Regulations on the Administration of Medical Institutions of the PRC

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Chapter I — General Provisions

Article 1 — These Regulations are formulated for the purpose of strengthening the administration of medical institutions, promoting the development of medical and health undertakings, and safeguarding the health of citizens.

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Article 2 — These Regulations shall apply to medical institutions such as hospitals, health centers, sanatoriums, outpatient departments, clinics, health offices (rooms), and first-aid stations that are engaged in disease diagnosis and treatment activities.

Article 3 — Medical institutions shall aim to save lives and heal the wounded, prevent and treat diseases, and serve the health of citizens.

Article 4 — The State shall support the development of medical institutions and encourage the establishment of medical institutions through multiple channels and in various forms.

Article 5 — The competent health department of the State Council shall be responsible for the supervision and administration of medical institutions throughout the country. The competent health departments of the local people's governments at or above the county level shall be responsible for the supervision and administration of medical institutions within their respective administrative areas.

The competent departments of the Chinese People's Liberation Army and the Chinese People's Armed Police Force shall, in accordance with these Regulations and the relevant State provisions, be responsible for the administration of the military medical institutions.

Chapter II — Planning, Establishment, and Registration

Article 6 — The competent health department of the local people's government at or above the county level shall, in accordance with the establishment planning for medical institutions within its respective administrative area, formulate plans for the establishment of medical institutions and submit them to the people's government at the same level for approval before implementation.

Article 7 — The establishment of a medical institution by any unit or individual shall be in accordance with the establishment planning for medical institutions and shall be subject to the approval of the competent health department of the local people's government at or above the county level. Specific measures shall be prescribed by the competent health department of the State Council.

Article 8 — To apply for the establishment of a medical institution, the following conditions shall be met:

(1) complying with the establishment planning for medical institutions;

(2) having a suitable name, organizational structure, and premises;

(3) having the funds, facilities, equipment, and professional health technical personnel appropriate to the business carried out;

(4) having corresponding rules and regulations; and

(5) being able to independently bear civil liability.

Article 9 — An entity or individual applying for the establishment of a medical institution shall submit a feasibility study report and a site selection report to the competent health department of the local people's government at or above the county level in accordance with the prescribed procedures.

Article 10 — Where an application for the establishment of a medical institution is approved, an approval document for the establishment of the medical institution shall be issued. Within the period specified in the approval document, the medical institution shall carry out preparatory work for establishment. Upon completion of the preparatory work, an application for practice registration shall be submitted to the competent health department of the people's government at or above the county level.

Where the preparatory work for establishment is not completed within the time limit, the approval document for establishment shall become void.

Chapter III — Practice Registration

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Article 11 — A medical institution shall undergo practice registration with the approval authority before commencing practice.

Medical institutions that have obtained the Practice License for Medical Institutions shall undergo practice registration and obtain the Practice License for Medical Institutions before commencing practice.

Article 12 — To undergo practice registration for a medical institution, the following conditions must be met:

(1) having an approval document for the establishment of a medical institution;

(2) meeting the basic standards for medical institutions;

(3) having a suitable name, organizational structure, and premises;

(4) having the funds, facilities, equipment, and professional health technical personnel appropriate to the business carried out;

(5) having corresponding rules and regulations; and

(6) being able to independently bear civil liability.

Article 13 — The competent health department of the people's government at or above the county level shall, within 45 days from the date of acceptance of the application for practice registration, conduct an examination and verification in accordance with the conditions specified in these Regulations and the basic standards for medical institutions. Where the conditions for practice are met, practice registration shall be granted and a Practice License for Medical Institutions shall be issued; where the conditions for practice are not met, the reasons shall be stated in writing.

Article 14 — No medical institution may change its name, location, legal representative, or main person in charge, diagnosis and treatment subjects, or bed size without approval. Where changes to the above items are necessary, an application shall be submitted to the original registration authority for change of registration.

Article 15 — Where a medical institution ceases practice, it must undergo the formalities for cancellation of registration with the original registration authority. Upon verification and approval by the registration authority, the Practice License for Medical Institutions shall be collected and cancelled.

Where a medical institution that is not located at its registered address ceases practice, it shall undergo practice re-registration.

Article 16 — The Practice License for Medical Institutions shall be verified periodically. The term of verification shall be prescribed by the competent health department of the people's government at or above the provincial level.

Where a medical institution fails to undergo verification within the prescribed time limit without justifiable reasons, the Practice License for Medical Institutions shall become void.

Chapter IV — Practice

Article 17 — Medical institutions shall carry out diagnosis and treatment activities within the scope of the registered diagnosis and treatment subjects. For the items involving special diagnosis and treatment operations such as surgery, radiation therapy, and high-risk interventional diagnosis and treatment, the relevant technical operation specifications and operating procedures shall be complied with.

Article 18 — Medical institutions must affix the Practice License for Medical Institutions, diagnosis and treatment subjects, diagnosis and treatment hours, and fee schedules in a conspicuous position.

Article 19 — Medical institutions shall strengthen the education and training of medical staff in medical ethics and practice norms, strengthen the administration of medical quality, ensure medical safety, and improve the

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standard of diagnosis and treatment.

Article 20 — When practicing medicine, medical staff shall wear uniforms bearing their name, position, or title. Medical institutions shall post the basic information of their practicing medical staff in a conspicuous position.

Article 21 — Medical institutions may not use non-health technical personnel to engage in health technical work.

Article 22 — In the event of a major disaster, accident, epidemic disease, or other emergency, medical institutions and their health technical personnel must obey the dispatch of the competent health department of the people's government at or above the county level.

Article 23 — Medical institutions must, in accordance with the provisions of the relevant laws and regulations, strictly enforce the systems of aseptic disinfection and isolation, adopt scientific and effective measures to treat sewage and waste materials, and prevent and control nosocomial infections.

Article 24 — Medical institutions shall manage their pharmaceuticals, medical devices, and disinfectant products in accordance with the relevant laws and regulations.

Article 25 — Medical institutions shall charge fees for diagnosis and treatment in accordance with the provisions of the people's government or the price department, and shall itemize the details of the fees in accordance with the relevant State provisions.

Article 26 — Medical institutions that issue medical documents such as medical certificates, birth certificates, and death certificates must meet the State provisions on the management of medical documents.

Without the personal diagnosis and treatment of a medical doctor or medical practitioner, no medical institution may issue documents such as disease diagnosis certificates, health certificates, or death certificates. No medical institution may issue false supporting documents.

Article 27 — Medical institutions shall respect the patients' right to know of their conditions, diagnosis, and treatment. Where a patient needs to undergo surgery or special examination or treatment, the medical institution must seek the patient's consent and obtain the signature of the patient's family member or a related person; where the patient's opinion cannot be obtained, the family member or related person shall be sought, and their signature shall be obtained. Where the patient's life is in danger and the opinion of the patient's family member or related person cannot be obtained in time, the attending physician shall propose a treatment plan, and the treatment may be carried out immediately upon approval by the person in charge of the medical institution or an authorized person in charge.

Article 28 — When treating a patient, a medical institution that is restricted by conditions and cannot provide further diagnosis and treatment or has limited capacity shall promptly refer the patient to another medical institution.

Article 29 — Where a medical institution suffers a medical accident, it shall handle the matter in accordance with the relevant State provisions.

Chapter V — Supervision and Administration

Article 30 — The competent health department of the people's government at or above the county level shall exercise the right of supervision and administration over medical institutions in accordance with the following:

(1) being responsible for the establishment, examination, approval, practice registration, and verification of medical institutions;

(2) conducting inspection and evaluation of the practice activities of medical institutions;

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(3) organizing appraisal and assessment of the medical quality and service quality of medical institutions; and

(4) other duties prescribed by laws and administrative regulations.

Article 31 — The State shall implement a system of appraisal and assessment of medical institutions, the specific measures for which shall be formulated by the competent health department of the State Council.

Article 32 — The competent health department of the people's government at or above the county level shall, in the course of supervision and administration, have the right to consult the medical records, fee schedules, account books, and other relevant materials of the medical institution. The medical institution shall not conceal, refuse to provide, or alter the materials.

Chapter VI — Penalties

Article 33 — Where a medical institution violates these Regulations by committing any of the following acts, the competent health department of the people's government at or above the county level may, depending on the circumstances, issue a warning, order it to make corrections, and impose a fine in accordance with the provisions of the relevant laws and regulations; where the circumstances are serious, its Practice License for Medical Institutions may be revoked:

(1) the medical quality of the medical institution is poor and it fails to make corrections after being ordered to do so;

(2) the medical institution violates the relevant laws and regulations on nosocomial infection control;

(3) the medical institution violates the relevant laws and regulations on the management of pharmaceuticals and medical devices; or

(4) other acts in violation of these Regulations.

Article 34 — Where a medical institution is ordered to suspend practice for rectification, a decision on suspension of practice for rectification shall be made in accordance with the following provisions:

(1) a decision on suspension of practice for rectification shall be made by the competent health department of the people's government at or above the county level;

(2) the period of suspension of practice for rectification shall be prescribed by the competent health department of the people's government at or above the county level in accordance with the specific circumstances.

Article 35 — Where a medical institution violates these Regulations and a crime is constituted, criminal liability shall be investigated in accordance with law.

Chapter VII — Supplementary Provisions

Article 36 — The competent health department of the State Council shall be responsible for the interpretation of these Regulations.

Article 37 — The specific standards and measures for the establishment, practice registration, and practice of medical institutions shall be formulated by the competent health department of the State Council.

Article 38 — These Regulations shall enter into force on September 1, 1994. The Measures for the Administration of Medical Institutions promulgated by the State Council on January 15, 1951 shall be repealed simultaneously.

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