A Practical Guide to Due Diligence for Investment in Internet Hospitals in China

July 20, 2020

Thriving in China these days, Internet hospitals are medical institutions that provide certain remote medical services based on the Internet technologies – from online consultation to electronic prescription, which is expected to greatly ease the difficulty of getting medical diagnosis in China. Especially amid COVID-19 outbreak, online diagnosis has become the new fashion. This, coupled with supportive policies promulgated by the National Health Commission of People’s Republic of China ("National Health Commission"), marks the advantageous conditions for Internet hospitals both from the market and the policy perspectives. This has speeded up the capital flow into the Internet hospital industry. In such a wave, due diligence and compliance review deserve more attention from investors to mitigate risks in a timely and effective manner, and based on that, this article summarizes the key points of due diligence for investing in Internet hospitals, especially in terms of compliance with relevant regulations and practices involved, to help investors anticipate risks.

1 Whether the Internet Hospital is Established Based on a Physical Medical Institution

Under the current regulatory framework set up by Administrative Measures for Internet Hospitals (for Trial Implementation), 3 modes are available for the establishment of an Internet hospital. As illustrated below, each mode requires that the establishment shall be based on an off-line physical medical institution to be granted the Practice License of Medical Institution, i.e., the "Internet hospitals" shall be based on “physical hospitals”.

<table>
<thead>
<tr>
<th>Mode of Establishment</th>
<th>Applicant</th>
<th>Nomenclature</th>
<th>Examples</th>
</tr>
</thead>
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<tr>
<td>A physical medical institution independently applies to establish an Internet hospital as its second name.</td>
<td>The physical medical institution</td>
<td>“The Internet Hospital of” + name of the physical medical institution</td>
<td>The Internet Hospital of No. 1 Hospital Afflicted to Zhejiang University, The Internet Hospital of West China Hospital, Sichuan University</td>
</tr>
<tr>
<td>A physical medical institution cooperates with a third-party institution in applying to establish an Internet hospital as a second name.</td>
<td>The physical medical institution</td>
<td>The name of the third party + “Internet Hospital of” + name of the medical institution</td>
<td>Guanzhong Internet Hospital of Xuhui Central Hospital, Shanghai</td>
</tr>
<tr>
<td>Relying on a physical medical institution, a third party applies to establish an Internet hospital.</td>
<td>The third party</td>
<td>The name of the third party + “Internet Hospital”</td>
<td>Yinchuan Dingxiang Internet Hospital, Shanghai Shangying Internet Hospital</td>
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</table>

In fact, “purely online” Internet hospitals established without reliance on physical medical institutions did come into July 20, 2020
transitory existence once. In December 2016, the municipal government of Yinchuan, Ningxia, the first Chinese city encouraging purely online Internet hospitals, promulgated the first regulation on the administration of Internet hospitals in the country—Administrative Measures of Yinchuan on Internet Hospitals (for Trial Implementation). The relatively low entry barriers according to this regulation attracted a considerable number of enterprises, including the first Internet hospital in Yinchuan – Yinchuan Smart Internet Hospital (“Hao Daifu”, literally meaning “Good Doctor”). The welcoming policy of Yinchuan has also enabled Hu Dong Feng Technology (Beijing) Co., Ltd., the operating entity of Hao Daifu, to be granted the Practice License of Medical Institution without reliance on any physical medical institution.

However, in accordance with the Opinions of the General Office of the State Council on Promoting the Development of "Internet Healthcare" and Administrative Measures for Internet Hospitals (for Trial Implementation) promulgated respectively in April and July of 2018, the National Health Commission expressed that “Internet hospitals shall be based on physical medical institutions”, cooling off investment in Internet hospitals. In line with the requirements set by the National Health Commission, Administrative Measures of Ningxia Hui Autonomous Region on Internet Hospitals (for Trial Implementation) promulgated in January 2019, requires, in a way “retrospectively”, that all established purely online Internet hospitals should cooperate with Level 2 or 3 hospitals in Yinchuan and reapply for the Practice License of Medical Institution. This completely closed the door for purely online Internet hospitals.

2 Whether the Internet Hospital Holds Relevant Qualifications

When conducting due diligence on an Internet hospital, emphasis could be placed on the following qualifications for the evaluation of its compliance status of establishment and operation.

(1) The Practice License of Medical Institution

Like physical medical institutions, Internet hospitals that carry out Internet-based diagnosis and treatment services also have to obtain the Practice License of Medical Institution. Taking the example of a third party independently applying an Internet hospital relying on a physical medical institution, the third party shall apply to the registration authority of the physical medical institution it relied upon for the establishment, and shall submit to the registration authority the following documents: Application for Establishment, the Feasibility Study Report for Establishment (the content of which may be appropriately simplified depending on specific circumstances), address of the physical medical institution it relied on, and a cooperation agreement on the establishment of the Internet hospital signed by the third party and the physical medical institution.

As for the legal consequences for the Internet hospital operating without the Practice License of Medical Institution, the Administrative Measures for Internet-based Diagnosis and Treatment (for Trial Implementation) and the Administrative Measures for Internet Hospitals (for Trial Implementation) have referred to the Administrative Regulations on Medical Institutions and other relevant laws and regulations. Pursuant to Administrative Regulations on Medical Institution, where a medical institution practices without obtaining a Practice License for Medical Institutions, the health administrative department shall order it to stop its practicing activities, confiscate its illegal gains, medicines and medical instruments, and may impose a fine of less than RMB 10,000.

(2) The Doctor's License

Doctors are the major subjects providing Internet-based diagnosis and treatment services. All online diagnosis and prescriptions must be with doctors’ electronic signatures. Like doctors practicing in physical medical institutions, pursuant to Administrative Measures for Internet-based Diagnosis and Treatment (for Trial Implementation) and Administrative Measures for Internet Hospitals (for Trial Implementation), doctors practicing Internet-based diagnosis and treatment services shall hold corresponding qualifications, and the information of these doctors shall be
accessible in the national electronic registration system for doctors. This is to say, these doctors shall have registered and hold the Doctor’s License.

Unlike practicing doctors in physical medical institutions, however, the threshold for doctors practicing in Internet hospitals are higher. First of all, the latter shall have more than three years of independent clinical experience. Furthermore, with the consent of the medical institutions with which they have been registered, they could practice in multiple institutions, but shall prioritize the work in their registered medical institution and shall ensure at first place that the diagnosis and treatment work required by their primary practicing institutions is completed.

Special attention should be paid to the fact that practicing Internet-based diagnosis and treatment without obtaining the Doctor’s License might constitute the Crime of Illegal Medical Practice. According to the Interpretation of the Supreme People's Court on Issues Concerning the Application of Law in the Trial of Criminal Cases Involving Crime of illegal Medical Practice, after being punished by the health administrative department twice for practicing without obtaining the Doctor’s License, practicing without Doctor’s License again could constitute the Crime of Illegal Medical Practice.

(3) The Qualification Certificate for Internet-based Drug Information Services

If the Internet hospital provides information services regarding drug and medical devices to Internet users through the Internet, including text, pictures, audio and video information, etc., it may be recognized as providing “Internet drug information service”. And, whether the Internet drug information service is provided for profit (in the case of paid information service) or on a non-for-profit basis (in the case of providing open and shared drug information free of charge), the Qualification Certificate for Internet-based Drug Information Services issued by the food and drug administration is required.

It should be noted that the application for the Qualification Certificate for Internet-based Drug Information Services should be conducted prior to the record filing or permit for telecommunications business. Besides, the website providing Internet-based drug information services shall provide the drug information accurately and on a scientific basis, and shall not publish any product information concerning narcotic drugs, psychotropic drugs, medical toxic drugs, radiopharmaceuticals, drug rehabilitation medications and preparations made by medical institutions. It shall also post the number of the Qualification Certificate for Internet-based Drug Information Service in a prominent place on its homepage. In practice, administrative punishments for engaging in Internet-based drug information services without obtaining the Qualification Certificate for Internet-based Drug Information Services, in most cases, take the form of warning.

(4) The Permit or Record Filing for Drugs and Medical Devices

The operation of an Internet hospital might involve business relating to drugs and medical devices. According to the 2019-revised Drug Administration Law, undertakings conducting drug wholesale and retail business shall obtain the Drug Business Permit. Undertakings selling drugs without the Drug Business Permit, apart from mandatory close and confiscation of drugs and illegal incomes, could be faced with a fine ranging from 15 times to 30 times the value of the drugs from the illegal sale (including sold and unsold drugs). This amount is significantly higher than the amount (“2 to 5 times”) stipulated in the 2015-revised Drug Administration Law. Special attention should also be paid to the fact that, according to the Interpretations of Supreme People’s Court and Supreme People’s Procuratorate on the Application of Law to Criminal Cases Concerning Drug Safety, for sale of drugs without obtaining a Drug Business Permit, i.e., for illegal sale of drugs, when the income from illegal business operation reaches RMB 100,000 or more, or the illegal gains reach RMB 50,000 or more, the perpetrator shall be punished under the Crime of Illegal Business Operation.

Pursuant to the Measures on Supervision and Administration of Business Operations of Medical Devices and
Regulations on Supervision and Administration of Medical Devices, no permit or record filing is required for sale of Category I medical devices, while record-filing administration applies to sale of Category II medical devices, and permit-based administration applies to sale of Category III medical devices. An undertaking engaging in medical devices-related business without permit could be faced with confiscation of illegal income, relevant medical devices and relevant objects. Further, if the value of relevant medical devices is not less than RMB 10,000, a fine ranging 10 to 20 times the goods value will be imposed; in a serious case, applications for a medical device permit filed by relevant liable persons and the undertakings will not be accepted within 5 years.

(5) Record Filing for Online Sales of Medical Devices

Internet hospitals sell medical devices via the Internet, thereby shall act in accordance with Administrative Measures on Supervision of Online Sales of Medical Devices. Pursuant to Administrative Measures on Supervision of Online Sales of Medical Devices, in addition to holding the permit or having completed the record filing for medical devices, the operating entity of the Internet hospital shall fill in an information sheet for the online sale of medical devices, and file with the local food and drug administrative authority information such as the name of the undertaking, the name of the legal representative or person in charge, the name of its website, the name of the application for the client, its domain name, the IP address of the website, the telecommunication business permit or the number of filing for non-profit Internet information service, permit or the number of filing certificate for the manufacturing and business of medical devices. In practice, in most cases, relevant administrative authorities issue warnings as the administrative punishment for the entities who fail to file a record pursuant to this rule.

(6) The Value-Added Telecommunications Business Permit

Pursuant to the Classification Catalogue of Telecommunications Services (Version 2015), it is very likely that Internet hospitals have to apply for the Value-Added Telecommunications Business Permit in accordance with the following categories of services.

<table>
<thead>
<tr>
<th>Permit</th>
<th>Categories</th>
<th>Descriptions</th>
<th>Service Provided by the Internet Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Value-Added Telecommunications Business Permit</td>
<td>B21</td>
<td>Online data processing and transaction processing services</td>
<td>Online medical consultation, online pharmacy, etc.</td>
</tr>
<tr>
<td></td>
<td>B25</td>
<td>Information services</td>
<td>Online appointment register, delivery of</td>
</tr>
</tbody>
</table>
(7) The Medical Advertisement Examination Certificate

Notwithstanding the lack of special rules regarding the advertisement of Internet hospitals in Administrative Measures for Internet Hospitals (for Trial Implementation), etc., based on factors including, for example, the opinions expressed or backed by administrations of market regulation, Internet medical advertisements are generally regarded as belonging both to the category of medical advertisement and Internet advertisement, and are therefore subject to the Advertising Law, Measures for the Administration of Medical Advertisement, and Interim Measures for Administration of Internet Advertising, etc.

Specifically, according to the Measures for the Administration of Medical Advertisement, a medical advertisement means an advertisement using various types of media or forms to directly or indirectly introduce a medical institution or medical services. Therefore, it could be concluded that the Measures for the Administration of Medical Advertisement may apply to advertisements using various types of media, including the Internet, television, social media platforms, etc., to directly or indirectly introduce a medical institution or medical services. And, according to the Measures for the Administration of Medical Advertisement, before publishing a medical advertisement, a medical institution shall apply to the local provincial-level health administrative authority and/or traditional Chinese medicine administrative authority for medical advertisement examination, and obtain a Medical Advertisement Examination Certificate, so that advertisement examiner of the advertising agent and advertising publisher can examine the certificate. In addition, attention should be paid to the content and forms of expression of the medical advertisement, and the published medical advertisement shall bear the original (first) name of the medical institution and the document number of the Medical Advertisement Examination Certificate. It should be noted that, the legal consequences of publishing medical advertisements in violation of Measures for the Administration of Medical Advertisement could include revocation of the Practice License of Medical Institution, and further, those publishing medical advertisement without the Practice License of Medical Institution would be punished for illegal medical practice.

3 Whether the Practice is Beyond the Scope Limit for Internet-based Diagnosis and Treatment

According to Administrative Measures for Internet-based Diagnosis and Treatment (for Trial Implementation) and Administrative Measures for Internet Hospitals (for Trial Implementation), the scope of Internet-based diagnosis and treatment services includes offering subsequent consultations for certain common and chronic diseases, issuing prescriptions and providing family doctor signing service. Based on these three types of services, special attention should be paid to the following three aspects when conducting due diligence.

(1) No Internet-based Diagnosis and Treatment Services Shall be Provided to Patients Seeking Initial Medical Consultations

As initial medical consultations require the in-person diagnosis of medical personnel, the scope of Internet-based diagnosis and treatment in this regard is limited to the subsequent consultations of the common and chronic diseases registered in the Practice License of Medical Institution of the Internet hospital, and no Internet-based
diagnosis and treatment services shall be provided to patients seeking initial medical consultations. Before a medical institution offers subsequent consultations of certain common and chronic diseases online, its doctors shall review the patients’ medical records, and may, after confirming that the patients have been diagnosed with one or more types of such common or chronic diseases in physical medical institutions, offer subsequent consultations for the same diagnosis.

However, current laws and regulations generally do not specify the scope of “certain common and chronic diseases”. At the local level, though, some clarifications have been made. Taking Shanghai as an example, the Administrative Measures of Shanghai on Internet Hospitals provide that Internet hospitals are not allowed to carry out “diagnosis and treatment services for patients with Class A infectious diseases, critical and severe diseases, and those who need to go to physical medical institutions for physical examinations or diagnoses that should be given with the help of auxiliary medical devices”. That is to say, such patients are excluded from the patients to whom the subsequent consultation of “certain common and chronic diseases” can be provided.

In addition, current laws and regulations generally do not specify for how long the period of the medical records should be which doctors shall review. In the meantime, the Administrative Measures of Shanghai on Internet Hospitals require that the patients provide the medical records of certain common or chronic diseases diagnosed by physical medical institutions for the past two months.

(2) Special Requirements for Issuing Prescriptions During Internet-based Diagnosis and Treatment

Internet hospitals shall strictly comply with the Measures for the Administration of Prescriptions and other rules for prescription management.

Before issuing prescriptions online, doctors shall review the patients’ medical records, and may, after confirming that the patients have been diagnosed with one or more types of common or chronic diseases in physical medical institutions, issue prescriptions online for diseases with the same diagnosis results.

Each online diagnosis or prescription shall be signed by a doctor with his/her electronic signature. A prescription is effective only after being reviewed by a pharmacist, and the medical institution or medical manufacturer may entrust a qualified third-party organization to deliver the medicine on the prescription.

A prescription on narcotic drugs, psychotropic drugs, or other drugs with high risks in drug use or under special management shall not be issued online.

Before issuing a prescription on pediatric drugs for young children (under 6), the doctor shall confirm that the children are accompanied by their guardians or relevant specialist physicians.

Internet hospitals shall establish electronic medical records for their patients, and make prescriptions and other medical records accessible online.

(3) Special Key Points for the Agreement for Family Doctors

According to the Guiding Opinion of the National Health Commission and the National Administration of Tradition Chinese Medicine Concerning Regulating the Administration of the Signing Service for Family Doctors and Administrative Measures for Internet-based Diagnosis and Treatment (for Trial Implementation), the followings are some key points when signing an agreement for family doctors.

Service Agreement for Family Doctors

Service Provider: various types
4 Restrictions on Foreign Investment Access to Internet Hospitals

China’s restrictions on Foreign investment access to Internet hospitals are represented in two major parts – the restrictions on the establishment of medical institutions and those on the licensing of value-added telecommunications services. For the establishment of medical institutions by foreign investors, according to the current Special Administrative Measures for Foreign Investment Access (Negative List) (2019 Edition), foreign-invested medical institutions are limited to equity and cooperative joint ventures. For Sino-foreign equity and cooperative joint venture medical institutions, according to the Interim Measures for the Management of Sino-foreign Equity and Cooperative Joint Venture Medical Institutions (2000), the shareholding ratio of the foreign party shall not...
exceed 70%, and the total amount of investment shall not be less than RMB 20 million, while the term of the equity or cooperative joint venture shall not exceed 20 years.

In fact, China’s access policy for foreign-invested medical institutions has gone through the process of “opening up and then tightening”. As early as 2014, the National Health and Family Planning Commission and the Ministry of Commerce issued the Notice on Carrying out the Pilot Work of Establishing Wholly Foreign-owned Hospitals, which allowed foreign investors to set up wholly foreign-owned hospitals in Beijing, Tianjin, Shanghai, Jiangsu, Fujian, Guangdong and Hainan by means of new establishment or merger and acquisition. Although this provision has not been abolished, the Negative List promulgated after that has clearly provided that foreign investment in medical institutions are limited to equity and cooperative joint venture medical institutions. Therefore, in most cases in practice, requirements on the ratio of shareholding by the foreign party are subject to the Provisions of the Interim Measures for the Management of Sino-foreign Equity and Cooperative Joint Venture Medical Institutions (2000).

Specially, however, for investors from Hong Kong, Macao and Taiwan, where the Negative List stipulates that more preferential open-up measures shall be implemented for investors, then the relevant provisions shall prevail. Therefore, according to the Interim Measures for the Administration of Service Providers from Hong Kong and Macao to Establish Wholly-owned Hospitals in the Mainland China issued by the Ministry of Health and the Ministry of Commerce in 2010 and the Interim Measures for the Administration of Service Providers from Taiwan to Establish Wholly-owned Hospitals in Mainland China, investors from Hong Kong, Macao and Taiwan are allowed to establish wholly-owned hospitals in some pilot areas in the mainland, and in 2014, the scope for pilot areas was expanded to cities above prefecture level. Similarly, the Negative List stipulates that “if more preferential opening-up measures are taken for eligible investors in special economic zones such as pilot free trade zones, relevant provisions shall apply”. Therefore, according to the Provisional Measures for the Administration of Wholly Foreign-owned Medical Institutions in China (Shanghai) Pilot Free Trade Zone (2013), foreign medical institutions are allowed to establish for-profit medical institutions in Shanghai Free Trade Zone in the form of wholly foreign-owned investment. In accordance with these provisions, Shanghai Towako Hospital, established by Towako Group of Japan, became the first wholly foreign-owned medical institution in Shanghai Pilot Free Trade Zone in 2015, and the first wholly foreign-owned medical institution in mainland China (with the exception of medical institutions wholly owned by investors from Hong Kong, Macao and Taiwan).

In addition, it is worth noting that although the Interim Measures for the Management of Sino-foreign Equity and Cooperative Joint Venture Medical Institutions (2000) constitute the basis at the national level, according to the Notice of the Ministry of Health on Adjustments to the Examination and Approval Authority over Sino-Foreign Equity or Cooperative Joint Venture Medical Institutions, the examination and approval authority over the establishment of Sino-foreign equity or cooperative joint venture medical institutions has been transferred from the Ministry of Health to the health administrative authority at the provincial level. Some regions have also provided for the ratio of shareholding for the foreign party in local medical institutions. Taking Sichuan as an example, the Administrative Measures of Sichuan Province on Sino-foreign Equity and Cooperative Joint Venture Medical Institutions stipulate that the ratio of shareholding for the foreign party shall not be higher than 90%. This also means that in practice, the health administrative authority at the provincial level should be reached out for consultation to confirm local policies in advance.

As for the Value-Added Telecommunications Business Permit required for the establishment of Internet hospitals, although according to the Negative List, the proportion of foreign shares in value-added telecommunications business can reach 50%, but in practice, it is by no means easy for domestic entities with foreign investment to apply for the Value-Added Telecommunications Business Permit. It is not known yet whether there will be any changes at policy level in the upcoming new version of the negative list.
When conducting due diligence, in addition to the key points peculiar to the Internet hospital industry listed above, common compliance matters and their special application in the Internet hospital industry shall not be neglected.

For instance, while doctors practicing in multiple hospitals usually sign labor contracts with the institution they majorly practice in, under the different modes of establishment for Internet hospitals, there may be different types of legal relations between doctors and Internet hospitals, such as service relations, cooperative relations, and labor relations. Another point is that commercial bribery has always been the focus of regulation for the medical industry, which therefore deserves special attention, and especially in case traditional commercial briberies take new forms with the help of Internet technology. Likewise, Internet hospitals shall not only take general measures to protect personal privacy, but also properly keep patient information in accordance with regulations, and shall not trade and disclose patient information illegally. Further, in the event of disclosure of patient information and medical data, Internet hospitals shall report to the competent authorities and take effective measures in a timely manner.

**Concluding words**

Laws shall be abided by regardless of the ebb and flow of the capital. In tandem with the opportunities brought by the emergence of Internet hospital, laws and regulations are coming out, many of which are very detailed. Due diligence should be conducted scrupulously for risk control in investing Internet hospitals.

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