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Regulation of foreign-invested medical institutions in China

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A summary of Chinese foreign investment policies on the medical institution sector. The note discusses the current regulatory regime and lists the general investment restrictions applicable to foreign investors. It also introduces the preferential policies available to qualified service providers from Hong Kong, Macau, and Taiwan.

Scope of this note

China's foreign investment policies in the medical institution sector have consistently changed over time. This note revisits three key stages of these policies, with table summaries of the key restrictive or liberalisation measures introduced at each stage. It discusses the current regulatory regime for the medical institution sector and looks at the general investment restrictions applicable for foreign investors. It also introduces the preferential policies available to qualified service providers from Hong Kong, Macau, and Taiwan.

Foreign investment in medical institutions: joint ventures required

Under the Special Administrative Measures for Market Access of Foreign Investment (Negative List) (2020 Version) (2020 Negative List, with effect from 23 July 2020), foreign investment in medical institutions is restricted, with the investee vehicle required to be a Sino-foreign equity joint venture (EJV). (For more information on the 2020 Negative List, see Article, China issues 2020 nationwide and FTZ negative lists.)

Consequently, foreign investors cannot establish any foreign-invested medical institution in the form of a wholly foreign-owned enterprise (WFOE) in China, (except for WFOE hospitals invested by qualified Hong Kong, Macau, or Taiwan service providers (see Preferential policies for Hong Kong, Macau, and Taiwan investors)).

Notable that under the Catalogue of Industries for Encouraging Foreign Investment (2020 Version) (2020 Catalogue, with effect from 27 January 2021), foreign investment into medical institutions is listed as an encouraged industry. Combining the 2020 Negative List with the 2020 Catalogue, foreign investment in this sector remains subject to a joint venture requirement but may receive benefits of being an encouraged industry (see Practice note, Chinese foreign investment law: overview: Catalogue of encouraged industries).

What is a medical institution?

Medical institutions generally include:

- · Hospitals.
- Clinics.
- Nursing homes.
- Emergency rooms.
- Medical laboratories.
- Medical imaging server centres.
- Other institutions of similar nature.

(Article 3, Implementation Rules for the Regulations on the Administration of Medical Institutions 2017 (医疗 机构管理条例实施细则) (2017 Medical Institutions Implementation Rules).)

Review of policy development

Foreign capital began direct investment into the Chinese medical institution sector in the late 1980s. Chinese government's policies for foreign investment in this sector consistently changed over time. Initially, the government restricted foreign capital from entering the domestic medical industry. These restrictions were relaxed towards the end of 2010 but were tightened again in 2015 with the release of the 2015 Foreign Investment Catalogue. These investment policies can be roughly grouped into the following three stages:

- **Prior-2010 restrictive measures.** From April 1997 to November 2010, foreign investors could not establish any WFOE medical institution in China.
- 2010-2015 liberalisation measures. From November 2010 to April 2015, foreign investors could establish



WFOE hospitals in the China (Shanghai) Pilot Free Trade Zone (Shanghai FTZ) and certain pilot cities, and qualified Hong Kong, Macau, and Taiwan service providers could establish WFOE hospitals in cities at or above the prefectural level.

• **Post-2015 retightened measures.** Since April 2015, foreign investors are generally not allowed

to establish any WFOE medical institution in China but qualified Hong Kong, Macau and Taiwan service providers still can establish WFOE hospitals in cities at or above the prefectural level.

Prior-2010 restrictive measures: table

Legislation	Restrictive measures	Remarks
Several Provisions on the Operation of Hospitals and Clinics for Foreigners and Overseas Chinese and the Practice of Medicine in China by Foreign Doctors 1989 (关于 开办外宾华侨医院、诊所和外籍 医生来华执业行医的几条规定)	 Prohibiting the establishment of any for-profit WFOE hospital or clinic. Allowing the establishment of non-profit WFOE hospitals and clinics as pilot projects. 	Under the 1995 Foreign Investment Catalogue, foreign investment in this sector was in the permitted category.
Supplementary Provisions on the Establishment of Foreign-invested Medical Institutions 1997 (关于设立 外商投资医疗机构的补充规定)	 Prohibiting the establishment of any WFOE medical institution, either for-profit or non-profit. Requiring the investee medical institution of being a Sino- foreign joint venture and the shareholding percentage of the Chinese party in the joint venture of not less than 50% generally and 30% in any circumstance. 	Under the 1997 Foreign Investment Catalogue, foreign investment in this sector was shifted back from the permitted category to the restricted category, with the requirement that the Chinese party must be the controlling shareholder or that the joint venture must be led by the Chinese party.
Interim Measures for the Administration of Sino-Foreign Equity/Co-operative Joint Venture Medical Institutions 2000 (2000 Measures on Joint Venture Medical Institutions)	 Prohibiting the establishment of any WFOE medical institution. Increasing the maximum shareholding percentage of foreign parties to 70% generally. 	The subsequent three revisions of the 1997 Foreign Investment Catalogue (that is, 2002, 2004, and 2007 revisions) kept grouping foreign investment in this sector into the restricted category, alongside the requirement that the investee vehicle must be a Sino- foreign joint venture.

2010-2015 liberalisation measures: table

Legislation	Liberalisation measures	Remarks
Notice of the General Office of the State Council on Forwarding the Opinions of the National Development and Reform Commission, the Ministry of Health and other Departments on Further Encouraging and Guiding Social Capital in Setup of Medical Facilities 2010	 The notice officially called on: Removing the foreign shareholding cap restriction in the medical institutions sector. Launching a pilot project for qualified foreign investors to establish WFOE medical institutions in China. 	 Subsequently, the 2011 Foreign Investment Catalogue classified the medical institution sector into the permitted category. Despite these relaxation policies, at that time, the foreign shareholding cap restriction set out in the 2000 Measures on Joint Venture Medical Institutions still applied across the country.

Legislation	Liberalisation measures	Remarks
Provisional Measures on the Administration of Wholly Foreign- invested Medical Institutions in the China (Shanghai) Pilot Free Trade Zone 2013 (中国(上海)自由贸易 试验区外商独资医疗机构管理暂 行办法)	WFOE medical institutions were allowed in the Shanghai FTZ.	 In 2015, the first WFOE medical institution, Shanghai Towako Hospital (上海永远幸妇科医院), was established in the Shanghai FTZ under this policy.
		 In practice, this policy was not implemented with the release of the Notice of the General Office of the State Council on Printing and Distributing the Special Management Measures for the Market Entry of Foreign Investment in Pilot Free Trade Zones (Negative List) 2015 (2015 FTZ Negative List) and its next four versions released in 2017, 2018, 2019 and 2020 respectively. In all the lists, the medical institution sector is a restricted industry and is subject to a joint venture requirement.
Notice of the National Health and Family Planning Commission and the Ministry of Commerce on the Pilot Scheme of Establishing Wholly Foreign-owned Hospitals 2014 (2014 WFOE Hospital Notice)	WFOE hospitals (except for hospitals of traditional Chinese medicine nature which are only allowed to be set up by Hong Kong, Macau, and Taiwan investors) were allowed in seven pilot provinces or cities (that is, Beijing, Tianjin, Shanghai, Jiangsu, Fujian, Guangdong and Hainan) on a trial basis	 No WFOE hospitals were reported to get registered under this notice. This notice was not implemented and is not likely to be
		implemented in the future as it contradicted the industry policy of the 2020 Negative List.

Post-2015 retightened measures

In April 2015, foreign investment in the medical institution sector was shifted back from the permitted category to the restricted category again, alongside the requirement that the investee vehicle must be a joint venture. The same rules have been adopted in all free trade zones (including the Shanghai FTZ) since 2015.

These post-2015 regulations mean that a foreign investor can no longer establish WFOE medical institutions in China, either in or outside the pilot cities once opened under the 2014 WFOE Hospitals Notice.

Current regulatory regime

The current key legislation regulating foreign investment in the medical institution sector is the 2000 Measures on Joint Venture Medical Institutions.

In addition, foreign-invested medical institutions are subject to those general industry rules applicable to all medical institutions, with the most important two being:

- Regulations on the Administration of Medical Institutions 2016 (医疗机构管理条例).
- 2017 Medical Institutions Implementation Rules.

All medical institutions in China (including any joint venture medical institution) must also comply with the *Basic Standards on Medical Institutions (Trial Implementation) 1994* (医疗机构基本标准(试行)) (revised in 2011). These standards are the minimum thresholds that a medical institution must meet to apply for a Medical Institution Practice Permit from the competent office of the National Health Commission (NHC) (which has been formed to replace the National Health and Family Planning Commission (NHFPC), according to the *Plan to Deepen Reform of Party and State Institutions* (深化党和国家机构改革方案) released on 21 March 2018), including requirements about:

- The number of beds.
- The setting of departments.
- The number of various healthcare professionals.

- The area of beds.
- · Medical devices and equipment.
- Robust internal rules and policies, and recognised health care technical operation manuals.
- Minimum paid-in registered capital, which is subject to corresponding local rules for the specific category of the medical institution and may vary from one province to another.

Impact of unified foreign investment law

On 15 March 2019, the National People's Congress passed the Foreign Investment Law 2019 (2019 FIL), which came into force on 1 January 2020 and has become the unified, basic law regulating Chinese foreign investment, repealing and replacing the Three FIE Laws (including the two joint venture laws and the one WFOE law) that have been in effect for decades.

With the commencement of the new regime, the existing distinctions between FIEs and the investment vehicles available to domestic investors are phased out. FIEs (including foreign-invested medical institutions) already in existence before 1 January 2020 may retain their existing organisational form for a period of five years. These FIEs should use this grandfathering period to restructure their organisational form and corporate governance framework to comply with the Chinese corporate and business law regime that currently applies to domestic-invested entities, which largely means the Company Law 2018 and the Partnership Law 2006, together with their subordinate legislation.

In addition, since the 2000 Measures on Joint Venture Medical Institutions belong to subordinate legislation of the Three FIE Laws, it is likely that the measures (same as other FIE subordinate legislation) will need to be amended to be consistent with the 2019 FIL. That might reset the establishment requirements and restrictions for FIE medical institutions (see Requirements on investor qualification and Restrictions on investee institution).

For details of the impact of the 2019 FIL, see Legal update, China enacts unified Foreign Investment Law.

General restrictions on foreign investors

The 2000 Measures on Joint Venture Medical Institutions set out several requirements that must be met before a foreign-invested medical institution can be established, including requirements on the investor qualification and certain establishment thresholds on investee institutions.

Requirements on investor qualification

In addition to those statutory basic standards applicable to both foreign-invested and domestic-owned medical institutions, both the Chinese and foreign investor of a joint venture medical institution must have direct or indirect healthcare investment or management experience and satisfy one of the following:

- Can provide internationally advanced management experience, modes, and service modes of medical institutions.
- Can provide internationally advanced medical technology and equipment.
- Can make up or improve the inadequacy of local medical service capacity, medical technology, funds, and medical facilities.

(*Article 7,* 2000 Measures on Joint Venture Medical Institutions.)

However, it is not mandatory for the investors to submit materials evidencing their satisfaction with these investor qualification requirements to set up a joint venture medical institution. Consequently, some local approving authorities may not strictly review whether these requirements are fully satisfied in certain cases and the local practice may vary from one city to another.

Restrictions on investee institution

A foreign-invested medical institution must meet the following conditions:

- It must be an independent legal person.
- Its total investment should not be less than RMB20 million.
- The proportion of equity interests or the rights and interests of the Chinese party to the joint venture should not be less than 30%.
- The operation term of the joint venture should not exceed 20 years.
- Other conditions prescribed by counterparts of the NHFPC (and now NHC) at or above the provincial level.

(*Article 8,* 2000 Measures on Joint Venture Medical Institutions.)

Minimum investment amount

The investment amount for a Sino-foreign joint venture medical institution should not be less than RMB20 million (*Article 8*, 2000 Measures on Joint Venture Medical Institutions). In contrast, Chinese law does not set up a uniform minimum registered capital or investment amount for domestic-owned medical institutions.

Maximum foreign shareholding ratio

For foreign investment in medical institutions, a foreign investor must have a local partner and may establish a foreign-invested medical institution solely in the form of a joint venture. Meanwhile, the proportion of equity interests or the rights and interests of the Chinese party to the joint venture should not be less than 30%. In other words, the foreign shareholding ratio in the joint venture is capped at 70%. (*Articles 2 and 8*, 2000 Measures on Joint Venture Medical Institutions.)

Under the Interim Provisions on Investment Made by Foreign-Invested Enterprises in China 2000 (2000 FIE Re-investment Provisions, revised in 2006 and 2015 respectively), an FIE's onshore investment activities must comply with the provisions of the 2020 Negative List. Taking a look-through approach, a foreign investor may not circumvent the 70% foreign shareholding limitation by establishing any intermediary holding vehicle, to eventually hold the target medical institution through the onshore intermediary vehicle. (See also Practice note, Onshore reinvestment by foreign-invested enterprises: overview.)

However, neither the Ministry of Commerce (MOFCOM) (the central competent authority regulating foreign investment) nor the NHC (the central competent authority regulating medical institutions) has made any formal interpretation on whether the 2000 FIE Reinvestment Provisions must apply when implementing the 2000 Measures on Joint Venture Medical Institutions.

In practice, uncertainty does exist regarding whether the 70% foreign shareholding cap should apply where the investment is structured through indirect ownership. For example,

- In May 2013, in connection with the listing of Phoenix Health (凤凰医疗, 01515.HK) in the Hong Kong Stock Exchange (HKEx), the Beijing Healthcare Bureau replied to the Beijing Municipal Commission of Commerce (Beijing MOFCOM) that, a hospital co-invested by a domestic company and a WFOE is not an EJV medical institution by definition, therefore should not be subject to the 70% foreign shareholding cap restriction under the 2000 Measures on Joint Venture Medical Institutions. The Beijing MOFCOM accepted that opinion and approved the pre-listing restructuring of Phoenix Health on that basis.
- In May 2016, however, in connection with the listing of NC Healthcare (新世纪医疗, 01518.HK) in the HKEx, the Beijing MOFCOM opined that any indirect ownership of a hospital must also comply with the shareholding cap requirement under the 2000 Measures on Joint Venture Medical Institutions, and therefore rejected the pre-listing restructuring of the NC Healthcare.

Note that these two conflicting opinions were issued from the same government authority, but in different industry policy stages, with the former granted in 2013 when the tone of foreign investment policy was to liberalise investment restrictions in the medical institution sector (see 2010-2015 liberalisation measures: table), and the latter granted in 2016 when the government had tightened up its control in this sector (see Post-2015 retightened measures).

Maximum operation term

The duration of a Sino-foreign joint venture medical institution should not exceed 20 years (*Article 8,* 2000 Measures on Joint Venture Medical Institutions).

In comparison, Chinese law does not impose a maximum operation term for domestic-owned medical institutions. In practice, many local hospitals were registered with an operation term of more than 20 years.

No branch hospitals or clinics

Sino-foreign joint venture medical institutions cannot establish branch hospitals or clinics (*Article 17,* 2000 Measures on Joint Venture Medical Institutions).

Higher level of approving authority

The establishment of a foreign-invested medical institution used to require approval from the central office of the NHFPC (*Articles 11,* 2000 Measures on Joint Venture Medical Institutions). However, the approval right has been delegated to the provincial counterparts of the NHFPC (and now NHC) since 2011 (Notice of the Ministry of Health on Adjusting the Examination and Approval Authority of Sino-Foreign Equity or Cooperative Joint Venture Medical Institutions 2011).

In comparison, the establishment of a domestic-owned medical institution should be approved by the local counterparts of the NHC at the county, prefecture or provincial level.

Preferential policies for central and western China

The investor qualification requirements and establishment criteria (see Requirements on investor qualification and Restrictions on investee institution) may be relaxed appropriately where both of the following conditions are met:

 Where the foreign-invested medical institution is to be established in central and western China or in the old revolutionary-base, minority-inhabited, remote or poor areas (老、少、边、穷地区). • Where the service scope and items to be provided by the joint venture medical institution belong to a service field encouraged by the state.

(*Article 14,* 2000 Measures on Joint Venture Medical Institutions.)

For example, the Sichuan provincial counterparts of the NHFPC and MOFCOM jointly promulgated the Administrative Measures of Sichuan Province for the Sino-Foreign Equity/Co-operative Joint Venture Medical Institutions 2012 (四川省中外合资、合作医疗机构管 理办法), which relaxed the 70% foreign shareholding limit in the 2000 Measures on Joint Venture Medical Institutions and raised the cap to 90% instead.

Note that the above-mentioned Sichuan local measures were adopted at a time when the tone of macroeconomic policy was to encourage foreign investors to set up WFOE medical institutions in China. Since April 2015, the policy has again become retightened (see Post-2015 retightened measures) and it is difficult to anticipate whether this preferential policy in Sichuan province would be implemented by the local government.

Besides, according to the Notice on the Reform of Examination and Approval of Sino-foreign Joint Venture and Co-operative Medical Institutions in China (Sichuan) Pilot Free Trade Zone 2017 (关于在中国(四川)自由贸 易试验区开展中外合资合作医疗机构审批等改革事项 的通知), foreign investors are not subject to limitations on the investment amount and the operation term when setting up a joint venture and co-operative medical institutions in the Sichuan FTZ.

Preferential policies for Hong Kong, Macau, and Taiwan investors

Investors from Hong Kong or Macau can receive preferential policies under the:

- Mainland and Hong Kong Closer Economic Partnership Arrangement 2003 (內地与香港关于建立更紧密经贸 关系的安排) and its subsequent supplements.
- Mainland and Macau Closer Economic Partnership Arrangement 2003 (内地与澳门关于建立更紧密经贸 关系的安排) and its subsequent supplements.

(Collectively, the CEPA.)

Similarly, investors from Taiwan can receive preferential policies under the Cross-strait Economic Co-operation Framework Agreement 2010 (海峡两岸经济合作框架协议).

Subsequently, subordinate legislation was issued to implement this economic partnership or co-operation arrangements, the most important being:

• Interim Administrative Measures for the Establishment of Wholly-owned Hospitals by Hong Kong/Macau Service Providers in the Mainland 2010 (2010 Measures on HK/Macau-invested WFOE Hospitals, with effect from 1 January 2011).

• Interim Administrative Measures for the Establishment of Wholly-owned Hospitals by Taiwan Service Providers in the Mainland 2010 (2010 Measures on Taiwaninvested WFOE Hospitals, with effect from 1 January 2011).

No foreign shareholding cap

Hong Kong, Macau or Taiwan service providers can set up WFOE hospitals in China and the 70% foreign shareholding cap applicable to general foreign investors does not apply.

In December 2011, the first wholly Taiwan-owned hospital, Landseed International Hospital (上海禾新 医院), was established in Shanghai. In January 2013, the first wholly Hong Kong-owned hospital, C-MER (Shenzhen) Dennis Lam Eye Hospital (深圳希玛林顺潮 眼科医院), was established in Shenzhen.

Place of location extended across China

Initially, WFOE hospitals could be established by:

- Hong Kong or Macao service providers solely in Shanghai, Fujian, Guangdong, Hainan, and Chongqing.
- Taiwan service providers solely in Shanghai, Jiangsu, Fujian, Guangdong, and Hainan.

These were subsequently extended to all cities at or above the prefectural level in China (Notice of the Ministry of Health and the Ministry of Commerce on Expanding the Scope of Regions Where Service Suppliers from Hong Kong and Macau May Establish Wholly-owned Hospitals in the Mainland 2012 and Several Opinions on Accelerating the Operations of Medical Institutions with Social Capital 2013 (关于加快 发展社会办医的若干意见)).

Higher establishment conditions

WFOE hospitals are subject to higher establishment conditions, including:

- Reaching the standards for a class II hospital with respect to the facilities, medical devices, physicians, and management system.
- Having a total investment of at least RMB50 million in the case of a class III hospital or RMB20 million in the case of a class II hospital. The total investment requirement may be appropriately reduced if the WFOE hospital is to be established in the old revolutionarybase, minority-inhabited, remote or poor areas.

(*Article 10*, 2010 Measures on HK/Macau-invested WFOE Hospitals and *Article 10*, 2010 Measures on Taiwan-invested WFOE Hospitals.)

Stricter investor qualification review standard

To establish a WFOE hospital, the investor must submit application materials to prove that the investor can provide either of the following:

- Internationally advanced hospital management experience, management models, and service models.
- Internationally leading medical technologies.

However, the submission of similar materials is not required in the application set for a joint venture hospital (see Requirements on investor qualification).

In addition, for Hong Kong or Macau investors to qualify for the benefits under the CEPA arrangements, they must meet the definition and relevant requirements of "service provider" as stipulated in the CEPA (see Practice note, Regulation of telecommunications sector in China: Preferential policies under CEPAs).

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