

## 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. Telemedicine is allowed in China<sup>1</sup>. China regulates two models of telemedicine:

1. internet diagnosis and treatment, which means online diagnosis and treatment by registered healthcare professionals to patients; and
2. remote medical services, which means two or more medical institutions collaborate with each other through IT and other technologies to diagnose and treat patients.

The first model is between a hospital and a patient, while the second model is between hospitals. The two models are subject to different legal requirements, as will be further elaborated below.

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

Telemedicine is a relatively new concept in China. In April 2018, the State Council promulgated the 'Opinions to Promote the Development of "Internet + Healthcare"', which generally requires government agencies, medical institutions and other players in the healthcare industry to embrace internet and other IT innovations in medical services, public health services, the supply of drugs and medical devices, and medical insurance coverage.

In July 2018, three implementing rules were promulgated:

1. the Measures for the Administration of Internet Diagnosis and Treatment (for Trial Implementation), which regulate the Internet Diagnosis and Treatment;
2. the Measures for the Administration of Internet Hospitals (for Trial Implementation), which regulate the establishment and operation of Internet hospitals; and
3. (the Specifications for the Administration of Remote Medical Services (for Trial Implementation), which sets the specifications for the provision of Remote Medical Services.

According to these regulations, (i) only medical institutions which obtain prior licensing and filing can practice telemedicine, (ii) Internet Diagnosis and Treatment is limited to carrying out follow-up consultations and for those common or chronic diseases approved by the competent health authority, and (iii) Remote Medical Services should only be provided by medical institutions with appropriate qualifications.

As an exemption to the follow-up consultations only requirement, from 12 December 2022, China has permitted the first diagnosis and treatment of Covid-19 and issuance of prescriptions

<sup>1</sup> The People's Republic of China (PRC) includes mainland China, Hong Kong Special Administrative Region, Macao Special Administrative Region and Taiwan. The four regions are jurisdictions subject to different laws. For the sole purpose of the discussions in this survey, reference to China or PRC means the mainland China.

<p>through internet hospitals to alleviate the burden of physical hospitals caused by the surge of Covid-19 cases after the termination of national 'zero covid' policy in November 2022.</p>
<p><b>3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.</b></p>
<p>To engage in Internet Diagnosis and Treatment, the platform must either apply for the new Practicing Permit for Medical Institution or add Internet Diagnosis and Treatment into its existing permit, from the competent health authority. Healthcare professionals providing services on the platform must also obtain appropriate practising certificates.</p> <p>The competent health authority refers to the PRC National Health Commission (NHC) and its local subordinates. NHC is the key licensing body in China to regulate telemedicine activities. In addition to NHC, the National Administration of Traditional Chinese Medicine (NATCM) is relevant where the telemedicine involves the online diagnosis and treatment using traditional Chinese medicine.</p>
<p><b>4. Was telemedicine authorised during the Covid-19 pandemic?</b></p>
<p>Yes. China started to promote telemedicine before the Covid-19 pandemic, but the use of telemedicine became more common during the pandemic.</p>
<p><b>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?</b></p>
<p>As at December 2022, China was still suffering from the Covid-19 pandemic. It is unlikely that the trend of telemedicine will be reversed after the pandemic. We expect that the trend will continue and the regulations will improve. More implementing rules regulating telemedicine are being introduced. For example, in February 2022, NHC and NATCM jointly promulgated the Administrative Rules of Internet Diagnosis and Treatment to further regulate Telemedicine activities.</p>
<p><b>6. What types of teleservices are allowed (eg, second opinion, teleconsultation, tediagnosis, telesurgery, among others)?</b></p>
<p>Under the Internet Diagnosis and Treatment model, all the types above are possible except telesurgery, but Internet Diagnosis and Treatment is limited to carrying out follow-up consultations (other than Covid-19, see discussion above) and for those common or chronic diseases approved by NHC.</p> <p>Under the Remote Medical Services model, all the types above are possible.</p>
<p><b>7. Who can use telemedicine services? Please indicate if whether only doctor-doctor or also patient-doctor remote medical services are allowed.</b></p>
<p>As discussed above, the Internet Diagnosis and Treatment model is a doctor-patient model, while the Remote Medical Services model is a doctor-doctor model, or more precisely, a hospital-hospital model.</p>

<p><b>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.</b></p>
<p>Internet Diagnosis and Treatment, including the medical services, drugs and medical devices purchased and used in the process, can be covered by the national medical insurance programme, provided that the medical institution providing Internet Diagnosis and Treatment shall obtain the approval from the National Medical Insurance Bureau. In relation to medical institutions which telemedicine services have yet to be covered by the national medical insurance programme, patients need to turn to commercial insurance programmes or cover their expenses on their own.</p>
<p><b>9. Please indicate whether any insurance requirements applicable to telemedicine services providers.</b></p>
<p>All telemedicine services providers in China must be qualified medical institutions. According to the PRC Laws on Doctors, medical institutions shall either participate in medical services liabilities insurance programme or set up or join medical services risk funds. Healthcare professionals may, but are not obligated, to purchase professional liabilities insurance.</p>
<p><b>REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS</b></p>
<p><b>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, alternative health therapies providers, etc).</b></p>
<p>Qualified doctors, nurses and pharmacists can practice telemedicine within their professional qualifications. Psychologists, nutritionists, alternative health therapies providers are typically not permitted to practice telemedicine.</p>
<p><b>11. Are there any specific education requirements or trainings that healthcare professionals need to meet or attend to provide telemedicine services?</b></p>
<p>PRC law requires that the healthcare professionals who practice telemedicine shall have higher qualifications than ordinary healthcare professionals. For example, under the Internet Diagnosis and Treatment model, a doctor who practices telemedicine shall have at least three years' independent clinical experience and shall be approved by the medical institution to which the doctor is affiliated. Under the Remote Medical Services model, the doctors invited to practice remote medical services shall have at least three years' independent clinical experience.</p>
<p><b>12. Is there any registration requirement applicable to physicians that provide telemedicine services?</b></p>
<p>Yes, a doctor must be subject to electronic identity certification before providing telemedicine services.</p>

<b>13. Please indicate whether special licences or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.</b>
Yes. Please refer to our comments in question 3.
<b>REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES</b>
<b>14. Are there specific requirements applicable to the telemedicine platform?</b>
In China, a telemedicine platform must be a qualified medical institution. All requirements applicable to medical institutions are also applicable to telemedicine platforms. PRC law also imposes various additional requirements on internet hospitals. For example, telemedicine platforms must have proper IT infrastructure, engineers and information security system, and must maintain e-medical records for the patients.
<b>15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?</b>
The general IT requirements on telemedicine services are as follows: (i) the IT system must ensure safe, real time, and accurate transmission of data; (ii) important equipment and infrastructure must be supported by uninterruptible power supply; and (iii) the network must have high speed (no less than 10Mbps) and reliable Internet connections provided by at least two network service providers.
<b>16. Does the legislation provide for specific rules concerning patients' medical records?</b>
Yes, as discussed above, telemedicine platforms must maintain e-medical records for the patients.
<b>17. Are there geographic location requirements applicable to the provision of telemedicine services?</b>
No, there are no geographic restrictions on the location of the patients or the location of the healthcare professionals during the provision of telemedicine services. However, a healthcare professional must have the approval of the medical institution they are affiliated with and the approval/filing of the competent health authority if they intend to practice telemedicine on different platforms.
<b>18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?</b>
Yes, there are. PRC law requires that internet hospitals must serve risk notices to patients and must obtain informed consent from patients.
<b>19. Is there any other important requirement that should be highlighted?</b>

<p>1. Under the Internet Diagnosis and Treatment model, internet hospitals must be subject to statutory naming rules: (i) if the Internet hospital is the online platform of a physical hospital, it must be named as 'name of the physical hospital + Internet Hospital'; (ii) if it is a collaboration between a physical hospital and a collaborating party, it must be named as 'name of the physical hospital + identity of the collaborating party + Internet Hospital'; and (iii) if it is an independent internet hospital, it must be named as 'name of the sponsoring party + Internet Hospital'.</p> <p>2. Under the Remote Medical Services model, the participating hospitals must enter into a collaboration agreement to define the collaboration terms and the allocation of responsibilities and liabilities.</p>
<b>DATA PRIVACY ASPECTS</b>
<p><b>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.</b></p>
<p>Yes. PRC law requires that all parties participating in telemedicine services must strengthen data security and the protection of patient privacy and must ensure the safety of the network, the operation, as well as data and privacy.</p>
<p><b>21. Does the applicable regulation provide for criteria and requirements for the security systems to protect the patient's information?</b></p>
<p>PRC law requires that the information system of telemedicine services be subject to Level 3 or higher information security protection. Telemedicine services are also subject to the Network Security Law, Data Security Law and other applicable laws, regulations, guidelines and standards.</p>
<p><b>22. Does the applicable regulation provide for requirements for the transfer of information abroad?</b></p>
<p>Yes. Depending on the nature of the data and the circumstances of the cross-border data transfer, cross-border data transfer may be subject to various regulatory requirements. The cross-border transfer of personal information may be subject to the informed consent of the relevant individuals, and the platform may be subject to national security assessment, personal information protection certification, or be required to execute standard contractual clause on personal information protection with the transferee.</p>
<p><b>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?</b></p>
<p>There have not been requirements on the registration of databases. Telemedicine platforms must maintain e-medical records for the patients for no less than 15 years from the last hospital visit or telemedicine experience of the patients. Records of graphic conversations, audio and video materials, and other processes generated in telemedicine practice must be kept for no less than three years.</p>

<b>LIABILITIES</b>
<b>24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.</b>
<p>Under PRC law, if a patient suffers damages from medical diagnosis or treatment (regardless of whether it is conducted through telemedicine or not), and if the medical institution or its healthcare professional has shown negligence or misconduct, the medical institution shall be liable to the patient. A healthcare professional affiliated to a medical institution usually will not be directly liable to the patient.</p> <p>The medical institution will not be liable to the patient under the following circumstances: (i) the patient or their close relatives refuses to collaborate with the norms-complying diagnosis or treatment of the medical institution; (ii) the healthcare professionals have discharged reasonable diagnosis or treatment obligations during the salvage of an endangered patient and other emergencies; and (iii) diseases which are difficult to be diagnosed or treated due to the limitation of the medical standard at the time.</p> <p>If a patient suffers damages due to defects in drugs, medical devices or other medical products or defective blood products, the patient may make claims against the authorised marketing holder of the drugs, medical devices or other medical products, the manufacturer of the products, supplier of the blood products, or the medical institution. If the patient make claims against the medical institution, the medical institution may make further claims against the authorised marketing holder, manufacturer, or supplier of the blood products after indemnifications to the patient.</p> <p>While precedents are rare, internet service providers and providers of telemedicine equipment and facilities may also be liable to the patients if their services or products are defective during the telemedicine practice.</p>
<b>TELEMEDICINE NUMBERS AND TRENDS</b>
<b>25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?</b>
<p>According to the statistics provided by the NHC as of the first half of 2021, China has more than 1,600 Internet hospitals,<sup>2</sup> and more than 7,700 Level 2 or higher hospitals providing online services.<sup>3</sup> According to the statistics provided by the China Internet Information Centre,<sup>4</sup> as of June 2022, more than 300 million people are using telemedicine services, accounting for 28.5 per cent of all internet users in China.</p>
<b>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.</b>

2 Source: Chinese government website at: [http://www.gov.cn/xinwen/2021-08/23/content\\_5632844.htm](http://www.gov.cn/xinwen/2021-08/23/content_5632844.htm).

3 Source: Chinese government website at: [http://www.gov.cn/xinwen/2021-04/28/content\\_5603633.htm](http://www.gov.cn/xinwen/2021-04/28/content_5603633.htm).

4 Source: website of China Internet Network Information Centre at: <http://www.cnnic.net.cn/n4/2022/0914/c88-10226.html>.

1. It is most likely that telemedicine will continue to develop in China. The end of the Covid-19 pandemic is unlikely to change this momentum. The regulators in China will continue the efforts to realise the full potential of telemedicine while safeguarding the interests of the patients.
2. At present, the scope of Internet Diagnosis and Treatment in China is limited to carrying out follow-up consultations (other than Covid-19) and those common or chronic diseases approved by NHC. In practice, some internet hospitals do not strictly follow the 'follow-up consultations only' requirement. The public is concerned that there could be more malpractices because doctors do not have the opportunity to see the patients in person and consequently may not have sufficient information to offer accurate diagnosis and treatment. NHC and other PRC authorities are still evaluating how to utilise the full potential of telemedicine while safeguarding the interests of patients.
3. Many internet hospitals in China have not been covered by the national medical insurance programme. Until the physical hospitals and internet hospitals enjoy equal insurance payment coverage, patients may still prefer physical hospitals despite the many conveniences offered by internet hospitals.
4. The line has not been entirely clear between internet health consultations, online health management services, and the internet diagnosis and treatment of diseases in China. Patients' interests may be compromised due to the lack of regulation on internet health consultations and online health management services.