



China's new rules on telemedicine
and Internet hospitals - some
things clarified, some questions
left unanswered

Hogan
Lovells

October 2018

China's new rules on telemedicine and Internet hospitals - some things clarified, some questions left unanswered

For years, Internet-based medical services in China have existed in a legal “grey” area caused by uncertainties to do with the Chinese regulator’s policies. On September 14, 2018, the Chinese National Health Commission (“NHC”) and the National Administration of Traditional Chinese Medicine released three trial measures with a scope of application wide enough to cover almost all key aspects of Internet-based medical services, all of which become effective on 17 July 2018:

- the *Telemedicine Services Administrative Specifications* (“**Telemedicine Specifications**”);
- the *Internet Diagnosis Administrative Measures* (“**Internet Diagnosis Measures**”); and
- the *Internet Hospital Administrative Measures* (“**Internet Hospital Measures**”), (together, the “**Three Measures**”).

The Three Measures go some way towards addressing complaints from stakeholders in the healthcare sector that the Internet healthcare market has not been heading in a positive direction due to the lack of a clear policy roadmap.

The Three Measures are a positive indication that Chinese regulators are trying to make use of Internet technology to optimize the allocation and delivery of medical resources, facilitate the distribution of medical resources to grass-root level, and integrate and share regional medical resources. In this alert, we set out the key takeaways from the Three Measures.

TELEMEDICINE SERVICES

Prior to the issuance of the Telemedicine Specifications, medical institutions relied mainly on the *Opinions regarding Promoting Telemedicine Services by Medical Institutions* (“**2014 Opinions**”) issued by NHC in 2014 to guide the roll-out of telemedicine services in China. However, the 2014 Opinions only provided very high-level and conceptual guidance, and left many practical questions unanswered. The Telemedicine Specifications clarify some of the longstanding ambiguities regarding the execution of telemedicine services, especially the scope of permitted telemedicine services.

The Telemedicine Specifications follow the methodology used in the 2014 Opinions when defining the expression “telemedicine”. “Telemedicine” continues to be defined as “hospital to hospital” (“**H2H**”) medical activities (i.e., both parties to the telemedicine services must be medical institutions) mainly covering the following two scenarios:

- A contractual arrangement whereby a host medical institution (“**Host Institution**”) **directly** invites other medical institutions (“**Guest Institution**”) to provide technology-based support to the diagnosis and treatment of patients of the Host Institution through the adoption of communications, computer, network technologies or other such-like information technologies; and

- A Host Institution or a third-party institution set up a ***telemedicine services platform*** and invite medical institutions to register as an institution on the platform and uses such platform to invite other Guest Institutions to provide technical support to the patients of the Host Institution during their diagnosis and treatment by means of communications, computers, network technologies and other such-like information technologies. The Host Institution posts its needs on such platform and the platform matches that need from the pool of Guest Institutions that are registered with the platform, or other institutions take the initiative to respond to those needs.

If a Host Institution intends to directly invite physicians to provide telemedicine services via the platform, it must apply for the establishment of an Internet Hospital in accordance with the Internet Hospital Measures.

ELIGIBILITY CRITERIA AND REQUIREMENTS

The Telemedicine Specifications reiterate the requirements in the 2014 Opinions that the only eligible participants in telemedicine services are medical institutions, the establishment of which has been approved by the NHC¹. Medical institutions conducting telemedicine services must have the required support in terms of talent, hardware and systems. For instance, the Host Institution must have at least one practicing physician take part, but an assistant practicing physician is acceptable for a grass-roots institution; the Guest Institution must have at least one practicing physician with the ability to provide corresponding diagnostic services to physicians of the Host Institution, and with three years or more of independent clinical work to provide telemedicine services; both the Host Institution and Guest Institution must have telemedicine equipment, facilities and information systems (with UPS for key equipment and networks).

CONTRACTUAL REQUIREMENTS AND PATIENT CONSENT

In order to provide telemedicine services, the relevant institutions must (a) execute a written cooperation agreement that clearly sets forth the rights and obligations of each party and the sharing of the risks of medical malpractice claims and responsibilities; and (b) obtain written consent from patients with respect to the scope and fees of telemedicine services. In light of the current data protection legal framework, and the inevitability of transferring a patient's medical data from a Host Institution to a Guest Institution, although it is not specifically required under the Telemedicine Specifications, it is recommended that the Host Institution obtains upfront consent from patients to the transfer of personal information (e.g., medical data) to the Guest Institution in addition to the required informed consent under the Telemedicine Specifications, to deploy telemedicine to treat any given patient referred to above, and so forth.

The Telemedicine Specifications also set forth in detail the requirements on how the patients' records should be stored by the Host Institution and the Guest Institution.

POSITION OF FOREIGN PARTICIPANTS

¹ According to the *Administration of Medical Institution Implementing Provisions* issued by the NHC, the scope of "medical institution" includes, for example, general hospitals, specialized hospitals, clinics, sanatoriums, emergency care centres, and clinical testing centres.

A major open issue in the Telemedicine Specifications is the question of whether they apply to foreign players. Unlike the 2014 Opinions, which expressly state that telemedicine services between a Chinese medical institution and a foreign medical institution can make reference to the 2014 Opinions, the Telemedicine Specifications are silent as to its applicability to overseas medical institutions that intend to cooperate with Chinese medical institutions to provide their advanced medical resources to patients in China. It is unclear at this stage whether or not Chinese regulators will clarify this with an official interpretation or in another form, or whether separate telemedicine rules will be promulgated specifically addressing cross-border or Sino-foreign telemedicine services.

INTERNET DIAGNOSTIC SERVICES AND INTERNET HOSPITALS

While telemedicine services are actually Hospital-to-Hospital ("**H2H**") Internet-based medical services, in the Chinese legal context, Internet diagnostic services are seen as "hospital to patient" ("**H2P**") medical services. Internet diagnosis and treatment means return visit services for certain common or chronic diseases or a family physician's services provided by physicians via information technologies such as the Internet. Eligible providers of such H2P services fall into two broad categories:

- (i) bricks-and-mortar medical institutions that are authorized to provide Internet diagnostic services as an extension of their own existing activities; and
- (ii) Internet hospitals formed by a tie-up between a provider and an external bricks-and-mortar medical institution.

Where a traditional bricks-and-mortar medical institution intends to provide Internet diagnostic services (but not to operate an Internet hospital), it must apply to NHC to add "Internet diagnostic services" to its approved practice scope in its Medical Institution Practicing License. Specifically, it must satisfy the following criteria before it can provide Internet diagnostic services:

- It must be a medical institution holding a valid Medical Institution Practicing License (except where such medical institution is in the process of establishment and has not yet obtained the Medical Institution Practicing License);
- It must have Internet diagnosis and treatment management rules, equipment and facilities, information system, technical personnel and information security systems commensurate with the Internet diagnostic services it intends to provide; and
- Physicians and nurses participating in Internet diagnostic services must be duly licensed to practice medicine or dispense patient care in China. For physicians, they must have at least three year independent clinical experience.

INTERNET HOSPITALS

Internet hospitals that offer Internet diagnostic services can be further divided into two sub-categories:

- (i) bricks-and-mortar medical institutions with Internet hospital as its "supplementary name" e.g. "Beijing No.1 Army Hospital, Internet Hospital" ("**Affiliated Internet Hospital**"); and

(ii) a pure Internet hospital that ties its services to a bricks-and-mortar medical institution (e.g., collaboration between a technology company and a medical institution) (a "**Tie-up Internet Hospital**").

The establishment of a pure Internet hospital (i.e. a Tie-up Internet Hospital) is also subject to prior approval by NHC. Therefore a Tie-up Internet Hospital that ties its services to a bricks-and-mortar medical institution must seek a Medical Institution Practicing License from NHC. Contrast this with a bricks-and-mortar medical institution operating an Affiliated Internet Hospital which only needs to apply to NHC for administrative approval to add Internet hospital to its current Medical Institution Practicing License, which still requires an administrative approval. Generally, the NHC sets out higher operational thresholds in terms of clinical personnel, hardware facilities and management rules and so forth for Tie-up Internet Hospitals than for Affiliated Internet Hospitals i.e. bricks-and-mortar medical institutions providing Internet diagnostic services as an 'add-on' service. Presumably this is due to concerns about the abilities of a third party to deliver medical services and the ability of a cooperating partner to manage the patient care risks associated with Internet-based medical services appropriately.

For foreign investors, the foreign investment restrictions set out for regular bricks-and-mortar medical institutions are very likely to be applicable to Internet hospitals. That is, as currently set out in the *Special Administrative Measures for Foreign Investments* (2018 Edition) (Negative List) jointly issued by the Ministry of Commerce and the National Development and Reform Commission, bricks-and-mortar medical institutions can only be established and operated in the form of a cooperative joint venture or an equity joint venture. The 70% shareholding ratio limitation for foreign investors as prescribed in the *Administration of Sino-Foreign Equity/Cooperative Joint Venture Medical Institutions Interim Measures* is still in force.

PERMITTED SCOPE OF INTERNET MEDICAL SERVICES

To ensure the safety of patients, the permitted scope of Internet diagnostic services (irrespective of the nature of the provider) is generally limited to certain common or chronic diseases, such as dermatosis, chronic hypertension and diabetes in a stable condition. To enhance accessibility to outpatient resources nationwide, patients are allowed to have follow-up visits via Internet tools with physicians with whom they had previously had a face-to-face medical consultation. Importantly, the patient's first visit cannot be conducted online, with the goal presumably being to ensure the safety of patients, and reduce the risk of patients being duped by people posing as Internet doctors, with medical credibility and professionalism and trust being an essential element of any Internet diagnostic service; if it is discovered during return visits conducted online that there has been a change in the patient's medical condition requiring in-person diagnosis by a physician, the rules required that the Internet diagnostic services must be stopped immediately and the patient must be directed to visit a bricks-and-mortar hospital. In the Internet Hospital Measures, Internet hospitals are given a bit more flexibility compared to bricks-and-mortar hospitals, such that a patient accompanied by his or her treating physician in a bricks-and-mortar medical institution, may invite external physicians (note that this is not a H2H model, which is governed by the Telemedicine Specifications) for a medical consultation. The external physician giving the consultation may make a diagnosis and issue prescriptions.

PRACTICAL ISSUES WITH ONLINE PRESCRIBING

Physicians are allowed to prescribe online during the course of Internet diagnostic services. However all online diagnosis and prescriptions must be affixed with the electronic signature of the treating physicians. In practice the number of physicians who currently have electronic signatures set up is pretty low. Moreover, as the online drug distribution rules in China have not been finalized, and under current rules, online distribution of prescription drugs is still prohibited, there may be practical difficulties in supplying drugs online, especially prescription drugs.

COMPARISON: THREE MODELS FOR INTERNET BASED MEDICAL SERVICES

Interested parties may struggle to understand what the differences are between an Internet hospital on the one hand and a bricks-and-mortar medical institution providing Internet diagnosis on the other ("**Add-on Service Hospital**"), as they are, in essence, providing the same Internet diagnostic services.

To put it simply, Internet hospitals may be viewed as an upgraded version of the bricks-and-mortar medical institution. In addition to having to meet higher threshold standards, the major differences between them is that while an Add-on Service Hospital can only use its internal medical resources (i.e., its own physicians) to provide Internet diagnostic services, a Tie-up Internet hospital can engage and invite external physicians to provide Internet diagnostic services via its digital platform. In addition, a Tie-up Internet hospital needs to independently obtain a Medical Institution Practicing License, and it is viewed as an independent entity that takes full responsibility for diagnostic activities performed by it. The Affiliated Hospital is a middle path falling somewhere between the two. Below please find a table summarizing the differences between a Tie-up Internet hospital and a bricks-and-mortar hospital that offers Internet diagnostic services.

	Add-on Service Hospital: Bricks-and-mortar hospital that offers Internet diagnosis	Affiliated Hospital: Internet hospital as the “supplementary name” of a bricks-and-mortar hospital	Tie-up Hospital: Pure independent Internet hospital that ties its service to a bricks-and-mortar hospital
Types of services provided	Internet diagnostic services.	Internet diagnostic services.	Internet diagnostic services.
Clinical personnel	Only physicians engaged by its own institution.	Both physicians engaged by its own institution and external physicians engaged by other medical institutions.	Both physicians engaged by its own institution and external physicians engaged by other medical institutions.
Licensing requirement	Apply to NHC to add Internet diagnostic services into the permitted practice scope of its Medical	Apply to the NHC to add Internet hospital as its “supplementary name” into its Medical Institution Practicing	Apply to the NHC for a <i>separate</i> Medical Institution Practicing License.

	Institution Practicing License.	License.	
Allocation of medical risks	Medical risks and liabilities are assumed by the bricks-and-mortar hospital.	Medical risks and liabilities are assumed by the bricks-and-mortar hospital.	Medical risks and liabilities are assumed by the Internet hospital.

INCREASING DATA PROTECTION REQUIREMENTS FOR INTERNET-BASED MEDICAL SERVICES

In response to the overall trend of tightening up regulation and supervision of cyberspace activities, in the Three Measures NHC also emphasizes the importance of protecting patients' privacy and data during the provision of telemedicine services and Internet diagnostic services. To secure the flow of medical data among medical institutions, stakeholders must ensure the information system or platform they use are capable of protecting patients' privacy and preventing patients' personal data from loss, modification, damage or unauthorized transmission. In addition to following the general rules applicable for the protection of personal data under the *Cyber Security Law of the People's Republic of China* and its implementing rules, the *Standard, Security and Service of National Health and Medical Big Data Administrative Measures (Trial)*, issued by the NHC and effective on 12 July 2018 must also be followed.

ICP LICENSE REQUIREMENTS

Assuming that a platform for Internet diagnostic services will be set up in China (i.e., housed on a server in mainland China), then it is likely to be regarded as being engaged in the provision of Internet Information Services (also known as an Internet Content Provider ("ICP") services) and regarded as a Category II type value added telecommunications service. Engaging in the provision of profit-making (operational) Internet information services requires the service provider to have obtained an ICP telecoms business operating permit ("**ICP Permit**"). "Profit-making Internet information services" means service activities such as the provision, via the Internet, of information or webpage making services, in exchange for payment by Internet users. On the other hand, engaging in the provision of non-profit-making (non-operational) Internet information services does not require the service provider to have obtained an ICP License; an ICP record-filing will suffice. "Non-profit-making Internet information services" are defined to mean such service activities as the provision, via the Internet, of information of an open and shareable nature free of charge. It seems fairly clear on the face of it that Internet diagnostic services in China constitute a for-profit service. This may prove to be the largest barrier in practice to Internet diagnostic services for foreign investors who will establish an Internet hospital and run a platform in China, as in its WTO commitments, China only committed to open up foreign investment in ICP services up to a maximum of 50%, whereas the cap on foreign investment in bricks-and-mortar hospitals is now 70%. Very few foreign investors have actually obtained an ICP Permit through a Sino-foreign joint venture in China, and the qualification requirements for a foreign investor in such ventures requiring a track record in providing ICP services outside China could be used to exclude applicants whose expertise lies elsewhere. It may be worth exploring whether it is possible to outsource the regulated ICP service element to a third party with an ICP Permit, whilst maintaining complete control over the medical services provided through it.

CONCLUSIONS

By resolving some of the uncertainties that previously existed, the Three Measures are likely boost the development of the medical sector and create more business opportunities for market players. In particular, the Internet Hospital Measures gives a green light to Internet hospitals, and the Internet Diagnosis Measures and Telemedicine Specifications provide more policy certainty and better guidance to players providing Internet-based medical services.

Any medical institutions which have already been providing Internet diagnosis services prior to the implementation of the Internet Diagnosis Measures must submit an application for approval to the NHC within 30 days of the effective date of the Internet Diagnosis Measures (i.e. 16 August 2018, which period has expired even before the Three Measures were released to the public).

However they do leave a rather big hole in terms of not addressing cross-border medical telemedicine collaborations, thereby surely missing a huge opportunity to bring the most advanced expertise and therapies to the Chinese market.

Contacts:

Andrew McGinty

Partner, Shanghai

andrew.mcGinty@hoganlovells.com**Jun Wei**

Partner, Beijing

jun.wei@hoganlovells.com**Steven N. Robinson**

Partner, Beijing/ Washington, D.C.

steven.robinson@hoganlovells.com**Lu Zhou**

Partner, Beijing

lu.zhou@hoganlovells.com**Jessie Xie**

Senior associate, Beijing

jessie.xie@hoganlovells.com

Alicante
Amsterdam
Baltimore
Beijing
Birmingham
Boston
Brussels
Budapest*
Colorado Springs
Denver
Dubai
Dusseldorf
Frankfurt
Hamburg
Hanoi
Ho Chi Minh City
Hong Kong
Houston
Jakarta*
Johannesburg
London
Los Angeles
Louisville
Luxembourg
Madrid
Mexico City
Miami
Milan
Minneapolis
Monterrey
Moscow
Munich
New York
Northern Virginia
Paris
Perth
Philadelphia
Riyadh*
Rome
San Francisco
São Paulo
Shanghai
Shanghai FTZ*
Silicon Valley
Singapore
Sydney
Tokyo
Ulaanbaatar*
Warsaw
Washington, D.C.
Zagreb*

*Our associated offices

www.hoganlovells.com

"Hogan Lovells" or the "firm" is an international legal practice that includes Hogan Lovells International LLP, Hogan Lovells US LLP and their affiliated businesses.

The word "partner" is used to describe a partner or member of Hogan Lovells International LLP, Hogan Lovells US LLP or any of their affiliated entities or any employee or consultant with equivalent standing. Certain individuals, who are designated as partners, but who are not members of Hogan Lovells International LLP, do not hold qualifications equivalent to members.

For more information about Hogan Lovells, the partners and their qualifications, see www.hoganlovells.com.

Where case studies are included, results achieved do not guarantee similar outcomes for other clients. Attorney advertising. Images of people may feature current or former lawyers and employees at Hogan Lovells or models not connected with the firm.

©Hogan Lovells 2018. All rights reserved.