

THE HEALTHCARE LAW  
REVIEW

SIXTH EDITION

Editor  
Ulrich Grau

THE LAWREVIEWS

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REVIEW

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# PREFACE

The sixth edition of *The Healthcare Law Review* covers six new jurisdictions and a total of 17 jurisdictions from Europe, North and South America and Asia. All chapters have been provided by leading experts in the field of healthcare law in their countries. The reviews have been prepared by the authors as a practical, business-focused analysis of recent changes and developments, their effects, and a look forward at expected trends. The reviews are intended to provide an overview of legal issues that are of interest for healthcare providers and related businesses.

The past two years have been dominated by the covid-19 pandemic. The pandemic not only affected all healthcare providers and staff working in health and social care but also scientists, public health officials and politicians throughout the world. Each country was hit hard by the pandemic, some countries were even overwhelmed, and major sources of the healthcare systems had to focus on maintaining the functioning of the health systems even in this exceptional situation. Therefore, all countries took additional exceptional measures to fight the pandemic. According to the reviews from the individual countries, these exceptional measures have now largely been scaled back or totally withdrawn, even though the pandemic is not yet over.

As a major result of the pandemic, many countries have geared their healthcare systems to ensure safe access to healthcare for citizens, even in extraordinary situations, through greater digitisation and use of telemedicine. This is not only about supplementing or replacing face-to-face doctor visits with communication options via telephone or video consultation. Many countries have also introduced electronic patient files, regulations for the exchange of health data and other digital communication channels. The next few years will show whether these innovations can also be successfully implemented in a healthcare reality that is no longer solely determined by a pandemic. A particular challenge in the future will also be to utilise the new digital tools not only within a national healthcare system in a single country, but also across borders. The European Union is already well on the way with the implementation of a European Health Data Space.

Even if individual countries solve their problems differently, we all can only benefit from knowing the different approaches to solving the problems and how successful the respective countries have been with their solutions in each case. I truly hope that the publication of *The Healthcare Law Review* will be particularly helpful in that respect.

I am more than happy to take over the editorship from Sarah Ellson from Fieldfisher LLP, London. I would like to sincerely thank her for her commitment over the past years. It is an extraordinary pleasure to work with this group of exceptional authors of *The Healthcare Law Review* in this edition and in the years to come to provide a practical overview of the

healthcare systems of the countries covered. We will continue our efforts to include more countries to this publication to be able to give a comprehensive worldwide approach to healthcare issues by each country.

**Ulrich Grau**

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# CHINA

*Min Zhu, Aaron Zhou, Li Zhang and Aaron Gu*<sup>1</sup>

## I OVERVIEW

China's healthcare system mainly comprises the healthcare services sector, the healthcare insurance sector, and the drugs and medical equipment sector, which are supervised by three separate government departments. Specifically, the PRC National Health Commission (NHC)<sup>2</sup> 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 National Medical Products Administration (NMPA)<sup>3</sup> 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 the scope of coverage and the extent of the specific services.

#### *Basic healthcare services*

Basic healthcare services consist of basic public healthcare services and basic medical care services, which the government provides free of charge. The scope of basic public healthcare services in China has been revised and expanded since the launch of China's healthcare reforms in 2009. The National Basic Public Healthcare Service Standard, promulgated in 2017, stipulates that basic public healthcare services consist of 13 types of services, including residents' health file management, vaccinations, healthcare 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

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1 Min Zhu, Aaron Zhou, Li Zhang and Aaron Gu are partners at Han Kun Law Offices.

2 The duties of the former PRC National Health and Family Planning Commission were merged into the newly established PRC National Health Commission following the implementation of the Programme for the Reform of State Council Organs on 18 March 2018.

3 The NMPA was newly established under the supervision of the State Administration for Market Regulation (SAMR) following the implementation of the Programme for the Reform of State Council Organs.

emergency reporting and treatment. In December 2019, the Law on Promoting Basic Medical and Health Care was promulgated to further the development of medical, hygiene, and healthcare services and ensure citizens' access to basic medical and healthcare services.

### ***Special healthcare services***

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

#### **ii The role of basic medical insurance**

According to the Law on Promoting Basic Medical and Health Care, promulgated in 2019, China is establishing a graded healthcare insurance system consisting principally of basic medical insurance and supplemented by commercial healthcare insurance, medical aid, employees' mutual healthcare assistance and healthcare charity services. Under this scheme, the basic medical insurance fund covers medical costs for identified pharmaceuticals, diagnosis and treatment services and the use of identified medical care facilities, and medical costs for emergencies and rescue services. Patients personally bear those medical costs not covered by the basic medical insurance fund, which may be partially reimbursed under commercial health insurance. By the end of 2021, the number of people participating in the basic medical insurance schemes reached 1.36 billion, with the coverage stabilising at over 95 per cent of the population of China.<sup>4</sup>

#### **iii Funding and payment for special healthcare services**

In addition to basic healthcare services, both public and non-public medical institutions also provide special healthcare services to satisfy non-basic medical needs. However, the amount of special healthcare services provided by a public medical institution cannot exceed 10 per cent of all healthcare services it provides.

Under the current basic medical insurance system in China, the national medical insurance system does not cover the cost of special healthcare services. Such costs are to be directly undertaken by the individuals incurring the costs or reimbursed under commercial health insurance.<sup>5</sup>

### **III PRIMARY/FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE**

#### **i China's healthcare service 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 levels of medical institutions, which are county hospitals, township hospitals and village clinics. The urban healthcare system is also made up of three levels of medical institutions, which are regional central hospitals,

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4 See 'Statistical Bulletin on the Development of Medical Security Undertakings in 2021' published by the National Healthcare Security Administration on 8 June 2022.

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

community healthcare service centres, as well as clinics and infirmaries. Densely populated cities also have tertiary hospitals with more advanced technologies 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 hospitals to receive medical treatment. However, public hospitals have often been overcrowded because they possess better medical resources.<sup>6</sup> By contrast, community hospitals are less frequently visited, although they provide more accessible and convenient healthcare services to residents. In response to this issue, the Guiding Opinions on Promoting Graded Medical Treatment System Construction was promulgated in 2015 to alleviate overcrowding and promote the rational allocation of medical resources. The guiding opinions describe the establishment of a graded medical treatment system that includes initial diagnosis at community medical institutions, two-way patient referrals, divisions for acute and chronic diseases, and communications between institutions. At present, China is promoting the implementation of this graded medical treatment system by building medical consortiums.<sup>7</sup>

## **iii Healthcare provision to the elderly**

China is actively establishing and improving its healthcare services system for the elderly: community healthcare service centres provide continuous health management and medical care; and general medical institutions are convenient for the elderly to make appointments with doctors. In addition, elderly care institutions that meet certain conditions may establish geriatric disease hospitals, rehabilitation centres and nursing homes that, if qualified, may be designated as being within the scope of basic healthcare insurance for urban and rural residents.<sup>8</sup> China also supports pension institutions to establish medical institutions and medical institutions to establish pension institutions.<sup>9</sup>

Meanwhile, Chinese central and local governments attach great importance to the development of elderly social care: the Ministry of Civil Affairs and other authorities encourage the establishment of pension institutions and elderly care services institutions to provide daily care services to the elderly, and the NHC is continuously improving the medical care service system in accordance with the requirements of the graded medical treatment system. In China, care services to elderly patients suffering from critical illnesses are primarily provided by Class III hospitals, care services to elderly patients suffering from common and chronic diseases are primarily provided by Class II hospitals, and daily medical care, elderly nursing, long-term care and other medical care services are mainly provided by primary-level medical institutions and continuing medical institutions. Medical care service fees provided

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6 China Health Industry Bluebook (2017), page 16 (China National Pharmaceutical Industry Information Centre, 2017).

7 Guiding Opinions on Promoting the Building and Development of Medical Consortiums (promulgated by the General Office of the State Council on 23 April 2017).

8 See Circular of the General Office of the State Council on Transmitting and Issuing the Guiding Opinions of the Health and Family Planning Commission and Other Departments on Promoting Integration of Medical and Elderly Care Services (No. 84, 2015).

9 Circular on Completing the Examination and Approval of Medical and Pension Institutions (promulgated jointly by the NHC, the Ministry of Civil Affairs, the SAMR and the National Administration of Traditional Chinese Medicine on 27 May 2019).

by qualified institutions may be covered by basic healthcare insurance for urban and rural residents as well as pilot long-term care insurance for employees who participate in basic healthcare insurance. Additionally, the NHC is vigorously developing community and home nursing services.

#### **iv Use of electronic medical records**

The use of electronic medical records is 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 NHC, initiated work on its hospital informatisation construction pilot scheme, focusing on the promotion of electronic medical records.<sup>10</sup> Since then, the use of electronic medical records has become more popular across the country. In 2017, the National Health and Family Planning Commission, also a predecessor to the NHC, promulgated the Regulations on the Management of Electronic Medical Records Applications (for Trial Implementation), 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 terminologies, constitute the framework for the management of electronic medical records in China. At present, the NHC continues to promote the nationwide digitisation of medical records in medical institutions and among different medical institutions, such as by evaluating the levels of electronic medical records management at different medical institutions.

#### **v Personal information protection**

China has gradually established and improved its personal information protection system through the promulgation of legislation, judicial interpretations, rules and voluntary national standards, including the PRC Civil Code, the Personal Information Protection Law, the Data Security Law, the Cybersecurity Law, the Interpretation of Several Issues concerning the Application of Law in the Handling of Criminal Cases of Infringement of Citizens' Personal Information, and the Information Security Technology – Personal Information Security Specification (GB/T 35273-2020).

Meanwhile, special attention has been paid to the healthcare sector with respect to personal information protection. Rules in this regard include the Provisions on Administration of Medical Records in Medical Institutions, the Measures for Administration of National Health and Medical Big Data Standards, Security and Services (for Trial Implementation), the Regulations on Administration of Human Genetic Resources, the Information Security Technology – Personal Information Security Specification, and the Information Security Technology – Guide for Health Data Security.

#### **vi Delivery of healthcare services**

Healthcare services in China are provided in a number of ways. Most people typically make in-person visits to medical institutions to obtain healthcare services, such as public hospitals and community hospitals. In recent years, digital technology has made the delivery of

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<sup>10</sup> Circular of the Ministry of Health on Launching Electronic Medical Records Pilot Reform and Working Plan for Electronic Medical Records Pilot Reform (promulgated by the Ministry of Health on 28 September 2010).

healthcare services more efficient and convenient for both hospitals and patients. An example of this is that medical institutions are allowed to use ‘internet hospitals’ as their second name and provide online re-diagnosis of some common and chronic diseases based on the services provided by their physical hospitals. Meanwhile, the NHC is promoting online healthcare services, including healthcare consultation, health management services and telemedicine, especially under the circumstances of covid-19 outbreak. Additionally, China is improving and encouraging home doctor services. Patients can set up contractual relationships with a home doctor who will diagnose and treat common diseases, frequently occurring diseases and chronic diseases for such patients by means of health records management, follow-up visits, health education and other health services.

#### **IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS**

##### **i Regulators**

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

- a* developing medical institutions, medical technology applications, medical quality, medical safety and medical service policies 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* leading the oversight of nationwide medical institution assessments and developing public hospital operating oversight and 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 are subject to different regulatory rules and application formalities depending upon the type of medical institution to be established. A two-step NHC approval process (i.e., approval to establish and approval to practise) is required to set up Class III hospitals, Class III maternal and child health centres, first aid centres, first aid stations, clinical testing centres, Sino-foreign joint venture and cooperative medical institutions, and medical institutions wholly owned by Hong Kong, Macao and Taiwan investors.

Establishment approval is not mandatory for other types of medical institutions. Instead, operators may directly apply to the NHC for a permit to practise medicine. Clinics are not subject to either establishment approval or practice approval; medical service providers that intend to set up clinics only need to submit a filing to the competent NHC before they begin operating.<sup>11</sup>

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11 Circular of the General Office of the National Health Commission on Issuing the Reform Measures for the Reform of Separating Operating Permits and Business Licences in the Medical Care Sector (promulgated by the National Health Commission on 2 July 2021).

### ***Penalties for violations by medical institutions and clinics***

When practising medicine, medical institutions and clinics must strictly comply with the approved business scope and approved medical treatment projects, relevant laws, regulations and technical standards. Medical institutions that operate without a permit, or clinics that operate without the appropriate filing or whose medical treatment activities exceed the scope specified in a permit or filing record, may be fined; have their illegal income, drugs and equipment confiscated; be ordered to cease their practice activities; or have their practice permits revoked.

### ***Appeals against refusal to grant or withdrawal of licences***

The NHC may refuse to grant a practice licence or reject a filing for medical institutions or clinics that fail to meet the statutory establishment requirements. In such instances, the medical institution or clinic operator may apply for administrative reconsideration within 60 days or initiate a lawsuit within six months upon being informed of such non-grant or rejection.

A medical institution operator whose medical institution practice permit is revoked or withdrawn due to malpractice may apply for administrative reconsideration within 60 days upon being informed of the revocation or withdrawal or initiate a lawsuit within six months upon being so informed.

### ***Regulations for doctors establishing personal clinics***

In February 2017, revisions made to the Rules for Implementation of the Regulations on Administration of Medical Institutions allow individuals who currently serve in medical institutions, are retired due to illness or have been suspended from duty without pay to apply to establish medical institutions. In April 2019, the NHC, together with four other government authorities, jointly issued the Circular on Printing and Issuing the Opinions on the Pilot Programme for the Promotion and Development of Clinics, which encourages doctors who have practised for at least five years with intermediate or higher qualifications to establish specialist clinics on a full- or part-time basis. After years of pilot implementation, this policy was eventually confirmed in the Interim Measures for Clinic Filing Management (Draft for Comment), released on 21 January 2022, which specify that doctors who have practised in a medical institution for at least five years may set up personal clinics. This is regarded as a major step in China's reforms to permit eligible doctors to freely practise medicine and establish personal clinics.

### ***More governmental support to relieve financial stress on medical institutions***

The outbreak of the covid-19 pandemic in early 2020 caused a notable impact on the normal practices of medical and healthcare institutions across the country. NHC statistics show that, during the period from January to November 2020, visits to public hospitals and private hospitals and clinics declined by 13.1 per cent and 9.6 per cent respectively.<sup>12</sup> A new surge of covid-19 that began in China in early 2022 has proved to be more severe and caused substantial uncertainty to the daily operations of the medical and health institutions. In May 2022, the General Office of the State Council issued the Notice on Deepening the Reform of the Medical and Health System in 2022, which advocates '[continuing] to aid

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12 According to statistics published by the NHC on 26 February 2021.

medical institutions that are in distress due to covid-19.’ Local governments in many places have echoed this central government request and released preferential treatment policies to medical institutions including loan support with reduced interest rates, increased financial support, and specific subsidies and allowances to medical institutions for unexpected costs caused by participating in the fight against covid-19.

### **iii Healthcare professionals**

In China, physicians, nurses and pharmacists must practise medicine in accordance with the PRC Law on Licensed Doctors, the Regulations on Nurses and the Regulations on Administration of Medical Institutions as well as 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 assistant physicians or have practised medicine after engaging in clinical practice for a certain period under the guidance of a practising physician may sit for the medical practitioner licensing examination. After passing the examination, candidates may obtain a medical practitioner’s licence and register to practise medicine with the healthcare administrative authority.

Medical practitioner registrations remain valid indefinitely. However, registered medical practitioners are subject to regular assessments of their professional abilities, work performance and professional ethics by an NHC-designated agency. Practitioners who fail an assessment will be ordered to suspend their practice for three to six months to attend training and continuing medical education.

Anyone who practises medicine without registration will be ordered to cease practising, be fined or have his or her illegal income, drugs and equipment confiscated. If an unregistered practitioner causes any serious consequences, such as injury to patients or spreading or potentially spreading diseases, the wrongdoer may be subject to criminal liability under Article 336 of the Criminal Law, which stipulates liabilities for illegally practising medicine. Any registered medical practitioner who commits serious violations of the professional ethics or medical ethics and further causes bad social influence will have their practice licence revoked, be ordered to cease their illegal practice and be prohibited from engaging in medical and health services or medical clinical research for five years or even for life.

Foreigners wishing to practise medicine in China (e.g., foreign-registered physicians) need to first obtain an invitation or employment from a Chinese hospital before applying for a Temporary Licence for Foreign Physicians to Practise Medicine in China, which allows foreign physicians to perform clinical diagnosis and patient treatment in China for no more than one year. Foreigners who intend to become long-term physicians in China must pass the national medical practitioners licensing examination and obtain a practice certificate before registering as medical practitioners in China.

#### ***Practice by nurses***

Candidates intending to practise nursing also need to pass a qualification examination and complete the registration process. Prior to registration, candidates need to complete the prescribed professional nursing courses and engage in clinical nursing practice for a certain

period. Registered nurses are required to practise nursing at their registered practice locations. Nursing practice registrations are valid for five years. Upon expiry of the registration term, registered nurses may apply to the health administrative authority to renew their registrations.

### ***Multi-site practice***

The previous Interim Measures for Registration of Medical Practitioners 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. Since the promulgation of the final Measures for Administration of Registration of Medical Practitioners in 2017, doctors have been able to practise medicine at multiple medical institutions in multiple locations, including internet hospitals. The latest revision to the PRC Law on Licensed Doctors further stipulates that physicians may practise medicine in two or more medical and healthcare institutions and encourages doctors to provide medical and healthcare services on a regular basis in designated medical and healthcare institutions in remote or less developed areas.<sup>13</sup>

### ***Appeals against refusal to grant or withdrawal of licences***

The NHC may refuse to issue a medical practitioner's licence and grant registration to candidates who fail to satisfy the application requirements. If the license or registration is not granted to a candidate, the NHC will serve a written explanatory notice to the candidate and the medical institution which employs such candidate within 20 working days of receipt of the registration application. The candidate may apply for administrative reconsideration within 60 days or initiate a lawsuit within six months upon receiving such rejection notice. If the medical practitioner's licence has been revoked due to malpractice, the medical practitioner may apply for administrative reconsideration within 60 days upon being informed of the withdrawal or initiate a lawsuit within six months upon being so informed.

## **V OWNERSHIP OF HEALTHCARE BUSINESSES**

The basic healthcare system is the cornerstone of China's medical and healthcare system, whereby 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, China has encouraged private capital to invest in medical institutions so that private medical institutions may participate in the provision of medical services. However, although the number of private medical institutions as of the end of November 2021 was twice that of public medical institutions,<sup>14</sup> public health institutions still dominate the medical services market because of the high-quality medical resources they possess.

Foreign-invested medical institutions wishing to enter the Chinese market should refer to the Special Administrative Measures (Negative List) for the Access of Foreign Investment

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13 PRC Law on Licensed Doctors, Article 15 (as revised by the Standing Committee of the National People's Congress on 20 August 2021 and effective on 1 March 2022).

14 According to statistics published by the NHC on 17 January 2022.

(2021) (the Negative List), which restricts foreign investment in medical institutions to the form of a Sino-foreign equity joint venture. Foreign capital or equity is generally not allowed to exceed 70 per cent in foreign-invested medical institutions. However, service providers from Hong Kong, Macao and Taiwan are permitted to establish wholly owned hospitals in some provinces and municipalities in mainland China. The Interim Measures for Administration of Sino-Foreign Joint Venture and Contractual Joint Venture Medical Institutions further stipulate the total investment amount, the minimum percentage of Chinese capital or equity and the term of operations of Sino-foreign joint venture medical institutions. In addition, the local Medical Institution Organisation Plan shall also be complied with when establishing foreign-invested medical institutions.

## **VI MARKETING AND PROMOTION OF SERVICES**

Healthcare service providers adopt various approaches to reach different consumers. For example, individuals may be reached through medical advertising, which is subject to applicable regulatory requirements such as administrative review by the competent NHC office. In addition, the content of medical advertisements is limited to basic information, including the name, type, address and services scope of the medical institution. In general, public hospitals rarely advertise as they are usually already reputable and lack a commercial incentive; however, both domestic and foreign-invested private hospitals have such demand and are more willing to advertise for business development and reputational purposes.

Under the Advertising Law (revised in 2021), medical service advertisements cannot include:

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

## **VII PROCUREMENT OF SERVICES AND GOODS**

### **i Healthcare services procurement**

Healthcare service procurers in China include individuals, central and local governments and other organisations. As mentioned in Section II, above, healthcare services in China can be divided into basic healthcare services and special healthcare services, of which basic healthcare services consist of basic public healthcare services and basic medical care services. Basic public healthcare services are public goods that are procured and paid for by the government. Basic medical care services are quasi-public goods, which are procured by individuals and paid for or subsidised by the individual and the government. Special healthcare services are market-based consumer goods, which are procured and paid for by individuals. Other organisations may also procure healthcare services; for example, companies may procure healthcare insurance for their employees and, accordingly, commercial insurance agencies may procure healthcare services for their policyholders, including but not limited to medical examinations.

Commercial insurance agencies influence procurement of healthcare service in significant aspects. They usually negotiate with designated healthcare service providers to determine the price, payment method, demand volume and other terms before the healthcare

services are provided. Healthcare costs paid by commercial insurance agencies are usually through a reimbursement or direct payment model. Under the reimbursement model, policyholders must pay first before presenting supporting documents to the agency to obtain reimbursement. Under the direct payment model, the policyholder need not pay or present supporting documents; payment is settled directly between the healthcare service providers and the commercial insurance agencies.

For government procurement, the finance departments of local governments at or above the county level are responsible for governmental procurement of healthcare services in their respective jurisdictions, while the Ministry of Finance is responsible for guiding and supervising such activities. In principle, the government may only purchase items listed in the 'Guiding Catalogue for the Purchase of Services by the Central Government at the Same Level' (updated on 22 December 2020) and local catalogues. Such catalogues are formulated and implemented at both the central and provincial levels from time to time.

## **ii Approaches for procuring healthcare services**

Healthcare service providers can actively participate in government procurement. Government procurement is undertaken via several methods, including open bidding, invitation bidding, competitive negotiation, inquiry, and single-source procurement; among these, open bidding is the principal method and mandatory if the procurement amount reaches a specified threshold.<sup>15</sup> Government healthcare service procurement is undertaken at both the central and local levels and usually covers epidemic and pandemic prevention and control, health management, pre-hospital accidents and emergency services. With respect to commercial insurance agencies, healthcare service providers may reach out by negotiating and contracting framework agreements. Medical institutions have also been continuously increasing their partnering with more commercial insurance agencies for better services and greater market participation.

Healthcare service providers should comply with applicable laws and regulations, including the Government Procurement Law (2014), the Regulations for the Implementation of the Government Procurement Law (2015), and other applicable standards and policies on procurement methods and procedures. Notably, there are strict requirements on government procurement participants' qualifications and credit records. If a company has violated laws and regulations, it may suffer from a bad credit record in addition to administrative penalties and potentially even criminal prosecution. Therefore, healthcare providers should comply with laws and regulations not only in government procurement activities, but also in the ordinary course of business. For example, as covid-19 continues in 2022, the Chinese government has procured a large amount of nucleic acid testing services. However, some testing service providers did not strictly comply with the standards and were administratively penalised, listed as dishonest enterprises committing serious violations of law, or even had their business licences revoked.

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15 See Government Procurement Law of the PRC, Articles 26, 27 (promulgated by the Standing Committee of the National People's Congress on 31 August 2014).

## VIII REIMBURSEMENT OF SERVICES AND GOODS

### i Requirements for reimbursement

As introduced above, there are different reimbursement policies corresponding to the three types of healthcare services in China: costs for basic public healthcare services are fully reimbursed by the central and local treasuries in China; costs for basic medical care services may be partially reimbursed by the Chinese government through the basic medical insurance plan; and special healthcare services are directly undertaken by the individuals incurring the costs or reimbursed under commercial health insurance.<sup>16</sup>

Basic medical insurance only covers costs for healthcare services under two government-issued catalogues, the ‘Basic Medical Insurance Drug Catalogue’ and the ‘Basic Medical Insurance Treatment Items’, and costs for emergencies and rescue operations.<sup>17</sup> The National Healthcare Security Administration is responsible for making and adjusting the ‘Basic Medical Insurance Drug Catalogue’ and the ‘Basic Medical Insurance Treatment Items’, and each provincial-level government can make limited adjustments during its local implementation. The ‘Basic Medical Insurance Drug Catalogue’ lists drugs by their generic names; drugs with the same generic name are automatically covered by basic medical insurance. The ‘Basic Medical Insurance Treatment Items’ refer to necessary, safe and effective clinical treatment items with appropriate costs charged at government-approved standards within a designated medical service scope and provided by the designated medical institutions.

To qualify for receiving payments from basic medical insurance, healthcare service providers, including medical institutions and retail pharmacies, need to apply to the competent healthcare security agency to become ‘designated entities’. Basic medical insurance funds are administered by healthcare security administrations and these funds are used to settle healthcare costs with designated medical institutions and retail pharmacies via healthcare security agencies.

### ii Recent developments and innovations

China is committed to optimising the price of medical services and drugs. Since the latter half of 2018, China has begun to carry out a pilot ‘centralised procurement policy’ for certain drugs in 11 cities, centralising the procurement of drugs by public medical institutions across regions. Procurement is made in large volumes to encourage pharmaceutical companies to reduce drug prices and to relieve the cost burden on patients.<sup>18</sup> Given the positive effect of the pilot policy, in 2022 China has continued its nationwide expansion of the centralised medical procurement policy. Under the National Healthcare Security Administration’s plan, each province will cover more than 350 drugs in 2022.<sup>19</sup>

In recent years, city-customised commercial medical insurance has realised explosive growth, with at least 120 cities and 70 million participants covered by the end of 2021.

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16 See Opinions of the CPC Central Committee and the State Council on Deepening Reform of the Medical and Healthcare Systems, Article 4, Paragraph 10 (promulgated by the CPC Central Committee and the State Council on 17 March 2009).

17 See Social Security Law of the PRC, Article 28 (promulgated by the Standing Committee of the National People’s Congress on 29 December 2018).

18 See the Circular of the General Office of the State Council on Printing and Issuing the Plan for the Government’s Pilot Organisation of the Centralised Procurement and Use of Medicine (promulgated by the General Office of the State Council on 1 January 2019).

19 According to State Council Policy Routine Briefing on 11 February 2022.

City-customised commercial medical insurance is a supplemental commercial medical insurance guided by the local healthcare security administration, with a low threshold for enrolment, payable in cash or in individual medical insurance balances, which is able to cover certain inpatient medical costs and high-priced drugs. Although few novel therapies and drugs, such as CAR-T products, are covered by basic medical insurance plans, many are covered by certain city-customised commercial medical insurances. In addition, since 2018, the Chinese government has been promoting ‘internet medical services’ and exploring insurance coverage for eligible internet healthcare services. Internet medical services have gradually entered nationwide coverage under basic medical insurance plans and digital therapies are starting to be considered and planned at the provincial level. In 2021, it was officially confirmed that basic medical insurance plans would begin to cover the costs of internet hospital services.

## **IX DIGITAL HEALTH DEVELOPMENTS**

The digitalisation of the healthcare sector in China accelerated following the 14th Five-Year Plan for National Informatisation, which was issued in 2021. Since then, a series of laws and policies have been adopted to boost the development of digital healthcare in China. Driven by recent legislative developments, technology innovation and the impact of covid-19, China’s healthcare sector is gradually marching into the new era of ‘digital governance’.

### **i Digitalisation of medical services**

A number of actions have been taken to promote the informatisation and digitalisation of medical services. The NHC has promulgated a series of standards regarding the assessment of the application of electronic medical records and the services and management of smart hospitals.<sup>20</sup> The government has emphasised the establishment of comprehensive smart hospital information systems that integrate electronic medical records, smart services and smart management. In addition, artificial intelligence technologies have been widely applied to enable and empower clinical-assisted diagnosis and treatment, medical robotics, public health services, drug research and development and medical equipment management. For example, digital radiology with artificial intelligence has become one of the greatest technological advancements in the medical imaging sector, and artificial intelligence technologies have been successfully utilised to assist in analysing computed tomography (CT) images and has been proved effective and efficient in detecting covid-19.

### **ii Digitalisation of medical insurance**

The Chinese government has taken a number of actions to digitalise the medical insurance system. For example, China has launched a smart medical insurance programme, aiming at the establishment of a unified national healthcare security information platform and the

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20 See the Evaluation and Grading Criteria for Electronic Medical Records (Trial Implementation) (promulgated by the National Health Commission on 3 December 2018), the Evaluation and Grading Criteria for Smart Hospital Services (Trial Implementation) (promulgated by the National Health Commission on 5 March 2019), and the Evaluation and Grading Criteria for Smart Hospital Management (Trial Implementation) (promulgated by the National Health Commission on 15 March 2021).

nationwide implementation of electronic medical insurance cards.<sup>21</sup> Also, a three-year action plan for the pricing and payment method reform of Diagnosis-related Groups (DRG) and Diagnosis-Intervention Packets (DIP) has been adopted.<sup>22</sup> This reform emphasises achieving the transition from retrospective payment of medical insurance to prospective payment and establishing the relevant information technology systems, which are expected to play an important role in controlling healthcare expenditure, thus reducing the financial burden on medical insurance funds and improving the management of medical institutions.

### iii Funding of digital healthcare services

Public medical institutions and governmental authorities obtain funding for digital healthcare services mainly from government financial funds, which are subject to stringent budget control and procurement processes. By contrast, private medical institutions and medical product manufacturers generally cover digitalisation costs themselves, while they may be eligible for financial subsidies.

The 'Internet Plus' medical services provided directly to patients in China are generally categorised into three types: online re-examination services, remote consultation services, and remote patient monitoring services. At the national level, from 2019 to 2021, the NHC and the National Healthcare Security Administration promulgated several guiding opinions on promoting medical insurance for 'Internet Plus' medical services,<sup>23</sup> pursuant to which the costs of diagnosis and medicine arising from online re-examination services provided to patients with common and chronic diseases may be covered by social medical insurance. At the local level, governmental authorities in Chongqing, Tianjin, Sichuan and Shandong have further stipulated that, apart from the online re-examination services as mentioned above, expenses incurred from remote consultation services and remote patient monitoring services could be partially paid by the local medical insurance funds.

## X CORONAVIRUS

Since the outbreak of the covid-19 pandemic in January 2020, China has conditionally approved multiple applications for registration of covid-19 vaccines pursuant to the PRC Vaccine Administration Law and the PRC Drug Administration Law. Meanwhile, the NMPA has also promptly initiated the emergency approval mechanism for medical devices and quickly approved a batch of urgently needed medical devices, especially in vitro diagnostic reagents. China successfully controlled the pandemic in a timely and efficient manner thanks to this quick response mechanism, among other control measures.

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21 See the 14th Five-Year Plan for National Informatization (promulgated by the Central Cyberspace Affairs Commission in December 2021).

22 See the Notice on the Issuance of a Three-year Action Plan for the Reform of DRG/DIP Payment Methods (promulgated by the National Healthcare Security Administration on 19 November 2021).

23 See Guiding Opinions on Improving the 'Internet Plus' Medical Service Prices and Medical Insurance Payment Policies (promulgated by the National Healthcare Security Administration on 17 August 2019), Guiding Opinions on Promoting the 'Internet Plus' Medical Insurance Services during the Period of Prevention and Control of the COVID-19 Epidemic (promulgated jointly by the National Healthcare Security Administration and the NHC on 28 February 2020), and Guiding Opinions on Actively Promoting Medical Insurance Payment for 'Internet Plus' Medical Services (promulgated by the National Healthcare Security Administration on 24 October 2020).

The Regulations on the Supervision and Administration of Medical Devices (revised in 2021) summarise the experience of epidemic prevention and control and introduce and improve the following systems to respond to major public health emergencies: first, a priority review and approval system, which gives priority to the review and approval of innovative medical devices; second, a conditional approval system, which allows conditional approvals for urgently needed medical devices in response to public health events based on a comprehensive balancing of risks and benefits; third, an emergency use system that permits medical devices to be used within a certain scope and a certain period of time in case of any major public health emergency or other emergencies that seriously threaten public health.<sup>24</sup>

## **XI FUTURE OUTLOOK AND NEW OPPORTUNITIES**

‘Internet Plus’ and medical big data are currently two popular concepts in China. Many start-ups and investment institutions are especially focused on emerging business models 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. Regulators have become more open to the application of the internet and big data technology in medical services. In April 2018, the State Council promulgated Opinions on Promoting the Development of ‘Internet plus Healthcare’, promoting a comprehensive online healthcare service system, encouraging medical institutions to use the internet and other information technologies in developing the scope and contents of healthcare services, allowing medical institutions to develop ‘internet hospitals’ that provide online diagnosis of common diseases and follow-up consultations for chronic diseases, supporting medical institutions to cooperate with third-party organisations to establish online platforms for long-distance healthcare consultations, health management and other services, and promoting the exchange of medical resources and information.

During the digitalisation of the healthcare sector, artificial intelligence companies and investment institutions are both faced with unprecedented opportunities. With the new round of digital healthcare reforms since 2021, there has been an increasing demand for software products and information services from medical institutions, medical product manufacturers and governmental authorities at all levels, which creates huge potential markets for relevant businesses and investors. Meanwhile, cutting-edge medical technologies such as artificial intelligence, medical robots, extended reality (including virtual reality, augmented reality, and mixed reality), digital twin, and digital therapy have drawn interest from investment institutions, resulting in more capital being injected into the digital healthcare industry.

Furthermore, with respect to the fast-developing field of gene detection and diagnosis, the Negative List provides that the ‘development and application of human stem cells, gene diagnosis and treatment technology’ is still a prohibited industry for foreign investment, and therefore foreign capital still cannot participate in gene detection and diagnosis projects in China.

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<sup>24</sup> See replies of the NMPA officials to journalists regarding the Regulations on the Supervision and Administration of Medical Devices on 26 March 2021.

## **XII CONCLUSIONS**

China has launched a new round of healthcare reforms since 2009. At present, this round of reforms is ongoing and faces challenges such as improving the graded healthcare system, implementing electronic medical records, relaxing restrictions on doctors to practise medicine, promoting the centralised procurement policy, continuing to promote payment method reforms for basic medical insurance and achieving the optimal allocation of medical resources. Nevertheless, as China is navigating these challenges, the reforms also present an unprecedented opportunity for private-sector investors to participate in the medical and healthcare industries.

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Mr Zhu has extensive legal practice experience in the life sciences and healthcare industries. He has served life sciences and healthcare companies in different stages of development, including financing and licensing deals for start-ups, mergers and acquisitions, and various regulatory and compliance matters, such as anti-corruption and anti-bribery, clinical trials, drug and medical device registration, distribution, advertising and promotion, as well as medical and healthcare data compliance. Prior to joining Han Kun, Mr Zhu practised law for many years at another leading Chinese firm and also in the Shanghai office of an international law firm. Mr Zhu has been consistently recognised as a highly recommended practitioner in life sciences, healthcare, and corporate compliance by leading global legal ranking organisations such as *Chambers and Partners* and *The Legal 500*.

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