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Regulations on Administration of Technical Services for Family Planning

(Promulgated by Decree No. 309 of the State Council of the People's Republic of China on June 13, 2001, and effective as of October 1, 2001)

Chapter I General Provisions

Article 1 These Regulations are formulated for the purpose of strengthening the administration of the technical services for family planning so as to control population quantity, improve population quality and protect the citizens' right to reproductive health.

Article 2 Institutions and their personnel engaged in family planning technical service activities within the territory of the People's Republic of China shall abide by these Regulations.

Article 3 The technical services for family planning shall follow the principle of combining the government guidance with individual voluntariness.

Citizens have the right to know and choose the contraceptive methods. The State guarantees the citizens' right to gain access to appropriate technical services for family planning.

The State provides contraceptive and birth control technical services free of charge to married couples at reproductive age in rural areas who practice family planning, and the necessary expenses shall be covered by the local financial budgets, while the central financial department shall offer reasonable subsidies to the western areas in difficulties.

Article 4 The family planning administrative department of the State Council shall be responsible for the administration of the family planning technical services throughout the country. The health administrative department and other relevant departments of the State Council shall, in their respective scopes of duties, make concerted efforts with the family planning administrative department to do a good job in providing family planning technical services.

Article 5 The family planning technical service network shall be composed of the family planning technical service institutions and the medical and health care institutions engaged in family planning technical services and shall be incorporated into the regional health programs.

The State encourages research, development, introduction and promotion of new techniques, medicaments and devices for family planning so as to improve the quality of the family planning technical services based upon the progress of science and technology.

Chapter II Technical Services

Article 6 The family planning technical services include family planning technical guidance, consulting and clinical services concerning family planning.

Article 7 The family planning technical guidance and consulting consist of the following:

- (1) popular scientific information, education and consulting on reproductive health;
- (2) delivery of contraceptive agents and devices and performance of relevant guidance, consulting and follow-up visits; and
- (3) performance of relevant consulting and follow-up visits for those who have undergone contraceptive or birth control surgeries and surgeries for tubal (vas) recanalization.

Article 8 The institutions engaged in family planning technical services of the cities at or above the county level may deliver the following family planning-related clinical services within the approved scopes:

- (1) medical examination for contraception and birth control;
- (2) diagnosis and treatment for family-planning surgical complications and adverse effects of family-planning medicaments and devices;
- (3) contraceptive or birth control surgeries and surgeries for tubal (vas) recanalization; and
- (4) provision of other services for reproductive health concerning fertility, birth control and infertility. The specific service

items shall be prescribed jointly by the family planning administrative department and the health administrative department of the State Council.

Article 9 Those who have children with diseases or disabilities from birth and request for another child shall apply to the family planning administrative department of the people's government at the county level for medical expertise, and upon preliminary examination and consent by the family planning administrative department of the people's government at the county level, the family planning administrative department of the people's government of the city divided into districts shall invite medical experts to conduct medical expertise; when having a dissenting opinion on the medical expertise, the party concerned may file an application for a new expertise with the family planning administrative department of the people's government of the province, autonomous region or municipality directly under the Central Government. The medical expertise organized by the family planning administrative department of the people's government of the province, autonomous region or municipality directly under the Central Government shall be the final expertise. The specific measures shall be formulated by the family planning administrative department of the State Council jointly with the health administrative department of the State Council.

Article 10 The family planning technical services, medicaments and devices offered to citizens shall be safe, effective and in conformity with the technical standards of quality as provided for by the State.

Article 11 The family planning administrative department of the State Council shall periodically compile and publish the catalogues of family planning techniques, medicaments and devices, and direct the promotion and application of family planning techniques, medicaments and devices included in the catalogues.

Article 12 The scientific research projects and international collaborative projects for family planning shall be subject to the examination and approval by the family planning administrative department of the State Council, and shall be under the supervision and administration of the family planning administrative department of the local people's government at or above the county level in the locality where the projects are carried out.

Article 13 The contents of the advertisements concerning family planning techniques shall be subject to the examination and approval by the family planning administrative department of the people's government of the province, autonomous region or municipality directly under the Central Government.

Article 14 The institution engaged in family planning technical services shall, when giving a contraceptive or birth control surgery, a special examination or a special treatment, obtain the personal consent of the recipient and guarantee the recipient's safety.

Article 15 No institution or individual shall conduct fetal sex identification for non-medical reasons or artificial termination of pregnancy for sex selection.

Chapter III Institutions and Their Personnel

Article 16 The institutions engaged in family planning technical services include the family planning technical service institutions and the medical and health care institutions engaged in family planning technical services.

Article 17 The institutions engaged in family planning technical services must conform to the criteria for establishment laid down by the family planning administrative department of the State Council.

Article 18 Establishment of a family planning technical service institution shall be subject to the approval by the family planning administrative department of the local people's government at or above the level of a city divided into districts, and the Practicing License of the Family Planning Technical Service Institution shall be issued, which shall clearly indicate the permitted technical service items for family planning.

Article 19 A medical or health care institution engaged in family planning technical services shall be subject to the examination and approval by the health administrative department of the local people's government at or above the county level, which shall clearly state the permitted family planning technical service items in the Practicing License of the Medical Institution, and notify the matter to the family planning administrative department at the same level .

Article 20 No new family planning technical service institutions may be set up in the towns and townships where there are medical institutions already; however, within these medical institutions, family planning technical service sections shall be set up to provide family planning technical services in full time. Where there are both medical institutions and family planning technical service institutions in the towns and townships, they shall provide family planning technical services within their respectively approved scopes. Where there are no medical institutions in the towns and townships and it is necessary to set up family planning technical service institutions, it shall be subject to strict examination and approval in accordance with the provisions of Article 18 of these Regulations.

Article 21 Where a family planning technical service institution is to engage in prenatal diagnosis, upon the consent of the family planning administrative department of the people's government of the province, autonomous region or municipality directly under the Central Government, the matter shall be subject to the examination and approval by the health administrative department at the same level and shall be reported for the record to the family planning administrative department of the State Council and the health administrative department of the State Council.

Where any institution engaged in family planning technical services is to apply techniques of assisted reproduction for the treatment of infertility, the matter shall be subject to the examination and approval by the health administrative department of

the people's government at or above the provincial level, and be notified to the family planning administrative department at the same level. The specific measures governing the application of techniques of assisted reproduction for the treatment of infertility shall be formulated by the health administrative department of the State Council jointly with the family planning administrative department of the State Council. The technical norms for the application of techniques of assisted reproduction for the treatment of infertility shall be formulated by the health administrative department of the State Council, which shall solicit opinions from the family planning administrative department of the State Council.

Article 22The certificate of the practicing license of any institution engaged in family planning technical services shall be checked every three years by the original approving authority.

No certificate of the practicing license of the institution engaged in family planning technical services may be allowed for sale, lending or lease, or for alteration or forgery.

Any institution engaged in family planning technical services that loses its certificate of the practicing license shall apply to the original certificate-issuing authority for a new one within 30 days from the date when the certificate of the practicing license is found lost.

Article 23Any institution engaged in family planning technical services shall engage in its practice in accordance with the approved professional scopes and service items, and abide by the relevant laws, administrative regulations and the general technical norms for medical treatment and the rules for rescue and referral services formulated by the health administrative department of the State Council.

Article 24The family planning administrative departments of the local people's governments at or above the county level shall periodically inspect the work of family planning technical service in their respective administrative regions.

Article 25The State shall establish the system of administration for the circulation of contraceptive agents and devices. The specific measures shall be formulated by the drug supervisory and administrative department of the State Council jointly with the family planning administrative department and other relevant competent departments of the State Council.

Article 26Among the family planning technical service personnel, those who engaged in clinical services concerning family planning in accordance with the provisions of these Regulations shall, in accordance with the law on licensed doctors and the relevant provisions of the State on the administration of nurses, acquire the qualifications as licensed doctors, licensed assistant doctors, rural doctors or nurses, , and serve at the institutions established in accordance with these Regulations. The licensed doctors and licensed assistant doctors working in the family planning technical service institutions shall, in accordance with the provisions of the law on licensed doctors, apply for registration to the health administrative department of the local people's government at or above the county level. The specific measures shall be formulated jointly by the family planning administrative department and the health administrative department of the State Council.

No medical institutions run by individuals may be engaged in family-planning surgeries.

Article 27The family planning technical service personnel must carry out family planning technical services in accordance with the approved service scopes and items and categories of surgery, and abide by the profession-related laws, regulations, rules, general technical norms, professional ethical norms and management systems.

Chapter IV Supervision and Administration

Article 28The family planning administrative department of the State Council shall be responsible for the supervision and administration of the family planning technical services throughout the country. The family planning administrative department of the local people's government at or above the county level shall be responsible for the supervision and administration of the family planning technical services within its own administrative region.

The health administrative department of the people's government at or above the county level shall be responsible for the supervision and administration of the medical and health care institutions engaged in family planning technical services in accordance with the provisions of these Regulations.

Article 29The State shall establish the statistical system for family planning technical services and the system for expertising and reporting on family planning technical service accidents, family-planning surgery complications and adverse effects of family-planning medicaments and devices.

The measures for expertising and handling of family-planning surgery complications shall be formulated by the family planning administrative department of the Stated Council jointly with the health administrative department of the State Council.

Where family planning technical service accidents occur, or family-planning surgery complications and adverse effects of family-planning medicaments and devices are found in an institution engaged in family planning technical services, a report shall be made concurrently to the family planning administrative department and the health administrative department of the local people's government within the time limit fixed by the family planning administrative department of the State Council; in case of major accidents in family planning technical services, serious birth control surgery complications, or serious or newly-emerged adverse effects of family-planning medicaments and devices, the report shall be concurrently forwarded level by level to the family planning administrative department and the health administrative department of the people's government at the higher level and up to the family planning administrative department and the health administrative department of the State Council.

Article 30The family planning administrative department of the State Council, jointly with the health administrative

department of the State Council, shall collect and analyze the data of family planning technical service accidents, family-planning surgery complications and adverse effects of birth control medicaments and devices, and notify the relevant departments in time. The family planning administrative department of the State Council shall, according to the relevant provisions of the State, publish in time the major accidents concerning family planning technical services, serious family-planning surgery complications and serious or newly-emerged adverse effects of family-planning medicaments and devices, and may authorize the family planning administrative departments of the provinces, autonomous regions and municipalities directly under the Central Government to timely publish and announce in a circular the family planning technical service accidents, family-planning surgery complications and adverse effects of family-planning medicaments and devices in their respective administrative regions.

Chapter V Penalty Provisions

Article 31 Where any institutions other than family planning technical service institutions or medical and health care institutions, or any individuals not serving in such institutions, in violation of the provisions of these Regulations, engage in family planning technical services without approval, the family planning administrative department of the local people's government at or above the county level shall, according to its functions and powers, order them to make corrections, give a warning and confiscate their illegal income and relevant pharmaceuticals and medical apparatus and instruments; if the illegal income is not less than 5,000 yuan, a fine of not less than two times but not more than five times the amount of their illegal income shall be concurrently imposed; if there is no illegal income or the illegal income is less than 5,000 yuan, a fine of not less than 5,000 yuan but not more than 20,000 yuan shall be concurrently imposed; if the consequences are so serious as to constitute a crime, criminal responsibility shall be investigated according to law.

Article 32 Where any family planning technical service institution, in violation of the provisions of these Regulations, conducts prenatal diagnosis or applies techniques of assisted reproduction for treatment of infertility without approval, the health administrative department of the local people's government at or above the county level, jointly with the family planning administrative department, shall, according to their functions and powers, order it to make corrections, give a warning and confiscate its illegal income, relevant pharmaceuticals and medical apparatus and instruments; if its illegal income is not less than 5,000 yuan, a fine of not less than two times but not more than five times the amount of its illegal income shall be concurrently imposed; if there is no illegal income or the illegal income is less than 5,000 yuan, a fine of not less than 5,000 yuan but not more than 20,000 yuan shall be concurrently imposed; if the circumstances are serious, the original certificate-issuing authority shall revoke the qualification for practice in family planning technical services.

Article 33 Where, in violation of the provisions of these Regulations, a certificate of the practicing license for family planning technical services is not checked in time but the family planning technical services continue, the original certificate-issuing authority shall order the checking procedures to be undertaken within a specified period of time; if it is still not checked, the certificate-issuing authority shall revoke the qualification for practice in family planning technical services.

Article 34 Where, in violation of the provisions of these Regulations, a certificate of the practicing license for family planning technical services is bought, sold, lent, leased, altered or forged, the original certificate-issuing authority shall order corrections to be made and confiscate the illegal income; if the illegal income is not less than 3,000 yuan, a fine of not less than two times but not more than five times the amount of the illegal income shall be concurrently imposed; if there is no illegal income or the illegal income is less than 3,000 yuan, a fine of not less than 3,000 yuan but not more than 5,000 yuan shall be concurrently imposed; if the circumstances are serious, the original certificate-issuing authority shall revoke the relevant qualification for practice.

Article 35 Where any institution engaged in family planning technical services, in violation of the provisions of Paragraph 3, Article 3 of these Regulations, collects charges for its contraceptive or family-planning technical services offered to married couples at reproductive age in rural areas who practice family planning, the family planning administrative department of the local people's government at the county level shall order it to return the money collected, give a warning and impose a fine of not less than two times but not more than five times the amount of the charges; if the circumstances are serious, the institution's chief in charge, the persons directly in charge and other persons directly responsible shall be given administrative sanctions such as demotion or discharge from office.

Article 36 Where any institution engaged in family planning technical services, in violation of the provisions of these Regulations, expands its family planning technical service items without approval, the original certificate-issuing authority shall order it to make corrections, give a warning and confiscate its illegal income; if its illegal income is not less than 5,000 yuan, a fine of not less than two times but not more than five times the amount of its illegal income shall be concurrently imposed; if there is no illegal income or the illegal income is less than 5,000 yuan, a fine of not less than 5,000 yuan but not more than 20,000 yuan shall be concurrently imposed; if the circumstances are serious, the original certificate-issuing authority shall revoke its qualification for practice in family planning technical services.

Article 37 Where any institution engaged in family planning technical services, in violation of the provisions of these Regulations, employs personnel without corresponding doctors' qualifications obtained according to law for clinical treatment in relation to family planning technical services, the health administrative department of the people's government at or above the county level shall, according to its functions and powers, order it to make corrections and confiscate its illegal income; if its illegal income is not less than 3,000 yuan, a fine of not less than the amount but not more than three times the amount of the illegal income shall be concurrently imposed; if there is no illegal income or the illegal income is less than 3,000 yuan, a fine of not less than 3,000 yuan but not more than 5,000 yuan shall be concurrently imposed; if the circumstances are serious, the original certificate-issuing authority shall revoke its qualification for practice in family planning technical services.

Article 38 Any institution engaged in family planning technical services which issues false certifying documents, if a crime has been constituted, shall be investigated for the criminal responsibility according to law; if no crime has been constituted,

the original certificate-issuing authority shall order it to make corrections, give a warning and confiscate its illegal income; if its illegal income is not less than 5,000 yuan, a fine of not less than two times but not more than five times the amount of its illegal income shall be concurrently imposed; if there is no illegal income or its illegal income is less than 5,000 yuan, a fine of not less than 5,000 yuan but not more than 20,000 yuan shall be concurrently imposed; if the circumstances are serious, the original certificate-issuing authority shall revoke its qualification for practice in family planning technical services.

Article 39 Where any family planning administrative department or health administrative department, in violation of the provisions, approves any family planning technical service institution or any medical or health care institution without prescribed conditions to conduct family planning-related clinical services or fails to carry out its duty of supervision, or fails to investigate and punish any discovered unlawful acts, and thereby causes serious accidents in family planning technical services, the department's chief in charge, the persons directly in charge and other persons directly responsible shall be given administrative sanctions such as demotion or discharge from office; if the case constitutes a crime, criminal responsibility shall be investigated according to law.

Chapter VI Supplementary Provisions

Article 40 Where institutions and professional personnel engaged in family planning technical services have been practicing or have started their practice before the enforcement of these Regulations, they shall, within three months from the date of the enforcement of these Regulations, go through the procedures for application, registration or approval and obtain the certificates in accordance with the relevant provisions of these Regulations.

Article 41 Any person who is engaged in family planning technical services in a rural family planning technical service institution or a rural medical or health care institution, if he conforms with the requirements of these Regulations, may obtain the qualification for practice after confirmation; for those who are not yet in conformity with the requirements of these Regulations, the matter shall be handled in accordance with the relevant provisions of the State Council.

Article 42 These Regulations shall be effective as of October 1, 2001.