

Regulations on the Administration of Medical Waste of the PRC

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Chapter I — General Provisions

Article 1 — These Regulations are formulated for the purpose of strengthening the safety management of medical waste, preventing the spread of diseases, protecting the environment, and safeguarding human health.

Article 2 — These Regulations shall apply to the collection, transport, storage, disposal, supervision, and administration of medical waste. The term "medical waste" refers to waste materials generated by medical and health institutions in the course of medical treatment, disease prevention, health care, and other related activities that are directly or indirectly infectious, toxic, or otherwise hazardous.

Article 3 — The administrative department of health under the State Council and the administrative department of environmental protection under the State Council shall, in accordance with the division of their respective functions and duties, be responsible for the supervision and administration of medical waste nationwide. The relevant departments of the local people's governments at or above the county level shall be responsible for the supervision and administration of medical waste within their respective administrative regions.

Chapter II — General Provisions on Medical Waste Management

Article 4 — The State shall promote a system of centralized and harmless disposal of medical waste. The people's governments at or above the county level shall incorporate the construction of centralized medical waste disposal facilities into their national economic and social development plans, and shall be responsible for organizing the construction of centralized medical waste disposal facilities.

Article 5 — Medical and health institutions shall, in accordance with the provisions of the State, classify and collect medical waste generated by them and deliver it to centralized medical waste disposal entities for disposal. Medical and health institutions in remote areas that are unable to deliver medical waste to centralized disposal entities shall dispose of the medical waste themselves in accordance with the requirements of the competent administrative departments.

Article 6 — Any entity or individual shall have the right to report or file complaints against violations of these Regulations, such as illegal collection, transport, storage, or disposal of medical waste.

Chapter III — Management of Medical Waste at Medical and Health Institutions

Article 7 — Medical and health institutions shall establish and improve a medical waste management responsibility system, the primary responsible person of which shall be the legal representative thereof.

Article 8 — Medical and health institutions shall adopt protective measures against occupational hazards, provide necessary protective articles to the personnel engaged in the collection, transport, storage, and disposal of medical waste, and organize regular health examinations for them.

Article 9 — Medical and health institutions shall classify and collect medical waste in accordance with the provisions. Special packaging materials and containers that meet the standards and are clearly marked shall be used for medical waste.

Article 10 — Medical and health institutions shall establish temporary storage facilities and equipment for medical waste and shall not store medical waste in the open air. The temporary storage time for medical waste shall not exceed two (2) days.

Article 11 — Medical and health institutions shall use special means of transport that are seepage-proof and spill-proof and meet the requirements for transporting medical waste. After each use, the means of transport shall be cleaned and disinfected at a designated location within the medical and health institution.

Article 12 — Medical and health institutions shall, in accordance with the provisions, promptly collect the medical waste generated by them, and classify and place it in special packaging materials and containers. Medical waste shall not be mixed with household waste.

Chapter IV — Centralized Disposal of Medical Waste

Article 13 — Entities engaged in the centralized disposal of medical waste shall apply to the administrative department of environmental protection of the people's government at or above the county level for a business license. Entities that have not obtained a business license shall not engage in activities related to the centralized disposal of medical waste.

Article 14 — Centralized medical waste disposal entities shall collect and transport medical waste from medical and health institutions at fixed times and dispose of them in a centralized manner. Where conditions permit, specialized transport vehicles with sealed compartment bodies shall be used.

Article 15 — Centralized medical waste disposal entities shall install facilities and equipment for the harmless disposal of medical waste that comply with the standards, and shall ensure the normal operation thereof. After completing disposal, the facilities and equipment shall be cleaned and disinfected in accordance with the provisions.

Article 16 — Centralized medical waste disposal entities shall, in accordance with the provisions, install online monitoring devices for pollution sources and maintain the normal operation thereof. They shall undergo regular testing of the effluents and emissions from medical waste disposal facilities.

Article 17 — Centralized medical waste disposal entities shall not charge medical and health institutions fees for centralized medical waste disposal in excess of the prescribed standards.

Chapter V — Supervision and Administration

Article 18 — The administrative departments of health and environmental protection of the local people's governments at or above the county level shall, in accordance with the division of their respective functions and duties, conduct supervision and inspection of the disease prevention and control work and the environmental pollution prevention and control work in the collection, transport, storage, and disposal of medical waste.

Article 19 — The administrative departments of health and environmental protection shall have the authority to enter the entities under inspection to conduct on-site inspections, have access to relevant materials, and take samples for testing. The entities under inspection shall cooperate and shall not refuse.

Article 20 — Where medical waste is transported across provincial-level administrative regions, the entity shall submit an application to the administrative department of environmental protection of the people's government of the province where the medical waste is to be moved out, and may transport the medical waste only after approval.

Chapter VI — Legal Liability

Article 21 — Where a medical and health institution or a centralized medical waste disposal entity commits any of the following acts, the administrative department of health or environmental protection shall order it to make corrections within a prescribed time limit and give it a warning. Where corrections are not made within the prescribed time limit, a fine of not less than 2,000 yuan but not more than 5,000 yuan shall be imposed:

- (1) failing to establish and improve a medical waste management system;
- (2) failing to conduct health examinations for relevant personnel or provide protective articles;
- (3) failing to classify and collect medical waste in accordance with the provisions; or
- (4) failing to clean and disinfect transport vehicles and tools in accordance with the provisions.

Article 22 — Where a medical and health institution or a centralized medical waste disposal entity commits any of the following acts, a fine of not less than 5,000 yuan but not more than 30,000 yuan shall be imposed:

- (1) storing medical waste in the open air, or temporarily storing medical waste for more than the prescribed time limit;

- (2) mixing medical waste with household waste;
- (3) failing to use specialized vehicles that meet the standards for transporting medical waste; or
- (4) failing to install online monitoring devices or maintain their normal operation.

Article 23 — Where a medical and health institution or a centralized medical waste disposal entity, in violation of these Regulations, causes the spread of an infectious disease or environmental pollution, the license of the entity shall be temporarily suspended or revoked. Where a crime is constituted, criminal liability shall be pursued in accordance with the law.

Chapter VII — Supplementary Provisions

Article 24 — The administrative department of health and the administrative department of environmental protection under the State Council may, in accordance with these Regulations, formulate specific management measures respectively.

Article 25 — These Regulations shall be effective as of the date of promulgation.

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