

Can My U.S. Company Offer Online Second Opinions in China?

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As U.S. companies continue to look abroad for telehealth opportunities, particularly in China, they are exploring direct-to-patient service offerings such as internet-based medical consultations and online second opinions. These services differ from institution-based telehealth arrangements, and companies must be sensitive to the differences on how government authorities define and regulate these offerings.

Case in point: How may a U.S.-based company offer online second opinions in China? Do China regulators differentiate between telemedicine at a medical institution and internet-based consults or online second opinions?

Chinese officials have promoted the use of information tools, including internet and other technologies, to augment local medical institution administration and patient-care capacities. A recent example is China's [National Medical Health Service System Plan \(2015-2020\)](#) [????????????????????2015—2020??], issued via Circular by the State Council March 30, 2015. The Plan highlights, among other things, the importance of promoting the use of information tools and mobile internet-based and telemedicine services in China's healthcare system.

This promotion contributed to a surge in investment, institutional cooperation and other activities, not only in the telemedicine space, but also with respect to Internet-based or online healthcare consultation services. It previously was a thinly regulated area, but the surge in activity has led Chinese authorities to now focus on ensuring that these services conform to Chinese regulatory requirements. This includes, but is not limited to, having duly licensed medical professionals involved.

In fact, a spokesperson from [China's National Health and Family Planning Commission](#) (NHFPC) was [quoted earlier this month](#) on the subject of "Internet-assisted online [medical] consultation" [?????????]. The spokesperson stated "some Internet-based [activities] involving diagnosis and treatment should not be carried out; one can provide health advice, but one cannot undertake diagnosis and treatment work."

What does that mean for U.S. or other foreign companies seeking to offer Internet-based consults or

online second opinions in China? The statement calls into question some ongoing and planned activities involving online medical consults and direct-to-patient second opinions. In reviewing this statement, filtered in conjunction with prior China guidance and feedback from the authorities, the following observations can be made.

- China authorities are only now starting to focus on the distinction between authorized Internet-assisted online “medical consultation” and prohibited Internet-assisted online “diagnosis and treatment” in China. China authorities do not necessarily interpret these services in the same manner as U.S. authorities, so U.S. companies must be particularly sensitive to the differences when considering online medical website offerings in China. But, even in the U.S., there is a difference between an Internet-based tool to assist a user in self-exploration of health conditions, and an online service where a professional reviews the user’s medical condition/records and renders an opinion (i.e., a diagnosis, prognosis and/or treatment recommendation).
- When the company or individual is not a medical institution, and plans to establish a web site providing medical consultation services in China, these services should steer clear of diagnosis and treatment (including but not limited to pathological diagnoses, medical image-based diagnoses, remote clinic/outpatient-type treatment activities) and focus on other medical and health knowledge-based services authorized under China law.
 - For instance, relevant laws include China’s [Administrative Measures for Internet-based Medical and Health Information Services](#) [????????????????] (“Measures”), issued by the (former) Ministry of Health May 1, 2009.
 - The Measures (see Article 12) provide that no web site providing Internet-based medical and health information services may...[include in those services] engagement in on-line diagnosis or treatment activities....”
 - The Measures (see Article 4) require that web sites providing authorized medical and health information services be registered with the government and applicants for such registrations are subject to government examination and approval.
 - These are only two examples from the Measures, and there are more requirements a company must follow when offering Internet-based medical and health information services in China.
- Medical diagnosis and treatment should properly occur using a website or online platform established by a medical institution.
 - Since the release of the Measures, the NHFPC issued revised [Opinions Regarding the Promotion of Medical Institution Telemedicine Services](#) [????????????????]. The Opinions constitute the government’s guidelines on remote telemedicine consultation activities lawfully conducted between medical institutions. The Opinions expressly indicate that “[n]on medical institutions are not permitted to perform telemedicine services.” Such telemedicine consultation activities include, in particular, remotely conducted peer-to-peer (physician-to-physician) second opinions on Chinese medical institution patient diagnosis and treatment. These consultation activities are based upon a legal framework, established between Chinese medical institutions or Chinese medical institutions and overseas healthcare providers, that is compatible with the

The opportunities for growth in Internet-based and telemedicine services in China's healthcare system are evident. Yet, it is also evident the Chinese government is developing one regulatory structure for Internet-assisted online medical and health information services that do not involve diagnosis and treatment, and second regulatory structure for online or Internet-based platforms that do involve diagnosis and treatment.

U.S. businesses undertaking projects or contemplating Internet-based healthcare-sector opportunities in China should take steps to assess the legality and compliance issues of these projects. Taking steps now to develop proper international arrangements can position providers to best harness these growth opportunities.

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1. English Translations of China's NHFPC Telemedicine Opinions

Foley's Telemedicine and China Practices have completed Chinese-to-English translations of two opinions issued in August 2014 by the NHFPC, available free for our readers at [Promotion of the Medical Institution Telemedicine Services](#).

2. Data Security and Intellectual Property in China Telemedicine Arrangements

Read Foley's [advice for U.S. businesses](#) on China intellectual property rights, as well as Foley's considerations on [China telemedicine data privacy and security](#).

3. China Healthcare Compliance and the "Nine Prohibitions"

Read about China's [Work Plan on Inspection of Large Hospitals](#) and the government's rules and expectations for healthcare compliance in China.

4. China's Plans for National Telemedicine Network

In 2015, China issued a new document, outlining an ambitious plan to build a uniform national telemedicine service network in China. The document, [Technical Guideline for Telemedicine Information System Construction](#), is a visionary 200-page blueprint for the creation of an interoperable, uniform service network in China, designed to allow China patients and medical institutions to enjoy seamless telemedicine services anywhere in China.

5. China's Plans for Long-Term Care Facilities and Telemedicine

Read about China's development program which uses telemedicine as the lynchpin in the promotion of healthcare services for the elderly, including accelerated pilot programs for telemedicine services

at elder care institutions in the Beijing municipality and Hubei and Yunnan provinces, as well as [access our exclusive Chinese-to-English translation of the official notice.](#)

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