#### **ALERT - China Life Sciences**

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## China's Health Authorities Issue New Rules on Telemedicine

On September 14, 2018, the PRC National Health Commission ("NHC") promulgated three administrative measures¹ (the "Measures") to regulate telemedicine. The Measures recognize the legitimacy of emerging internet-based healthcare services, in addition to traditional telemedicine services defined by the existing regulations. By way of background, the NHC defined telemedicine narrowly in its 2014 Circular. Telemedicine only referred to physician-to-physician consultations by means of modern information and communication technologies. The Measures broaden the scope of telemedicine to include internet-based diagnosis and treatment offered by hospitals to their existing patients, as well as internet hospitals that offer online diagnosis and treatment of common and chronic illnesses to all patients.

#### Remote physician-to-physician consultations

The Chinese authorities began to regulate remote physician-to-physician consultations in 1999.<sup>2</sup> The Measures further clarify that remote physician-to-physician consultations cover two major scenarios:

- a. One medical institution renders remote healthcare services at the request of another, to assist with patient diagnosis and treatment through information technology.
- b. A medical institution or a third party establishes a telemedicine platform; another medical institution registers on this platform as a user to render remote healthcare services at the request of the inviting medical institution or through matching services by the third party.

A medical institution does not need advance approval to facilitate remote physician-to-physician consultations, unless it intends to establish a telemedicine platform accessible by multiple medical institutions. The medical institution requesting remote consultations is ultimately responsible for the diagnosis and treatment of patients. Physicians at the requesting medical institutions can incorporate recommendations offered by the remote physicians to form their diagnoses and treatment.

#### **Internet-based Diagnosis and Treatment and Internet Hospitals**

Internet-based diagnosis and treatment and internet hospitals refer, generally, to a medical institution rendering remote healthcare services to patients directly. A medical institution can choose to offer telemedicine services through its own medical team, or can set up an affiliated internet hospital and invite external medical teams for telemedicine.<sup>3</sup> Both arrangements require advance approval by the local health authorities, and the medical professionals offering telemedicine must be licensed to practice in China.

In the Measures, the NHC acknowledges the legitimacy of these concepts for the first time, but limits legitimate telemedicine to hospitals offering follow-up examinations, treatment and prescriptions<sup>4</sup> for common and chronic illnesses. Patients cannot seek telemedicine services without first visiting an offline hospital. If the disease progresses

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<sup>&</sup>lt;sup>1</sup> These rules include (i) Measures for the Administration of the Internet-based Diagnosis and Treatment; (ii) Measures for the Administration of the Internet Hospitals; and (iii) Measures for the Administration of Telemedicine.

<sup>&</sup>lt;sup>2</sup> See the *Circular for Strengthening the Administration of Remote Medical Consultations* issued by the Ministry of Health, effective as of January 4, 1999 ("1999 Circular"). In August 2014, the National Health and Family Planning Commission issued the *Opinion on Facilitating Telemedicine Services in Medical Institutions*, which modified the 1999 Circular to reflect the latest industry developments and regulatory needs.

<sup>&</sup>lt;sup>3</sup> A newly established internet hospital can be an independent legal entity, but it must be affiliated with an offline hospital.

<sup>&</sup>lt;sup>4</sup> Online prescriptions exclude narcotic drugs and psychotropic drugs.

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and the patient is no longer suitable for telemedicine, physicians must direct the patient to an offline hospital for further diagnosis and treatment.

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The Measures clarify longstanding ambiguities regarding the scope of permitted telemedicine. Nevertheless, they do not provide clear guidance on cross-border telemedicine. Cross-border telemedicine is permitted under the 2014 Circular, but it is limited to remote physician-to-physician consultations. Whether and to what extent the health authorities will apply the Measures *mutatis mutandis* to cross-border telemedicine remains an open question. Also, the Measures delegate responsibility to define the guidelines and operating procedures for telemedicine to medical societies, and authorize provincial healthcare authorities to supervise healthcare services offered online or by internet hospitals. The actual implementation and enforcement of the Measures is unclear for now. We advise that stakeholders continue monitoring the announcement of detailed implementation rules and adapt their investment strategy or business models accordingly.

If you would like to discuss the foregoing or any other related matter, please contact <u>Katherine Wang</u> or your usual Ropes & Gray advisor.