine under Vietnamese legislation. However, the Department of Health Insurance had announced that it would coordinate with the Vietnam Social Insurance and related units in formulating regulations on insurance payment for telemedicine services at health facilities. Accordingly, it is determined that telemedicine is a type of medical service that is covered by the health insurance fund, in a similar way to face-to-face consultations for each specific patient.
9. Please indicate whether any insurance requirements applicable to telemedicine services providers.
There are currently no insurance requirements specifically applicable to telemedicine service providers.
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.)
Doctors, nurses, technicians and pharmacists can practice telemedicine in Vietnam under Decision No 4054/QĐ-BYT of the MoH, dated 22 September 2020 on promulgating interim guidelines and regulations for the organisation of remote medical examination and treatment consultations and advising.
11. Are there any specific education requirements or trainings that healthcare professionals need to meet or attend to provide telemedicine services?
No further education or training is required for physicians to provide telemedicine services.
12. Is there any registration requirement applicable to physicians that provide telemedicine services?
There is no registration requirement applicable to physicians who provide telemedicine services.
13. Please indicate whether special licenses or authorizations are mandatory for institutional healthcare providers engaged in telemedicine services.
According to Article 1.2 of Circular 49, health facilities that provide telemedicine services must be entities based in Vietnam. Furthermore, according to Article 5 of Circular 49, only a health facility responsible for disease prevention or having a licence for medical examination and treatment in accordance with regulations of the Law on Medical Examination and Treatment and other relevant legislative documents can provide telemedicine.
REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES
14. Are there specific requirements applicable to the telemedicine platform?
<p>Under Circular 49, requirements applicable to the telemedicine platform in Vietnam are:</p> <p>(i) The platform has to ensure confidentiality of information to satisfy all the provisions of Article 3 and Article 4 of Circular No 53/2014/TT-BYT of the MoH dated 29 December 2014 on provision of online healthcare services, which are:</p> <p>‘Article 3. Requirements for information technology infrastructure</p> <p>1. Services provided using server and system software</p> <p>a) Ensure server infrastructure and associated equipment deliver sufficient performance and efficiency, and data processing and retrieval speed to satisfy requirements for provision of online healthcare services;</p> <p>b) Ensure the server system operates in a highly available manner and provides a flexible backup for continuous operation.</p> <p>c) Ensure the operating system and system software installed on servers are legitimate or have clear origin.</p> <p>2. Network system</p> <p>a) The network system (telecoms network, internet, wide area network, local area network, other connections) is designed and implemented in an appropriate manner, and includes bandwidth. In the case of using a telecoms network, all rights and obligations prescribed in Article 16 of the Law on Telecommunications must be exercised and fulfilled.</p> <p>b) The network equipment and network monitoring and analysis software must be legitimate or have clear origin;</p> <p>c) The backup plan must be available to ensure operation of the network system.</p> <p>3. Database</p> <p>a) The database used for provision of online healthcare services must be stable and able to process any necessary data;</p>

b) Database management systems shall have clear origins or use open-source databases widely used in the country and the world.

4. Workstation

There must be enough workstations with appropriate configurations suitable for online healthcare services.'

'Article 4. Requirements for information security assurance

1. Policies on information security must be formulated in accordance with regulations on ensuring the security of State and the provider's own information technology system.

2. Network system security

- a) Technical measures must be available to control access to the network system;
- b) Measures for intrusion detection and prevention, and malicious code prevention must be available;
- c) System patches and equipment configuration must be updated on a periodic basis;
- d) Information security must be ensured when workstations are connected to network resources;
- d) Physical security at the location of the server systems must be ensured;
- e) Network equipment, security equipment, antivirus software, network monitoring and analysis tools that are installed within the provider's network must have clear origins.

3. Application software security

- a) There must be regulations on error logging and the error handling process, especially errors in assurance of security in checking and testing application software;
- b) Software versions, including the source program that needs to be managed in a centralised manner, must be stored and secured. There must be regulations on granting privileges to each user to manipulate files;
- c) A periodic plan for source code verification must be formulated to prevent malicious codes and vulnerabilities;
- d) The application software vendor must undertake that its product contains no malicious code.

4. Data security

- a) There must be regulations on protecting and granting privileges to access database resources;
- b) Access to database and actions performed on database configuration must be logged;
- c) Where necessary, backup and data recovery plan must be formulated;
- b) Proper encryption algorithms must be used to ensure security and processing capacity of the system;
- d) Database management system patches must be reviewed and updated on a periodic basis and according to the manufacturer's recommendations;
- e) Database attack prevention measures must be available.

5. Breakdown management

- a) There must be procedures for breakdown management, specifying responsibilities of relevant departments and steps and informing users and information technology system operators. In case the information technology infrastructure is outsourced, the service provider must offer breakdown handling procedures;
- b) Breakdown and remedial measures for breakdown handling procedures must be reviewed and updated on a periodic basis;
- c) Technical solutions must be adopted to promptly detect and deal with network system attacks;
- d) There must be measures for preventing technology risks and disasters in a systematic manner to minimise risks in provision of online healthcare services.'

(ii) The data recording system of the platform has a minimum ten-year storage capacity.

15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?
<p>The requirements regarding electronic equipment and internet speed are in accordance with Articles 3 and 4 of Circular No 53/2014/TT-BYT of the MoH, dated 29 December 2014 on provision of online healthcare services, which are mentioned above.</p> <p>Furthermore, Article 4.2 of Circular 49 also sets out the requirements for telemedicine service internet speed. Accordingly, the internet speed for telemedicine must be stable so that consultant and client can continue transmission while the telemedicine is provided.</p>
16. Does the legislation provide for specific rules concerning patients' medical records?
There is no specific regulation concerning patients' medical records for telemedicine services under Vietnamese legislation.
17. Are there geographic location requirements applicable to the provision of telemedicine services?
Telemedicine services may only be provided by entities based in Vietnam.
18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?
In Vietnam, the rule for telemedicine is that telemedicine shall be provided on the principle of voluntary cooperation between participants. Therefore, healthcare professionals need to obtain patient consent to engage in telehealth.
19. Is there any other important requirement that should be highlighted?
Telemedicine platforms in Vietnam must be operated by a qualified IT operator. Furthermore, health facilities shall make reports on provision and effectiveness of telemedicine to superior health authorities in December of each year.
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>Yes, there are data privacy issues that should be considered for the exploitation of the telemedicine market. Patients' personal data in the medical records must be preserved, in accordance with privacy and professional secrecy of the information set out in the applicable legal framework. This includes: the Law on Information Technology No 67/2006/QH11 adopted by the National Assembly of Vietnam on 29 June 2006; Law on Network Information Security No 86/2015/QH13 adopted by the National Assembly of Vietnam on 19 November 2015; and Law on Cybersecurity No 24/2018/QH14 adopted by the National Assembly of Vietnam on 12 June 2018; as well as Law on Medical Examination and Treatment No 40/2009/QH12 adopted by the National Assembly of Vietnam on 23 November 2009.</p> <p>Nevertheless, there are specific provisions in Decision No 4054/QĐ-BYT concerning data privacy aspects which also must be complied with, including the following obligations.</p> <p>a) Directors of medical examination and treatment establishments:</p> <ul style="list-style-type: none"> • strictly manage information technology devices which store data, not allow movement or change of location without permission of an authorised person; • manage and assign access rights to application software and databases in accordance with the functions and tasks of users; • set up an internal network protection mechanism to ensure information security when connecting the internal network to an external network such as the internet or other agency networks;

- use internal network protection systems such as firewall systems, anti-intrusion systems, etc;
- develop and apply measures to protect, monitor, log activities and manage technical infrastructure and information systems in order to prevent and detect unauthorised access early.

b) Medical staff participating in remote medical consultation and treatment consultations:

Medical Staff must be responsible for keeping data confidential and not share the information of patients and participants in consultation during the implementation of remote medical examination, treatment and consultation; strictly comply with the contents of the Guide to their obligations and the internal regulations of the workplace.

c) The patient and the patient's family member:

If the patient or their legal representative agrees to participate in consultations and consultations for medical examination and treatment remotely, they or a family member must not disclose their identity and other personal information during the consultation, examination and treatment consultation. They must also follow the instructions of the medical facility during the remote consultation, examination and treatment.

d) Organisations, individuals and enterprises involved in the management, provision, operation, exploitation and application of information technology in telemedicine examination and treatment are responsible for the following:

- The application of software systems and databases which must have a backup mechanism. Data must be stored in a safe place and be checked regularly to ensure that it can be recovered in the event of an emergency or if network information security incidents occur.
- They must ensure data safety and security in archiving and conducting remote medical consultation and consultation in accordance with state regulations.
- Database management system software must be set up to update security patches from the manufacturer automatically.
- They must work closely with the medical facilities which conduct remote medical consultation in keeping the privacy of personal and health information of patients participating in remote medical consultation as required by the Guide to their obligations.
- They must take legal responsibility in cases of self-disclosure of personal information and the health information of patients participating in remote medical consultations.
- They must not use images or data stored in the process of remote medical examination and treatment consultation for commercial or any other purposes.

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

Yes, the applicable regulation provides for criteria and requirements for security systems to protect patient information. Circular No 53/2014/TT-BYT on the requirements for the provision of online healthcare services provide requirements for provision of online healthcare services in terms of information technology infrastructure, information security assurance, human resources and application of information technology.

See the provisions of Article 4 of Circular No 53/2014/TT-BYT on requirements for information security assurance, in the response to Question 14, above.

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

Any type of health data can be shared with third parties for development of digital health technology and other purposes, provided that the prior consent of the data subjects (ie, yje patients) is obtained.
To clarify, in general, Vietnam does not separate personal data into general data and sensitive data, except in specifically controlled sectors such as financial services. According to Vietnamese data protection and privacy laws/regulations, generally, all types of personal data are treated in the same way. The key principles for the collection, processing and use of personal data (data processing) in Vietnam are that the data processing must be notified and consented to by the data subject, and the use of such data must be in line with the purposes as notified and consented to. Personal data can only be transferred to a third party if the data subject consents, it is at the request of a relevant authority, or the law provides otherwise. Personal data can be transferred across borders to and from Vietnam if prior consent is obtained from the data subject.
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?
Circular 49 specifically requires that companies providing data storage for telemedicine services must have their headquarters in Vietnam.
Regarding the recording of data in the patient's medical records, Circular 49 requires the health facility to ensure that there is at least one connecting point having the data recording system (Art 7.2). Therefore, the data recording system has a minimum ten-year storage capacity (Art 4.3).
LIABILITIES
24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.
Telemedicine in Vietnam is provided on the principle of voluntary cooperation between participants. This means that distributed clients shall decide and take responsibility for the use of consulting contents provided by consultants and shall inform consultants of telemedicine results.
TELEMEDICINE NUMBERS AND TRENDS
25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?
There is currently no publicly disclosed information concerning the use and acceptance of telemedicine in Vietnam.
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>The perspectives and trends relating to telemedicine over the next few years are:</p> <ul style="list-style-type: none"> • market growth in telemedicine and the segmentation of the market; • an increase of adjacent telemedicine sectors; and • the search for more reliable and secure solutions considering the need to ensure data security.