Provisions on the Administration of Foreign-Invested Medical Institutions of the PRC

Dan Young Business Consultancy — www.danyoungcpa.com

Unofficial English translation prepared for reference only. The official Chinese text prevails.

Contents

Table of Contents 1

Chapter I — General Provisions 1

Chapter II — Conditions for Establishment 2

Chapter III — Examining and Approving Procedures 3

Chapter IV — Operation and Supervision 3

Chapter V — Supplementary Provisions 4

Issued jointly by the Ministry of Health (now National Health Commission) and the Ministry of Foreign Trade and Economic Cooperation (now Ministry of Commerce) on May 15, 2000

Effective: July 1, 2000

Table of Contents

- Chapter I — General Provisions
- Chapter II — Conditions for Establishment
- Chapter III — Examining and Approving Procedures
- Chapter IV — Operation and Supervision
- Chapter V — Supplementary Provisions

Chapter I — General Provisions

Article 1 — These Provisions are formulated in accordance with the Law of the PRC on Sino-Foreign Equity Joint Ventures, the Law of the PRC on Sino-Foreign Cooperative Joint Ventures, the Law of the PRC on Wholly Foreign-Owned Enterprises, the Practicing Physicians Law of the PRC, the Regulations on the Administration of Medical Institutions, and other relevant laws and regulations for the purposes of further opening up to the outside world, promoting the development of the medical and healthcare sector, and regulating the establishment of foreign-invested medical institutions.

Article 2 — For the purposes of these Provisions, the term "foreign-invested medical institution" refers to a medical institution established within the territory of China by a foreign medical institution, enterprise, or other economic organization (hereinafter referred to as "foreign investor") in the form of a Sino-foreign equity joint venture or a Sino-foreign cooperative joint venture. The establishment of wholly foreign-owned medical institutions is prohibited.

Source: https://www.danyoungcpa.com/provisions-foreign-invested-medical-institutions-prc-2000/

Article 3 — Foreign-invested medical institutions shall be established in compliance with state policies, conform to the regional health planning and the planning for the establishment of medical institutions, and meet the state-prescribed basic standards for medical institutions.

Article 4 — The health administrative department under the State Council shall be responsible for the supervision and administration of foreign-invested medical institutions nationwide. The health administrative departments of local people's governments at or above the county level shall be responsible for the routine supervision and administration of foreign-invested medical institutions within their respective administrative areas. The administrative department of foreign trade and economic cooperation under the State Council and the local foreign trade and economic cooperation administrative departments shall, within the scope of their respective duties, be responsible for the examination, approval, and administration of foreign-invested medical institutions.

Article 5 — In principle, foreign-invested medical institutions shall not be established as branches. The duration of operation of a foreign-invested medical institution shall not exceed 20 years. Upon expiration of the duration of operation, an application for extension may be submitted in accordance with relevant state provisions.

Chapter II — Conditions for Establishment

Article 6 — The Chinese party to a Sino-foreign equity joint venture or Sino-foreign cooperative joint venture medical institution shall satisfy all of the following conditions: (a) it is a medical institution, enterprise, or other economic organization with the status of a legal person; (b) it has experience in investment in and management of medical institutions; (c) it is capable of providing necessary operational conditions for the foreign-invested medical institution.

Article 7 — The foreign investor in a foreign-invested medical institution shall satisfy all of the following conditions: (a) it is a medical institution, enterprise, or other economic organization with the status of a legal person; (b) it has experience in investment in and management of medical institutions or medical-related sectors; (c) it has strong financial strength and advanced medical technology; (d) it is capable of providing internationally advanced management experience and service models for the medical institution; (e) it has a sound reputation and reputation in international medical practice.

Article 8 — A foreign-invested medical institution shall satisfy the following conditions: (a) it is independently established as a legal person; (b) its total investment shall not be less than RMB 20 million; (c) the proportion of capital contribution or shareholding of the Chinese party in a Sino-foreign equity joint venture medical institution shall not be less than 30 percent; (d) the duration of the joint venture or cooperative operation shall not exceed 20 years; (e) the institution meets the basic standards for medical institutions prescribed by the state and the relevant regulations on practicing physicians and medical technology personnel; (f) the institution has the ability to provide medical services commensurate with the level of an international medical institution.

Article 9 — A foreign-invested medical institution may be established as a general hospital, a specialized hospital, or a specialized disease prevention and treatment center (institution).

Article 10 — The establishment of a foreign-invested medical institution shall not be approved under any of the following circumstances: (a) the application does not conform to the regional health planning or the planning for the establishment of medical institutions; (b) the Chinese party or the foreign investor fails to satisfy the conditions prescribed by these Provisions; (c) the total investment or other conditions of the medical institution fail to meet state requirements; (d) the foreign-invested medical institution fails to meet the basic standards for medical institutions prescribed by the state; (e) the proposed establishment might compromise state security or the public interest.

Source: https://www.danyoungcpa.com/provisions-foreign-invested-medical-institutions-prc-2000/

Chapter III — Examining and Approving Procedures

Article 11 — The establishment of a foreign-invested medical institution shall be subject to the following examination and approval procedures: (a) the Chinese party applying to establish the medical institution shall submit an application and the relevant documents to the health administrative department at the provincial level of the place where the proposed medical institution is to be located; (b) the provincial-level health administrative department shall, within 45 working days from the date of receipt of all application documents, complete the preliminary examination and, where the conditions are met, report the application to the health administrative department under the State Council for examination and approval; (c) the health administrative department under the State Council shall, within 45 working days from the date of receipt of the preliminary examination opinion and the complete set of application documents submitted by the provincial-level health administrative department, make a decision on approval or disapproval; (d) upon obtaining the approval document from the health administrative department under the State Council, the Chinese party shall apply to the administrative department of foreign trade and economic cooperation for a certificate of approval for a foreign-invested enterprise; (e) upon obtaining the certificate of approval for a foreign-invested enterprise, the Chinese party shall apply to the health administrative department that conducted the preliminary examination for a practice license for a medical institution within the prescribed time limit.

Article 12 — The application documents to be submitted for establishing a foreign-invested medical institution shall include: (a) the application for the establishment of the medical institution; (b) the feasibility study report; (c) the joint venture or cooperative contract and the articles of association signed by the Chinese and foreign parties; (d) the capital verification report or credit certificate issued by a certified public accountant; (e) the certificate of registration (photocopy), the identity certificate of the legal representative, and the bank credit certificate of each of the Chinese and foreign parties; (f) the credentials and identification documents of the proposed principal responsible person and the medical and technical personnel; (g) the approval document on the site selection, the land use approval, and the environmental protection approval, among other relevant approval documents, for the proposed medical institution; (h) other documents required by the examining and approving authorities.

Article 13 — The health administrative department under the State Council may, when examining and approving the establishment of a foreign-invested medical institution, organize an expert panel to conduct an assessment and review as needed.

Chapter IV — Operation and Supervision

Article 14 — A foreign-invested medical institution, as an independent legal person, shall be responsible for its own profits and losses, bear civil liability independently, and accept the supervision and administration of the health administrative department and other relevant administrative departments.

Article 15 — A foreign-invested medical institution shall practice within the scope of its approved practice and shall comply with the laws, regulations, and rules of the PRC on medical institutions and practicing physicians.

Article 16 — A foreign-invested medical institution shall comply with relevant state provisions on foreign exchange control and shall not, without authorization, transfer assets or funds abroad.

Article 17 — The fees of a foreign-invested medical institution shall be governed by relevant state provisions. A foreign-invested medical institution may, with the approval of the pricing authority, set its own prices for certain medical services.

Article 18 — A foreign-invested medical institution shall employ medical and technical personnel in accordance with the relevant provisions of the Practicing Physicians Law of the PRC and the Regulations on the Administration of Medical Institutions. The proportion of foreign physicians and technical personnel in a

Source: https://www.danyoungcpa.com/provisions-foreign-invested-medical-institutions-prc-2000/

foreign-invested medical institution shall not exceed the proportion prescribed by the state. Foreign physicians shall obtain a permit for short-term practice of medicine in China in accordance with the law.

Article 19 — A foreign-invested medical institution shall strictly comply with laws and regulations on infectious disease prevention and control, maternal and child healthcare, blood management, drug administration, medical device supervision, medical waste management, and other relevant fields.

Article 20 — Where a foreign-invested medical institution falls under any of the following circumstances, the health administrative department shall, depending on the circumstances, order it to make corrections within a prescribed time limit, issue a warning, impose a fine, or revoke its practice license for a medical institution: (a) practicing beyond the approved scope of practice; (b) employing personnel not qualified under the law to engage in medical and health technical work; (c) failing to comply with relevant provisions on infectious disease prevention and control, maternal and child healthcare, or other public health management; (d) other circumstances in violation of laws and regulations.

Article 21 — The health administrative department shall, on an annual basis, conduct a practice inspection of the foreign-invested medical institution. An institution that fails the practice inspection shall be dealt with in accordance with relevant provisions.

Chapter V — Supplementary Provisions

Article 22 — Medical institutions established in the mainland of China by investors from the Hong Kong Special Administrative Region, the Macao Special Administrative Region, and the Taiwan region shall be governed by the relevant provisions of the state, and matters not covered by such provisions shall be handled with reference to these Provisions.

Article 23 — The application for the establishment of branches by foreign-invested medical institutions shall be subject to the examination and approval of the health administrative department under the State Council in accordance with the provisions of the regional health planning.

Article 24 — These Provisions shall enter into force on July 1, 2000. The Interim Provisions on the Administration of Foreign-Invested Medical Institutions jointly promulgated by the Ministry of Health and the Ministry of Foreign Trade and Economic Cooperation on February 27, 1989 shall be repealed simultaneously.

Disclaimer: This translation is provided for informational purposes only and does not constitute legal advice. While every effort has been made to ensure accuracy, only the original Chinese-language text issued by the relevant Chinese authorities carries legal force. Users should consult qualified legal professionals regarding the application or interpretation of these Provisions in specific circumstances. Dan Young Business Consultancy assumes no liability for any errors, omissions, or reliance on this translation.

Source: https://www.danyoungcpa.com/provisions-foreign-invested-medical-institutions-prc-2000/