

THE HEALTHCARE
LAW REVIEW

Editor
Sarah Ellson

THE LAWREVIEWS

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LAW
REVIEW

The Healthcare Law Review

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LAW REVIEW

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CHINA

*Min Zhu*¹

I OVERVIEW

China's healthcare system is mainly composed of the healthcare services sector, healthcare insurance sector and drugs and medical equipment sector, which are supervised by three separate government departments. Specifically, the PRC National Health and Family Planning Commission (NHFPC) is responsible for supervising the medical institutions and medical services industry, the Ministry of Human Resources and Social Security is responsible for formulating the basic healthcare insurance system and policy and for managing healthcare insurance funds, and the China Food and Drug Administration is responsible for drug and medical equipment registration and supervision.

II THE HEALTHCARE ECONOMY

i General

Healthcare services can be divided into basic healthcare services and special healthcare services, depending on coverage scope and extent of the specific services.

Basic healthcare services

Basic healthcare services are composed of public healthcare services and basic medical services. The scope of basic public healthcare services in China has been revised and expanded since the launch of China's healthcare reform in 2009. The National Basic Public Healthcare Service Standards (Third Edition), promulgated in 2017, stipulate that basic public healthcare services consist of 13 types of services, including residents' health file management, vaccinations, health administration for special groups (children aged under six, pregnant women, the elderly, and patients with hypertension, type 2 diabetes, severe mental disorders and tuberculosis), infectious diseases and public healthcare emergency reporting and treatment, and so on.

¹ Min Zhu is a partner at Han Kun Law Offices. The firm also wishes to acknowledge the contributions to this publication by Serina Wei, an associate at the firm.

Special healthcare services

In addition to basic healthcare services, the Chinese healthcare system also includes special healthcare services, which refer to medical services provided by medical institutions to satisfy special medical needs, such as specified surgical operations, full nursing care, special wards, specialist outpatient services and medical cosmetic surgery.

ii The role of health insurance

China's basic healthcare insurance system currently includes a basic urban employee healthcare insurance system, a healthcare system for urban residents and a new rural cooperative healthcare insurance system. Among these, the basic urban employee healthcare system is compulsory, and requires all urban employers and employees to contribute to the system. Urban residents who are not covered by the basic urban employee healthcare insurance system, including students, children and other non-employed urban residents, may voluntarily choose to purchase the urban resident healthcare insurance. A new rural cooperative healthcare insurance system, the rural medical mutual aid system, has been designated for rural residents and is mainly funded by government financial appropriations and supplemented by individual and collective contributions. Rural residents may choose to participate in the system at their discretion.²

According to the Opinions on the Integration of the Basic Healthcare Insurance System for Urban and Rural Residents promulgated by the State Council in 2016, the above three basic healthcare insurance systems will be integrated into a unified basic healthcare insurance system applicable to both urban and rural residents. At present, the healthcare insurance system for urban residents and the new rural cooperative medical insurance system have been successfully integrated.

iii Funding and payment for specific services

In addition to basic healthcare services, medical institutions also provide special healthcare services to satisfy non-basic medical needs. Special healthcare services may be provided by both public and non-public medical institutions. However, the amount of special medical services provided by public medical institutions is limited, and cannot exceed 10 per cent of all healthcare services that such institutions provide.

According to the relevant provisions of the current basic healthcare insurance system in China, the cost of special healthcare services will not be covered by the national healthcare insurance system. Such costs are to be directly undertaken by the individual incurring such costs or reimbursed by commercial health insurance.³

III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

i China's healthcare services system

China's healthcare service system is developed under a dual structure for urban and rural areas. The rural healthcare system is composed of three grades of medical institutions, which

2 China Health Industry Bluebook (2017), pages 13 and 14 (China Medical Indus. Info. Ctr., 2017), hereinafter, 'Bluebook 2017'.

3 Opinions of the CPC Central Committee and the State Council on Deepening Reform of the Medical and Healthcare Systems, Article 10 (CPC Central Comm., St. Council, promulgated 17 March 2009).

are county hospitals, township hospitals and village clinics. The urban healthcare system is also made up of three levels of medical institutions, which are the regional central hospitals, community healthcare service centres, and clinics and infirmaries. Densely populated cities also have tertiary hospitals with advanced technology and equipment. The entire healthcare service system is known as the 'dual and three grades' system.

ii Graded treatment system

In China, patients can freely choose the hospitals from which to receive medical treatment. However, for a long period of time, public hospitals have often been overcrowded since they possess better medical resources.⁴ By contrast, community hospitals are less frequently visited, although they provide more accessible and convenient healthcare to residents. In response to this issue, the General Office of State Council, in September 2015, promulgated the Guidance on Promoting Graded Medical Treatment System Construction in order to alleviate overcrowding and promote the rational allocation of medical resources. The guidance describes a graded medical treatment system framework and stipulates that, by 2020, China will improve the graded medical treatment system through graded treatment methods for primary initial diagnoses, two-way referrals, divisions for acute and chronic diseases and communication between institutions.

iii Application of electronic medical records

Electronic medical records are an important means to promote healthcare services informatisation and will help to improve the quality and efficiency of medical services. In 2010, the Ministry of Health, a predecessor to the NHFPC, initiated work on its hospital informatisation construction pilot scheme, focusing on the promotion of electronic medical records.⁵ Since then, the use of electronic medical records has been gradually phased in across the country. In 2017, the NHFPC promulgated the Regulations on the Management of Electronic Medical Records Applications (for Trial), which stipulate a series of requirements for the content, writing and saving, use and storage of electronic medical records. The Regulations, together with a series of supporting national and industry standards for electronic medical record systems, data management and medical terminology, constitute the management framework for electronic medical records in China.

iv Personal information protection

The Regulations on Management of Medical Records at Medical Institutions stipulate that medical institutions and their medical staff should keep strictly confidential the personal information contained in patients' medical records and should not disclose personal information for non-medical, teaching or research purposes.

Recently, the government has promulgated a series of laws and regulations and judicial interpretations, with the purpose of more effectively protecting citizens' personal information. The General Principles of Civil Law, which is to be implemented on 1 October 2017, for the first time defines the right of citizens to their personal information as an independent civil right. The Cybersecurity Law, which came into force on 1 June 2017, and the majority

4 Bluebook 2017 at page 16.

5 Circular of the Ministry of Health on Launching Electronic Medical Records Pilot Reform and Working Plan for Electronic Medical Records Pilot Reform (Ministry of Health, promulgated 28 September 2010).

provisions of Chapter 4, ‘Network Information Security’, are intended to provide more protection for personal information. The Interpretations on Several Issues Concerning the Application of Law in the Handling of Criminal Cases Involving Infringement of Citizens’ Personal Information, which came into force on the same day as the Cybersecurity Law, defines the constitutive elements for several criminal acts involving the infringement of personal information and significantly reduces the threshold for imposing criminal penalties on personal information infringement.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

The NHFPC is the department primarily responsible for approving the establishment of medical institutions in China, and for practice approval and administrative oversight. Specifically, the NHFPC is responsible for:

- a* developing medical institutions, medical technology applications, medical quality, medical safety and medical service policy and organisational standards;
- b* developing medical personnel practice and service standards;
- c* formulating medical institution and healthcare industry administrative measures and exercising supervision;
- d* participating in drug and medical equipment clinical trial administration; and
- e* being responsible for leading the oversight of nationwide medical institution assessments, and for developing public hospital operating oversight, performance evaluations and assessments.

ii Institutional healthcare providers

Establishment of medical institutions

Medical service providers that intend to set up medical institutions and practise medicine in China must comply with the Medical Institutions Establishment Plan, and fully consider the location and coverage radius of the medical institutions, the distribution of medical resources and medical service needs.

The approval process before a medical institution may commence operations can be divided into two steps: establishment approval and approval to practise medicine. When preparing to establish a medical institution, the medical institution operator should submit a detailed report to the NHFPC to describe the establishment preparation plans, including site selection, diagnosis and treatment projects, institution size (number of ward beds), funding sources and planning, personnel status, management system and so on. Construction of medical institutions may commence after obtaining the approval of the NHFPC and acquiring the approval for establishment of medical institutions. After completing the necessary preparatory work before the medical institutions commence business, such as site construction, equipment purchase, personnel hiring and system construction, the medical institutions should apply to NHFPC to practise medicine and apply for the issuance of the Permit for Medical Institutions to Practise Medicine.

Penalties for medical institution violations

When practising medicine, medical institutions must strictly comply with the approved business scope and approved medical treatment projects, the relevant laws and regulations

and technical medical standards. Medical institutions that practise business without a permit for medical institutions to practise medicine, or whose medical treatment activities exceed the scope specified therein, may be imposed with fines, have illegal income, drugs and equipment confiscated, and have their practice permits revoked.

New regulations for doctors establishing personal clinics

In February 2017, the NHFPC revised the Detailed Rules on the Implementation of Administrative Regulations of Medical Institutions, to delete the stipulation that ‘personnel in services with medical institutions, retired due to illness or suspended from duty without pay shall not apply to establish medical institutions.’ This means that, in the future, doctors who are employed with hospitals, retired or suspended from duty without pay may apply to establish clinics or serve as the legal representative or person in charge for medical institutions, provided other conditions for establishing medical institutions are not violated. This is regarded as a major signal for the beginning of reforms in China that will permit doctors to freely practise medicine.

iii Healthcare professionals

In China, physicians, nurses and pharmacists need to practise medicine in accordance with the Medical Practitioners Law, Nurses Regulation and the Regulations on the Administration of Medical Institutions and other relevant administrative requirements.

Medical practice by medical practitioners

Medical practitioners are subject to a registration system. Candidates who possess the requisite degree, have work experience as an assistant physician or have practised medicine after engaging in clinical practice for a certain period of time under the guidance of a practising physician may sit for the medical practitioner licensing examination. Upon passing the examination, candidates may obtain a medical practitioner’s licence and may register to practise medicine with the healthcare administrative department.

The registration of medical practitioners will remain valid indefinitely. However, registered medical practitioners are subject to an assessment of their professional abilities, work performance and professional ethics by an agency under the purview of the NHFPC on a regular basis. Those practitioners who failed the assessment will be ordered to suspend their practice for three to six months to receive training and continuing medical education.

Anyone who practises medicine without completing registration will be ordered to cease practising, subject to the confiscation of illegal income and medical equipment and imposed with a fine at least 100,000 yuan by the healthcare department. If serious consequences result from unauthorised practice, such as causing injury to visiting patients, spreading or potentially spreading diseases, the violator will be regarded subject to criminal liability in accordance with the Article 236 of the Criminal Law, which stipulates liabilities for the illegal practice of medicine.

Practice by nurses

Candidates intending to practise nursing also need to pass a qualification examination and complete registration to commence practice. Prior to practice registration, candidates need to complete the prescribed professional nursing courses and engage in clinical nursing practice for a certain period of time. Registered nurses should practise nursing at their registered

practice location. Nursing practice registrations are valid for five years. Upon expiry of the term, registered nurses may apply to the health administrative department to renew their registrations.

Multi-site practice

The previous Interim Measures on Medical Practitioner Practice Registration stipulated that physicians were only permitted to practise medicine at the medical institution registered as their place of practice, which effectively meant that physicians could only practise medicine at one medical institution. In February 2017, the NHFPC promulgated the new Administrative Measures on Medical Practitioners' Practice Registration. One of the highlights of the measures is to provide for medical practitioners to practise medicine at multiple locations. Thus, in the future, doctors may practise medicine at multiple medical institutions located in multiple locations.

V NEGLIGENCE LIABILITY

Medical institutions and physicians that harm patients during the provision of medical services are held liable in accordance with the relevant provisions of Chapter 7 of the Tort Liability Law, 'Medical Damage Liabilities'. Liability is determined based upon the fault liability principle and, to some extent, in accordance with the presumption of fault principle.⁶ In addition, the Medical Malpractice Treatment Regulation also specifies rules related to the prevention, handling, technical evaluation and administrative handling of medical malpractice cases. When physical injury occurs, if the relevant liability is not provided for in the Tort Liability Law or the Medical Malpractice Treatment Regulation, the relevant provisions apply from the Interpretation of the Supreme People's Court on Several Issues Concerning the Application of Law in Hearing Cases of Compensation for Personal Injury Tort Liability Act and the Medical Malpractice Law.

i Overview

When hearing a medical dispute, the courts often assess whether the medical institutions should be subject to liability based on three aspects. First, whether the medical institution is at fault and the role the medical institution played in contributing to the malpractice. Second, the cause and effect between the fault of the medical institution and damage suffered by the patient. Third, the scope of loss suffered by the patient. In general, a medical malpractice determination is regarded as a neutral and credible basis to determine the allocation of fault between medical institutions and patients. Unless the procedure for making the medical

⁶ Tort Law of the People's Republic of China (Standing Comm., Nat'l People's Cong., promulgated 26 December 2009, effective 1 July 2010). Article 54 provides that medical institutions bear compensatory liability in cases where both the medical institution and medical practitioners are at fault for harming patients during diagnosis and treatment. Article 55 stipulates that medical practitioners must fully explain the medical risks of treatment and alternatives to treatment and receive consent from the patient or family, failure by a medical practitioner to do so which results in harm to the patient will subject the medical institution to compensatory liability. Article 58 provides for the presumption of fault by the medical institution in cases where the medical institution conceals, refuses to provide, forges, tampers with or destroys case data in a dispute in violation of laws and regulations or other medical standards.

malpractice determination was not lawful, courts tend to depend upon the determination to allocate fault attributable to the medical institution and to decide the liabilities to be undertaken by the medical institution.

ii Notable cases

The dispute over medical damages between Shen Bo, Meng Xiaoxia and the Second Affiliated Hospital of Zhengzhou University in 2014⁷ is of notable significance with respect to application of the presumptive fault principle in determining the liability of medical institutions. In this case, the plaintiff held that the defendant hospital should bear full responsibility for the death of the patient because the hospital had committed serious malpractice in treating the patient and had tampered with medical records for the purpose of avoiding responsibility. However, the defendant argued that the hospital revised the medical records solely for the purpose of improving the content of the records and that there was no substantial difference between the original records and the modified records. The defendant's argument was not adopted by the court for lack of reasonableness. In fact, both the first instance and the second instance courts found that the hospital was presumed to be at fault and subject to primary liability for the malpractice claim, since it had tampered with and concealed medical records and failed to give a reasonable explanation of such conduct.

VI OWNERSHIP OF HEALTHCARE BUSINESSES

China's medical and healthcare system is established on the basis of the basic healthcare insurance system, by which public medical institutions are obliged to provide the substantial part of basic healthcare services. Public medical institutions include government-funded medical institutions and medical institutions run by state-owned enterprises. For historical reasons, public medical institutions have easier access to high-quality medical resources, including scientific research and teaching, clinical trials, advanced equipment and professionals.

In recent years, the government has encouraged social capital to invest in the establishment of medical institutions and to participate in the provision of medical services. However, while the number of private medical institutions has exceeded public medical institutions,⁸ the public health institutions still occupy an unshakably dominant position in the medical services market because of the high-quality medical resources that they possess.⁹

Foreign-invested medical institutions wishing to enter the Chinese market should refer to the Guidance Catalogue of Foreign Investment Industries (revised in 2017), which stipulates that medical institutions belong to the foreign investment restricted industries, and foreign-invested medical institutions may only be established in the form of a joint venture or a cooperative enterprise. The Interim Measures for the Administration of Sino-Foreign Joint Ventures and Cooperative Medical Institutions further stipulate the total amount of investment, the minimum proportion of Chinese capital or equity and the term of operations

7 Ref. doc. no.: (2014) Zheng Min Yi Zhong Zi No. 500.

8 See the latest statistics of April 2017 at www.moh.gov.cn/mohwsbwstjxxzx/s7967/201706/41573016be1b41719c8ca68dfab05e9d.shtml.

9 Bluebook 2017 at page 16.

of the Sino-foreign joint ventures and cooperative medical institutions. In addition, the local Medical Institution Organisation Plan should also be complied with when establishing foreign-invested medical institutions.

VII COMMISSIONING AND PROCUREMENT

As mentioned above, China's healthcare services are divided into basic healthcare services and special healthcare services. Basic healthcare services include public healthcare services and basic medical services. Public healthcare services are regarded as a form of public goods, which are mainly funded by government outlays and provided to urban and rural residents on an equal basis.

Medical services for treating non-basic diseases, or those regarded as discretionary diagnosis and treatment measures are considered special healthcare services. The costs of special healthcare services are to be undertaken by individual patients or reimbursed by the patient's commercial medical insurance. Patients have the freedom to choose what medical services to receive, and the medical expenses will be directly deducted from the basic medical insurance fund, if covered, or will otherwise be paid for by the individual patients.

VIII MARKETING AND PROMOTION OF SERVICES

In China, the publication of medical, pharmaceutical, medical equipment and health food advertising is subject to content reviews by the advertising authorities prior to publication.¹⁰ Advertising review organs include the food and drug regulatory authorities, health-planning committee and the industrial and commercial administrative departments.

In accordance with the provisions in the PRC Advertising Law, drug and medical device advertising cannot include:

- a* assertions or guarantees as to efficacy and safety;
- b* efficacy rates or cure rates;
- c* comparisons of the safety or effectiveness of drugs or medical devices with those of other medical institutions;
- d* the use of advertising spokespersons to endorse or provide testimonials; and
- e* medical advertising disguised as health and well-being advice.

IX FUTURE OUTLOOK AND NEW OPPORTUNITIES

'Internet plus' and medical big data are currently two popular concepts in the medical services market in China. Many start-ups and investment institutions are especially focused on emerging businesses in these areas, including telemedicine, internet hospitals, mobile medicine, smart medicine and other medical service sub-sectors.

These emerging forms of healthcare have played a significant role in promoting the diversification of medical services as advocated by the state. While government regulators have maintained an open and welcoming attitude towards these new services, they have also exhibited a certain degree of caution. For example, the current NHFPC regulations

¹⁰ Advertising Law of the People's Republic of China, Article 46 (Standing Comm., Nat'l People's Cong., amended 24 April 2015, effective 1 September 2015).

limit telemedicine services to occur only between medical institutions,¹¹ which has caused a number of mobile healthcare companies to abandon or amend their business plans in this area.

X CONCLUSIONS

In 2009, the government of China launched a new round of healthcare reforms. To date, this round of reforms is ongoing and continues to face significant difficulties. Integrating urban and rural resident insurance systems, improving the graded healthcare system, implementing electronic medical records, allowing doctors to practise medicine more freely and achieving the optimal allocation of medical resources are all difficulties being faced during the current reform effort. The reforms also present an unprecedented opportunity for social capital to participate in the medical and health industry that cannot be overlooked.

11 Opinions of the National Health and Family Planning Commission Concerning the Advancement of Medical Institution Telemedicine Services (Nat'l Health and Family Planning Comm., promulgated and effective 21 August 2014).

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