

Regulations on the Administration of Medical Wastes

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The Regulations on the Administration of Medical Wastes, which were adopted at the 10th executive meeting of the State Council on June 4, 2003, are hereby promulgated and shall be implemented as of the day of promulgation.

Wen Jiabao, Premier
June 16, 2003

Regulations on the Administration of Medical Wastes

Chapter 1 General Provisions

Article 1 In order to strengthen the safety administration of medical wastes, to prevent the spreading of diseases, to protect the environment and to guarantee the people's health, the present Regulations are enacted in accordance with the Law of the People's Republic of China on Prevention and Treatment of Infectious Diseases and the Law of the People's Republic of China on Prevention and Treatment of the Environmental Pollution by Solid Wastes.

Article 2 In the present Regulations, "medical wastes" refer to the directly or indirectly infectious, or poisonous, or otherwise harmful wastes generated by medical institutions in medical treatment, prevention, health care, and other relevant activities.

The classified catalogue of medical wastes shall be formulated and promulgated jointly by the administrative departments of public health and environmental protection under the State Council.

Article 3 The present Regulations shall apply to the activities of collection, carrying, storage, and disposal of medical wastes, and the supervision and administration thereof, etc.

The living garbage generated by the infectious patients or suspect infectious patients treated by medical institutions shall be administered and disposed of as medical wastes.

Administration of the anesthetic, psychoactive, radioactive, and poisonous drugs, etc. and the relevant wastes discarded by medical institutions shall be carried out in accordance with the relevant laws and administrative regulations, and the relevant standards and criteria of the state.

Article 4 The state promotes the concentrated no-harm disposal of medical wastes, and encourages the research and development of the technology relating to safe disposal of medical wastes.

The people's governments at the county level and above shall be responsible for organizing the construction of concentrated disposal facilities of medical waste.

The state will give relevant support to the remote and poor areas in the construction of concentrated disposal facilities of medical waste.

Article 5 The administrative departments of public health of the people's governments at the county level and above shall carry out unified supervision and administration of the prevention and treatment of diseases in the activities of collection, transport, storage, and disposal of medical wastes; the administrative departments of environmental protection shall carry out unified supervision and administration of the prevention and treatment of environmental pollution in the activities of collection, transport, storage, and disposal of medical wastes.

Other relevant departments of the people's governments at the county level and above shall, within the scope of their respective duties, be responsible for the relevant supervision and administration relating to the disposal of medical wastes.

Article 6 Every entity and individual shall have the right to disclose, complain, report, and charge against the illegal acts of the medical institutions, of the entities of concentrated disposal of medical wastes, of the supervision and administration departments and the functionary thereof.

Chapter 2 General Provisions on the Administration of Medical Wastes

Article 7 Medical institutions and entities of concentrated disposal of medical wastes shall establish and perfect the system of responsibility for medical waste administration, with their legal representatives as the primary responsible person, and shall earnestly perform their duties to prevent the spreading of infectious diseases and occurrence of environmental pollution accidents caused by medical wastes.

Article 8 Medical institutions and entities of concentrated disposal of medical wastes shall formulate the systems and rules relating to safe disposal of medical wastes and the emergent schemes for accidents; shall set up monitoring departments or equip full-time (part-time) personnel to inspect, supervise and urge, and implement the administration of medical wastes, and to prevent any violation of the present Regulations.

Article 9 Medical institutions and entities of concentrated disposal of medical wastes shall give training on the relevant knowledge of law, professional technology, safety protection, and emergent treatment, etc., to their personnel engaging in collection, transport, storage, and disposal, etc., of medical wastes, and to their managerial personnel.

Article 10 Medical institutions and entities of concentrated disposal of medical wastes shall take effective measures for vocational hygiene and protection, equip necessary protection articles and make regular health inspections for their personnel engaging in collection, transport, storage, and disposal, etc. of medical wastes, and for their managerial personnel; and shall give immunity vaccination to the relevant personnel to protect them from harms to their health.

Article 11 Medical institutions and entities of concentrated disposal of medical wastes shall carry out the set-bill administration in transfer of dangerous wastes in accordance with the Law of the People's Republic of China on Prevention and Treatment of the Environmental Pollution by Solid Wastes.

Article 12 Medical institutions and entities of concentrated disposal of medical wastes shall make registration of the medical wastes, the registered contents shall include the source, type, weight or quantity, time of handover, disposal method, and eventual whereabouts of the medical wastes, and the signature of the handling person, etc. The registration materials shall be kept for at least 3 years.

Article 13 Medical institutions and entities of concentrated disposal of medical wastes shall take effective measures to prevent the medical wastes from losing, leaking or spreading. In the case of losing, leaking or spreading of medical wastes, medical institutions and entities of concentrated disposal of medical wastes shall take emergent treatment measures to mitigate the

harm, and provide medical rescue and on-spot aid to the personnel caused ill; shall at the same time report to the administrative departments of public health and environmental protection of the local people's government at the county level, and notify the entities and residents that might be harmed.

Article 14 Any entity or individual is prohibited from transferring or trading medical wastes. It is prohibited to discard any medical wastes on the way of transport, to dump or pile medical wastes at places not for storage, or to mix the medical wastes with other wastes and living garbage.

Article 15 It is prohibited to mail any medical wastes. It is prohibited to transport medical wastes by railway or air. Where there is a land route, transport of medical wastes by waterway is prohibited; where it is necessary to transport the medical wastes by waterway in absence of any land route, approval must be obtained from the administrative department of environmental protection of the people's government at the level of city divided into districts, and only after strict environmental protection measures have been applied, may the wastes be transported by waterway. It is prohibited to carry medical wastes and passengers on the same conveyance. It is prohibited to transport medical wastes on the waters of the protection zones of drinking water source.

Chapter 3 Administration of Medical Wastes by Medical Institutions

Article 16 A medical institution shall collect the medical wastes it generates in a timely manner, and shall put those wastes, according to their types, in the anti-leaking and anti-penetrating special packages or sealed containers.

There shall be obvious warning signs and instructions on the special packages and containers of medical wastes.

The standards of the special packages and containers and the provisions on the warning signs of medical wastes shall be set forth jointly by the administrative departments of public health and environmental protection under the State Council.

Article 17 A medical institution shall set up facilities and equipment for temporary storage of medical wastes, and may not keep medical wastes in the open air; and the temporary storage of medical wastes may not exceed 2 days.

The facilities and equipment for temporary storage of medical wastes shall be far from the medical treatment area, food processing area, personnel activity area, and the storage places of living garbage, and shall have obvious warning signs and safety measures against leaking, rats, mosquito and flies, cockroaches, theft, and contact by children, etc.

The facilities and equipment for temporary storage of medical wastes shall be disinfected and cleaned regularly.

Article 18 A medical institution shall use anti-leaking and anti-spilling special conveyances to collect and transport the medical wastes to the place of temporary storage according to the time and route of the transport of medical wastes within the institution.

The conveyances shall be promptly disinfected and cleaned at the designated place within the medical institution.

Article 19 A medical institution shall, according to the principle of near and concentrated disposal, hand over the medical wastes to the entity of concentrated disposal of medical wastes in good time. The highly dangerous wastes, such as the culture medium and samples of pathogen, and the storing liquid of bacterium and poisonous seedling shall be disinfected on the spot before being handed over to the entity of concentrated disposal of medical wastes for disposal.

Article 20 The sewage generated by medical institutions and the excretion of the infectious patients or suspect infectious patients shall be strictly disinfected pursuant to the provisions of the state; and only after those wastes have met the discharge standards set forth by the state, may they be

discharged into the sewage disposal system.

Article 21 In the rural areas without the necessary conditions for concentrated disposal of medical wastes, the medical institutions shall dispose on the spot by themselves the medical wastes they generate pursuant to the requirements of the administrative departments of public health and environmental protection of the people's governments at the county level. A medical institution shall meet the following basic requirements in disposal of medical wastes by itself:

- 1) The used disposable medical tools and the medical wastes that can easily harm humans shall be disinfected and destroyed;
- 2) Those that can be burnt shall be burnt in good time;
- 3) Those that can not be burnt shall be buried in a concentrated way after being disinfected.

Chapter 4 Concentrated Disposal of Medical Wastes

Article 22 An entity to engage in the concentrated disposal of medical wastes shall apply for the operation license with the administrative department of environmental protection of the people's government at the county level or above; and an entity without the operation license may not engage in any activities relating to concentrated disposal of medical wastes.

Article 23 An entity of concentrated disposal of medical wastes shall satisfy the following conditions:

- 1) Having the facilities or equipment for storage and disposal of medical wastes meeting the requirements on environmental protection and hygiene;
- 2) Having the trained technical personnel and the corresponding technicians;
- 3) Having the bodies and personnel responsible for the testing and evaluation of the effects of medical waste disposal;
- 4) Having the systems and rules guaranteeing safety disposal of medical wastes.

Article 24 The storage and disposal facilities of the entities of concentrated disposal of medical wastes shall be far from the residence areas of the residents (villagers), the water source protection zones, and with an appropriate protective distance from the work places such as factories and enterprises, etc., and shall comply with the provisions of the administrative department of environmental protection under the State Council.

Article 25 An entity of concentrated disposal of medical wastes shall, at least in every 2 days, go to the medical institutions to collect and transport the medical wastes, and shall be responsible for storage and disposal of the medical wastes.

Article 26 An entity of concentrated disposal of medical wastes shall, when transporting medical wastes, abide by the provisions of the state on the administration of transport of dangerous goods, and shall use the special vehicles with obvious signs for medical wastes. The special vehicles for medical wastes shall be anti-leaking, anti-spilling, and meet other requirements on environmental protection and hygiene.

The special vehicles for medical wastes shall, after the use, be disinfected and cleaned in good time at the place of concentrated disposal of medical wastes.

A special vehicle for medical wastes may not carry any other articles.

Article 27 An entity of concentrated disposal of medical wastes shall, on the way of transport of medical wastes, ensure the safety and may not discard or discharge any medical wastes.

Article 28 An entity of concentrated disposal of medical wastes shall install the on-line monitoring device of pollutant discharge, and ensure constant normal operation of the monitoring device.

Article 29 An entity of concentrated disposal of medical wastes shall, in disposal of medical wastes,

comply with the standards and criteria on environmental protection and hygiene set forth by the state.

Article 30 An entity of concentrated disposal of medical wastes shall, pursuant to the provisions of the administrative departments of environmental protection and public health, make regular testing and evaluation of the effects of environmental pollution prevention and treatment and the hygienic effect of the medical waste disposal facilities. The results of the testing and evaluation shall be kept in the archives of the entity of concentrated disposal of medical wastes, and be reported to the local administrative departments of environmental protection and public health every half a year.

Article 31 An entity of concentrated disposal of medical wastes shall charge the medical institutions the fees for medical waste disposal pursuant to the relevant provisions of the state. The fees for medical waste disposal paid by the medical institutions pursuant to the provisions may be included in their medical costs.

Article 32 The localities shall utilize and reform the existing disposal facilities of solid wastes and other facilities, dispose the medical wastes in a concentrated way, and meet the basic requirements on environmental protection and hygiene.

Article 33 With respect to the cities that have no facilities for concentrated disposal or have insufficient disposal capacities, as of the day of implementation of the present Regulations, the cities at the level of city divided into districts and above shall complete the construction of medical waste concentrated disposal facilities in one year; and the cities at the county level shall complete the construction in 2 years. The people's governments of the provinces, autonomous regions, and municipalities directly under the Central Government shall make provisions on the construction of the concentrated disposal facilities of medical waste of the counties (banners). While the construction of concentrated disposal facilities of medical wastes has not been completed, the relevant local people's government shall organize formulation of the transitional scheme on disposal of medical wastes that is in conformity with the requirements on environmental protection and hygiene, and determine the methods and entities of collection, transport, and disposal of medical wastes.

Chapter 5 Supervision and Administration

Article 34 The administrative departments of public health and environmental protection of the local people's governments at the county level and above shall, pursuant to the present Regulations and the division of their duties, carry out supervision and administration of the medical institutions and the entities of concentrated disposal of medical wastes.

Article 35 The administrative departments of public health of the local people's governments at the county level and above shall make regular supervision and inspection or irregular selective inspection of the disease prevention work, as well as the hygienic protection of the working personnel, in the collection, transport, storage, and disposal of medical wastes undertaken by the medical institutions and the entities of concentrated disposal of medical wastes.

Article 36 The administrative departments of environmental protection of the local people's governments at the county level and above shall make regular supervision and inspection or irregular selective inspection of the environmental pollution prevention and treatment work in the collection, transport, storage, and disposal of medical wastes undertaken by the medical institutions and the entities of concentrated disposal of medical wastes.

Article 37 The administrative departments of public health and environmental protection shall regularly exchange the results of the supervision and inspection and the selective inspection. And if any medical institution or entity of concentrated disposal of medical wastes has been found out to

have any hidden safety danger in the supervision and inspection or the selective inspection, that institution or entity shall be ordered to eliminate the hidden danger immediately.

Article 38 After receiving disclosures, complaints, reports, and charges against the medical institutions, entities of concentrated disposal of medical wastes, departments of supervision and administration, as well as the functionary thereof, the administrative departments of public health and environmental protection shall verify the cases in good time, handle the cases according to law, and promulgate the handling results.

Article 39 The administrative departments of public health and environmental protection have the right to take the following measures in performance of their supervision and administration duties:

- 1) Making on-spot inspection of the relevant entities, getting to know the information, making on-stop monitoring, and making investigation and collecting evidence;
- 2) Consulting or duplicating the relevant materials concerning the administration of medical wastes, and collecting samples;
- 3) Ordering the entities and individuals violating the present Regulations to stop the illegal acts;
- 4) Sealing or temporarily detaining the places, equipment, conveyances and articles suspected of violating the present Regulations;
- 5) Investigating and punishing the acts violating the present Regulations.

Article 40 Where spreading of infectious diseases or any environmental pollution accident is caused as a result of improper administration of medical wastes, or there is evidence to prove possible occurrence of spreading of infectious diseases or of any environmental pollution accident, the administrative departments of public health and environmental protection shall take temporary control measures to evacuate the people and control the scene, and shall, according to the needs, order suspension of the operation that has caused or might cause the spreading of infectious diseases or any environmental pollution accident.

Article 41 Medical institutions and entities of concentrated disposal of medical wastes shall cooperate with the relevant departments in the inspection, monitoring, investigation and evidence collection, and may not refuse or obstruct, or provide falsified materials.

Chapter 6 Legal Liabilities

Article 42 Where any local people's government at the county level or above fails to follow the present Regulations to organize the construction of the concentrated disposal facilities of medical waste or the formulation of the transitional scheme on disposal of medical wastes, the people's government at the next higher level shall circulate a notice of criticism to it, and order it to complete the construction of the concentrated disposal facilities of medical waste or to formulate the transitional scheme on disposal of medical wastes within a prescribed time limit; and may give administrative sanctions to the major principals of the government and the liable personnel in charge.

Article 43 Where any administrative department of public health or environmental protection, or any other relevant department of the people's government at the county level or above fails to follow the present Regulations to perform the supervision and inspection duty, fails to deal with in good time any illegal act of the medical institution or entity of concentrated disposal of medical wastes, which has been found out, fails to take timely measures to mitigate the danger in the case of spreading of infectious disease or environmental pollution accident or possible spreading or accident, or has committed any other act of neglect of duty, breach of duty, or malfeasance, the people's government at the corresponding level or at the next higher level shall order it to get right and circulate a notice of criticism to it; where spreading of infectious disease or any environmental pollution accident is caused, the major principals, the liable personnel in charge, and other directly liable personnel shall be given the administrative sanctions of demotion, removal from office, or dismissal according to

law; the criminal liabilities shall be investigated for according to law if a crime has been constituted.

Article 44 Where any administrative department of environmental protection of the people's government at the county level or above issues the operation license to any entity of concentrated disposal of medical wastes in violation of the present Regulations, the people's government at the corresponding level or at the next higher level shall circulate a notice of criticism to that department and order it to take back the issued license; and may give administrative sanctions to the major principals, the liable personnel in charge and other directly liable personnel.

Article 45 Where any medical institution or entity of concentrated disposal of medical wastes is under any of the following situations in violation of the present Regulations, the administrative department of public health or environmental protection of the local people's government at the county level or above shall, according to their respective duties, order that institution or entity to get right within a prescribed time limit, and give it a warning; and impose on it a fine ranging from 2,000 Yuan to 5,000 Yuan for failure to get right within the said time limit:

- 1) Failing to establish and perfect the system of medical waste administration, or failing to set up the monitoring body or equip the full-time (part-time) personnel;
- 2) Failing to give training to the relevant personnel on the relevant knowledge of law, professional technology, safety protection, and emergent treatment, etc.;
- 3) Failing to take vocational hygienic protection measures for the personnel engaging in collection, transport, storage and disposal of medical wastes, and to the managerial personnel;
- 4) Failing to make registration of the medical wastes or failing to keep the registration materials;
- 5) Failing to promptly disinfect and clean the used conveyance or vehicle of transport of medical wastes at the designated place;
- 6) Failing to collect or transport the medical wastes in good time;
- 7) Failing to make regular testing or evaluation of the effects of environmental pollution prevention and treatment and the hygienic effects of the medical waste disposal facilities, or failing to keep in archives or report the testing or evaluation results.

Article 46 Where any medical institution or entity of concentrated disposal of medical wastes is under any of the following situations in violation of the present Regulations, the administrative department of public health or environmental protection of the local people's government at the county level or above shall, according to their respective duties, order that institution or entity to get right within a prescribed time limit, give it a warning and may impose on it a fine of no more than 5,000 Yuan concurrently; and shall impose a fine ranging from 5,000 Yuan to 30,000 Yuan for failure to get right within the said time limit:

- 1) Using the storage facilities or equipment failing to meet the requirements on environmental protection and hygiene;
- 2) Failing to place the medical wastes in the special packages or containers according to their types;
- 3) Failing to use the special vehicles in conformity with the standards to transport the medical wastes or using the vehicles of transport of medical wastes to transport any other articles;
- 4) Failing to install the on-line monitoring device for discharge of pollutants or the monitoring device is not in constant normal operation.

Article 47 Where any medical institution or entity of concentrated disposal of medical wastes is under any of the following situations, the administrative department of public health or environmental protection of the local people's government at the county level or above shall, according to their respective duties, order that institution or entity to get right within a prescribed time limit, give it a warning and impose on it a fine ranging from 5,000 Yuan to 10,000 Yuan concurrently; and shall impose on it a fine ranging from 10,000 Yuan to 30,000 Yuan for failure to get right within the said time limit; where spreading of infectious disease or any environmental pollution accident is caused, the practice license or operation license shall be suspended or revoked by the department that issued the license; and the criminal liabilities shall be investigated for according to law if a crime has been constituted:

- 1) Discarding medical wastes on the way of transport, dumping or piling medical wastes at any place not for storage, or mixing the medical wastes with other wastes or living garbage;
- 2) Failing to execute the system of set-bill administration of transport of dangerous wastes;
- 3) Giving medical wastes to any entity or individual without the operation license for collection, transport, storage, or disposal;
- 4) Failing to dispose of the medial wastes in conformity with the standards and criteria for environmental protection and hygiene fixed by the state;
- 5) Failing to strictly disinfect the sewage, or the excretion of the infectious patients or suspect infectious patients pursuant to the present Regulations, or discharging the sewage not in conformity with the discharge standards fixed by the state into the sewage disposal system;
- 6) Failing to administer and dispose of the living garbage of the infectious patients or suspect infectious patients under treatment as medical wastes.

Article 48 Where any medical institution, in violation of the present Regulations, discharges the sewage, or the excretion of the infectious patients or suspect infectious patients not in conformity with the standards fixed by the state into the urban discharge pipelines, the administrative department of construction of the local people's government at the county level or above shall order that institution to get right within a prescribed time limit, give it a warning, and impose on it a fine ranging from 5,000 Yuan to 10,000 Yuan; and impose on it a fine ranging from 10,000 Yuan to 30,000 Yuan for failure to get right within the said time limit; where spreading of infectious disease or any environmental pollution accident is caused, the practice license of that institution shall be suspended or revoked by the department that issued the license; and the criminal liabilities shall be investigated for according to law if a crime has been constituted.

Article 49 In the event of losing, leaking or spreading of medical wastes, if any medical institution or entity of concentrated disposal of medical wastes fails to take emergent treatment measures or fails to report to the administrative department of public health or environmental protection in good time, the administrative department of public health or environmental protection of the local people's government at the county level or above shall, according to their respect duties, order that institution or entity to get right within a prescribed time limit, give it a warning, and impose on it a fine ranging from 10,000 Yuan to 30,000 Yuan concurrently; where spreading of infectious disease or any environmental pollution accident is caused, the practice license or operation license of that institution or entity shall be suspended or revoked by the department that issued the license; and the criminal liabilities shall be investigated for according to law if a crime has been constituted.

Article 50 Where any medical institution or entity of concentrated disposal of medical wastes, without justified reasons, obstructs the law enforcement personnel of the administrative department of public health or environmental protection in execution of their duties, refuses the law enforcement personnel to enter the scene, or refuses to cooperate with the law enforcement department in the inspection, monitoring, or investigation and evidence collection, the administrative department of public health or environmental protection of the local people's government at the county level or above shall, according to their respective duties, order that institution or entity to get right within a prescribed time limit, and give it a warning; if it refuses to get right, its practice license or operation license shall be suspended or revoked by the department that issued the license; if it violates the Regulations of the People's Republic of China on the Punishment of Public Security and commits any violation of public security administration, the public security organ shall punish it according to law; and the criminal liabilities shall be investigated for according to law if a crime has been constituted.

Article 51 Where any medical institution in the rural area without the necessary conditions for concentrated disposal of medical wastes fails to dispose the medical wastes pursuant to the requirements of the present Regulations, the administrative department of public health or environmental protection of the people's government at the county level shall, according to their respective duties, order that institution to get right within a prescribed time limit, and give it a

warning; and impose on it a fine ranging from 1,000 Yuan to 5,000 Yuan for failure to get right within the said time limit; where spreading of infectious disease or any environmental pollution accident is caused, the practice license of that institution shall be suspended or revoked by the department that issued the license; and the criminal liabilities shall be investigated for according to law if a crime has been constituted.

Article 52 If any party engages in the activities of collection, transport, storage, or disposal of medical wastes without obtaining the operation license, the administrative department of environmental protection of the local people's government at the county level or above shall order that party to stop the illegal act immediately, confiscate the illegal gains, and may impose on it a fine of no more than 1 time of the illegal gains.

Article 53 In the event of transfer or trade of medical wastes, mailing of or transport of medical wastes by railway or air, or transport of medical wastes by waterway in violation of the present Regulations, the administrative department of environmental protection of the local people's government at the county level or above shall order the two parties to the transfer or trade, or the mailer, or consignor to stop the illegal act immediately, give them a warning, and confiscate the illegal gains; if the illegal gains are more than 5,000 Yuan, a fine ranging from 2 times to 5 times of the illegal gains shall be imposed; if there is no illegal gain or the illegal gains are less than 5,000 Yuan, a fine ranging from 5,000 Yuan to 20,000 Yuan shall be imposed concurrently. If a carrier who is well aware that the consignor transports the medical wastes in violation of the present Regulations, and still undertakes the transport, or a carrier transports the medical wastes and passengers on the same conveyance, that carrier shall be punished pursuant to the preceding paragraph.

Article 54 If any medical institution or entity of concentrated disposal of medical wastes, in violation of the present Regulations, causes the spreading of infectious disease or occurrence of any environmental pollution, and thus do damage to others, that entity or institution shall be held liable for civil compensation.

Chapter 7 Supplementary Provisions

Article 55 Administration of the directly or indirectly infectious or poisonous, or otherwise harmful wastes generated in the technical services of birth control, medical scientific research, teaching, corpse inspection, and other relevant activities shall be carried out by referring to the present Regulations.

Article 56 The administrative department of hygiene of the People's Liberation Army of China shall formulate measures for the administration of the medical wastes of the army medical institutions by referring to the present Regulations.

Article 57 The present Regulations shall be implemented as of the day of promulgation.