**Hainan Provincial Health Commission Notice on Issuing Hainan Province’s Implementation Measures on Optimizing the Health Business Environment**

QWZF [2019] No.2

To: all municipal, county and autonomous county Health and Family Planning Commissions, the Sansha Social Undertaking and Rear Base Administrative Bureau, Yangpu Health and Family Planning Bureau, all units directly under the Commission and all of the Commission’s departments: *Hainan Province’s Implementation Measures on Optimizing the Health Business Environment* (as attached hereto) have been formulated by the Hainan Provincial Health Commission in accordance with requirements of the *Notice of the State Council on Several Measures for Supporting the Deepening of Reform and Innovation in Pilot Free Trade Zones* (GF [2018] No.38), the *Notice of the State Council on the Nationwide Implementation of “Separate Operating Permits and Business Licenses” Reform* (GF [2018] No.35), and the *Notice of the General Office of the CPC Provincial Committee and the General Office of the Provincial Government on Issuing the Hainan Action Plan on Improving the Business Environment (2018-2019)* (QBF [2018] No.69). We hereby issue you with these *Implementation Measures* and request you to conscientiously implement the same in combination with actual conditions.

Hainan Provincial Health Commission

March 5, 2019

(This document is public and is to be publicly disseminated without prejudice)

**Hainan Provincial Implementation Measures on Optimizing the Health Business Environment**

In order to effectively solve the problems in optimizing the provincial health system’s business environment, and to provide high-quality and efficient health services, the Commission—in connection with the actual health work in Hainan Province and in accordance with requirements of the *Notice of the State Council on Several Measures for Supporting the Deepening of Reform and Innovation in Pilot Free Trade Zones* (GF [2018] No.38), the *Notice of the State Council on the Nationwide Implementation of “Separate Operating Permits and Business Licenses” Reform* (GF [2018] No.35), and the *Notice of the General Office of the CPC Provincial Committee and the General Office of the Provincial Government on Issuing the Hainan Action Plan on Improving the Business Environment (2018-2019)* (QB [2018] No.69)—has formulated eight reform measures to optimize the health business environment, including the implementation of a notification and commitment system for the deployment of Class B large-type medical equipment in socially-run medical institutions.

I. Allocation of Class B large-type medical equipment in social medical institutions subject to the notification and commitment system.

The Hainan Provincial Health Commission Review and Approval Office shall—according to the application materials set forth in Article 20 of the *Notice on Issuing (for Trial Implementation) Administrative Measures for Allocation and Use of Large Medical Equipment* (GWGHF [2018] No.12)—review the application materials submitted by the applicant (limited to social medical institutions) for allocation. Where the materials meet the requirements, after the applicant signs a letter of commitment on notification whereby the applicant undertakes to be in compliance with the review and approval conditions, the application for allocation shall be accepted and the *Allocation License for Class B Large Medical Equipment* shall be issued on the spot, and the applicant organization shall complete the allocation of corresponding large medical equipment within 18 months of obtaining the *Allocation License*.

Strengthening supervision measures during and after the *Allocation License* has been issued:

1. The third-party expert shall review and evaluate the items declared by the medical device user within 10 working days after the license has been issued. Should the evaluation result prove it not appropriate for an *Allocation License* to be issued, the applicant shall be deemed to have violated his/her commitment, in which case the Hainan Provincial Health Commission Review and Approval Office shall revoke the *Allocation License* according to Article 69 of the *People's Republic of China Administrative License Law* and dispose of the same as required by Article 78 thereof.
2. Within 10 working days after the license is issued, the Hainan Provincial Health Commission Review and Approval Office shall—in writing—notify the health administrative authorities of the place where the institution which will use the large medical equipment is located that the license has been issued. All municipal, county (or district) administrative health departments shall carry out the supervision and inspection at least once within the 5 day period after the large medical equipment has been installed. Where the applicant's conduct is found to be inconsistent with the applicant’s commitment, a written report shall—in accordance with Articles 69 and 78 of the *People's Republic of China Administrative License Law*, or relevant clauses of the *Notice on Issuing (for Trial Implementation) Administrative Measures for the Allocation and Use of Large Medical Equipment*—be submitted to the Hainan Provincial Health Commission for disposal based on that fact.
3. For those who have obtained—via the notification and commitment system—the *Allocation License* and whose license has been revoked, the notification and commitment system is not applicable to their re-application for an *Allocation License*.
4. If, lacking justifiable reasons, the Class B large medical equipment fails to be allocated within the prescribed period, the *Allocation License* will be automatically invalidated, and shall be canceled by the Hainan Provincial Health Commission.
5. If it is found that the applicant fails to act in conformity with the commitment, the applicant shall—in accordance with the law—be held liable for severe punishment.

II. *Short-Term Practice Permit for Foreign Doctors in China* subject to the notification and commitment system.

1. All municipal, county (or district) administrative health departments shall review the submitted application materials according to the requirements set forth by Article 10 of the *Interim Measures for the Administration of Foreign Doctors' Temporary Practice of Medicine in China* (Order No. 24 of the former Ministry of Health) as amended on January 19, 2016. Where such materials prove satisfactory after review, a letter of commitment on notification whereby the applicant undertakes to be in compliance with the review and approval conditions shall be signed by (or on behalf of) the applicant, after which the *Short-Term Practice Permit for Foreign Doctors in China* shall be issued on the spot.
2. With the exception of Haikou and Sanya, the matters related to reviewing and approving short-term medical practice in China by foreign medical groups shall be delegated to the administrative health departments of counties (districts) or municipalities.

Strengthening supervision measures during and after the issuance of permit:

1. For those who have obtained—via the notification and commitment system—the *Short-Term Practice Permit* and whose permit has been revoked, the notification and commitment system is not applicable to the re-application for the *Short-Term Practice Permit*.
2. Where the applicant deliberately conceals any relevant information or provides false materials to obtain the *Short-term Practice Permit*, Article 78 of the *Administrative License Law* shall apply.
3. If it is found that the applicant fails to act in conformity with the commitment, Article 69 of the *Administrative License Law* shall apply and the applicant shall—in accordance with the law—be held liable for severe punishment.

III. Public place sanitation permit subject to the notification and commitment system.

All municipal, county (or district) administrative health departments shall review the application submitted materials according to the application materials set forth by Article 23 of the Detailed Rules for the Implementation of the Regulation on the Administration of Sanitation in Public Places (Order No.80 of the former Ministry of Health) as amended on December 26, 2017. Where such materials are proved satisfactory after review, a letter of commitment on notification whereby the applicant undertakes to be in compliance with the review and approval conditions shall be signed by the applicant, after which the Public Place Sanitation Permit shall be issued on the spot.

Strengthening supervision measures during and after the issuance of permit:

1. Within 15 working days after the issuance of the permit, all municipal, county (or district) administrative health departments shall carry out on-site review of the public places. Where it is found that the actual situation is not in conformity with the commitment, the applicant shall be ordered to rectify within a specified period. If the applicant refuses to make rectification within such period or fails to meet the statutory conditions after rectification, the Public Place Sanitation Permit shall be revoked in accordance with Article 69 of the Administrative License Law.

(ii) For those who have obtained the Public Place Sanitation Permit through the notification and commitment system and whose permit has been revoked, the notification and commitment system is not applicable to the re-application for the Public Place Sanitation Permit.

(iii) Where the applicant conceals any relevant information or provides false materials to obtain the Public Place Sanitation Permit, Article 78 of the Administrative License Law shall apply and any application submitted by such applicant for the Public Place Sanitation Permit will not be accepted within one year from the date of revocation.

1. If it is found that the applicant fails to act in conformity with the commitment, the applicant shall—in accordance with the law—be held liable for severe punishment.

IV. According to their own technical capabilities and all relevant regulations, medical institutions may carry out stem cell cutting-edge clinical medical technology research projects. The medical institution carrying out clinical stem cell research shall be responsible for the clinical research’s quality management. The medical institution shall review, register and record clinical stem cell research projects; shall supervise the process; and, shall carry out quality management and risk control over the whole process of clinical research.

The medical institution carrying out clinical stem cell research projects shall comply with the *Notice on Issuing (for Trial Implementation) Administrative Measures for Stem Cell Clinical Research* (GWKJF [2015] No.48) jointly issued by the former State Health and Family Planning Commission and the China Food and Drug Administration. Any medical institution carrying out clinical stem cell research in the Hainan Bo'ao Lecheng International Medical Tourism Pilot Zone (Hope City) shall be subject to the regulations otherwise formulated by Hope City.

V. You shall encourage the recruitment of TCM professionals to provide treatment and health care services in medical institutions; shall actively explore reforms in terms of improved service standards for the “preventive treatment of disease”, for personnel access and charging standards; and shall make efforts to meet the people's growing demand for multi-tiered and diversified TCM treatment and health care services.

You shall form and improve the technical service system of TCM “preventive treatment of disease” throughout the whole province, with provincial TCM hospitals as the leader, TCM hospitals in cities and counties, private TCM hospitals and other non-medical TCM health care institutions as the backbone, and township hospitals and community health service institutions as grassroots; standardize the construction of the department of “preventive treatment of disease” in TCM medical institutions, standardize the service content of TCM health care institutions, and improve the service quality of “preventive treatment of disease” and health care.

You shall—on the premise of completing their work tasks in medical institutions—encourage TCM doctors to provide health care consultation and conditioning services in TCM health care institutions; allow qualified professional and skilled personnel in TCM health care institutions to provide conditioning services in medical and health institutions after examination; strengthen the construction of teams of TCM technicians in the fields of health and health care in TCM medical institutions; and encourage medical institutions to carry out the training on TCM knowledge and skills for practitioners in TCM health and health care institutions.

VI. Optimizing access services for physician practice registration.

The optimization measures include:

1. The administrative health departments of all municipalities and counties (districts) shall comprehensively promote online business handling, shall guide applicants to handle business online and shall provide free online registration services;
2. If the conditions for practicing registration of doctors and the materials submitted meet the requirements, the statutory time limit for review and approval of practicing registration of doctors shall be reduced from 20 working days to on the spot completion;
3. The materials for review and approval shall be simplified. In the process of registration review and approval (or registration for filing), the municipal or county (district) administrative health department may—for verification—obtain online materials such as the physicians’ *Qualification Certificate* and the physicians’ *Practicing Certificate*, and shall not require the applicant to provide physical originals;
4. After obstetricians and gynecologists have passed the maternal and infant health care technical training and examination, the relevant content of maternal and infant health care technical services shall be added to the physicians’ practicing certificates, and a *Maternal and Infant Health Care Technical Examination Certificate* will not be issued separately.

VII. Medical institutions’ access services shall be optimized in terms of establishment approval and practice registration. The optimization measures include:

(i) The administrative health departments shall comprehensively promote online business handling, shall guide applicants towards handling business online, shall accelerate electronic registration management and shall provide free online registration services;

(ii) Statutory time limits shall be shortened. For the review and approval of an establishment, they shall be shortened from a max of 30 days to no more than 15 working days; for review and approval of a practice’s registration, they shall be shortened from a max of 45 days to no more than 20 working days; for the review and approval in the event of a “Two-In-One Certificate” for establishment approval and practice registration to no more than 20 working days; for establishment registration of out-patient departments, clinics and health centers (rooms) established by legal persons and other organizations to serve internal staff and workers, they shall be shortened from a max of 15 days to no more than 10 days; and for the carrying out of practicing activities of TCM clinics, they shall be provided immediately;

(iii) The materials for review and approval shall be simplified. Materials such as the *Business License*, *Qualification Certificate* and the person in charge of each of a medical institution’s departments *Practice Certificate* can be obtained online for verification by sharing information or network;

(iv) The applicant for the practice registration of a medical institution will not be required to provide a *Capital Verification Certificate*, and the applicant shall be responsible for the authenticity of the registered capital;

1. Where for-profit medical institutions carry out business activities related to medical treatment (such as drugs and devices), the premises for such medical activities shall be separated from other premises for business activities. The establishment approval and practicing registration of medical institutions in Hope City shall be subject to the regulations otherwise formulated by Hope City.

VIII. Access services for hygiene licenses of enterprises producing disinfection products (except those producing disposable medical supplies) shall be optimized.

The optimization measures include:

1. The administrative health departments of all municipalities and counties (districts) shall comprehensively promote online business handling, shall guide the applicants to handle business online and shall provide free online registration services;
2. The statutory time limit for approval shall be shortened from a max of 20 days to 10 working days.
3. The materials for review and approval shall be simplified. After verification, materials such as the *Business License* will be available online.

Administrative health departments at all levels throughout Hainan Province shall attach great importance to the construction of the China (Hainan) Pilot Free Trade Zone (Port), shall effectively change the concept of service, shall establish the concept of patient and enterprise priority, and shall implement various reform measures including the implementation of the notification and commitment licensing system. Applicants have the right to choose whether or not to adopt it. Those who choose not to adopt shall be subject to review and approval in accordance with the relevant provisions of laws, rules and regulations. The applicant who violates the notification commitment shall be recorded as such. All municipalities and counties shall strengthen the construction of review and approval windows, shall allocate sufficient staff and strengthen their work teams. In order to ensure that the reform measures are effectively implemented, the review and approval window for accepting, handling and processing shall be centralized. All departments of Hainan Provincial Health Commission shall further improve related systems, shall optimize the health business environment, and constantly stimulate market vitality and social creativity.

Copy: Regulations Department of National Health Commission of the People’s Republic of China, Office of Commission for Deepening Overall Reform of Provincial Party Committee, General Office of the Provincial Government.

Issued by the Office of the Hainan Provincial Health Commission on March 5, 2019.