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REVIEW

SEVENTH EDITION

Editor
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PREFACE

The seventh edition of *The Healthcare Law Review* covers three new jurisdictions (India, Mexico and Nigeria), summing up to a total of fifteen jurisdictions from countries in Europe, North and South America Asia and – for the first time – Africa. All reports 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 which are of interest for healthcare providers and related businesses.

The global covid-19 pandemic has come to an end this spring. The WHO chief Tedros Ghebreyesus declared the end to covid-19 as a global health emergency on 5 May 2023. According to the reviews from the individual countries, most of the exceptional measures, which had been implemented by the countries to fight the pandemic, have largely been scaled back or totally withdrawn. Therefore, the authors report back to normal in their reviews.

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 more digitisation and telemedicine. This is not just about supplementing or replacing face-to-face doctor visits with communication options via telephone or video consultation. Many countries, not only in Europe, have also introduced electronic patient files, regulations for the exchange of health data and other digital communication channels. It seems that it is still a long way to go to implement these innovations successfully 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. Furthermore, the European Commission has published a proposal of a new pharma package, which may have major impact on the healthcare systems in the member states of the European Union in particular.

Germany however, the largest healthcare system in the European Union, still faces many hurdles before implementing electronic prescriptions, electronic patient records or statutes for the secondary use of health data. The authors report from South Korea that the strict measures for telemedicine services are back in force. These examples show that healthcare systems in the individual countries tend to defend the status quo rather than to implement digital and electronic tools with fast speed.

Even if the individual countries solve the 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 new edition of *The Healthcare Law Review* will particularly be helpful in that respect.

Like in past years, it has been 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 be able to give a comprehensive worldwide approach to health issues by each country.

Ulrich Grau

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CHINA

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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 National Health Commission (NHC)² 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)³ 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 (Third Edition), promulgated in 2017, stipulates that basic public healthcare services consist of 13 types of services, including 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 emergency reporting and treatment. In December 2019, the Law on

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.

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 health 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 2022, the number of people participating in basic medical insurance schemes reached 1.348 billion, with the coverage stabilising at over 95 per cent of the population of China.⁴

iii Funding and payment for specific 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.⁵

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.⁶

4 See 'Statistical Bulletin on the Development of Medical Security Undertakings in 2022 published by the National Healthcare Security Administration on 10 March 2023.

5 Circular on Issuing the Opinions on Promoting the Medical Service Pricing Reform (promulgated by National Development and Reform Commission, National Health and Family Planning Commission, Ministry of Finance, Ministry of Human Resources and Social Security on 1 July 2016).

6 Opinions 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).

III PRIMARY/FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

i China's healthcare system

China's healthcare 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, community healthcare service centres, and clinics and infirmaries. Densely populated cities also have tertiary hospitals with more advanced technologies and equipment. The entire healthcare 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.⁷ 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.⁸

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.⁹ The country also supports pension institutions in establishing medical institutions and medical institutions establishing pension institutions.¹⁰

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

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

9 See Circular 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 (General Office of the State Council, No. 84, 2015).

10 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).

China's central and local governments also 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 healthcare 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 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.¹¹ 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 requirements for electronic medical records as to their content, writing and retention, use and storage. 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. These include the Civil Code, the Personal Information Protection Law, the Data Security Law, the Cybersecurity Law, the Measures for the Standard Contract for Outbound Transfer of Personal Information, 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).

11 Circular 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, annulled on 7 June 2018).

Significant regulatory attention has focused on personal information protection in the healthcare system. 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) and the Regulations on Administration of Human Genetic Resources.

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 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 rediagnosis 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. 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:

- f* developing medical institutions, medical technology applications, medical quality, medical safety and medical service policies and organisational standards;
- g* developing medical personnel practice and service standards;
- h* formulating medical institution and healthcare industry administrative measures and exercising supervision;
- i* participating in drug and medical equipment clinical trial administration;
- j* leading the oversight of nationwide medical institution assessments and developing public hospital operating oversight and performance evaluations and assessments; and
- k* organising and coordinating the work to cope with infectious diseases, leading the prevention and control of public health emergencies and medical treatment and health interventions for all kinds of public emergencies.

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, Macau 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.¹²

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 (if any).

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 for 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 of 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 of being informed of the revocation or withdrawal or initiate a lawsuit within six months of 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 allowed individuals who served in medical institutions, and those who were retired due to illness or 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 in 10 cities (including Beijing, Shanghai and Guangzhou) 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 two years of pilot implementation (2019 to 2020), this policy was eventually confirmed in the Interim Measures for Clinic Filing Management, released and implemented on 20 December 2022, which specify that doctors may set up personal

¹² Circular on Issuing the Reform Measures for the Reform of Separating Operating Permits and Business Licences in the Medical Care Sector (General Office of the NHC, 2 July 2021).

clinics if they have registered and practised in a medical institution for at least five years. This is regarded as a major step in China's reforms to permit eligible doctors to freely practise medicine and establish personal clinics.

iii Healthcare professionals

In China, physicians, nurses and pharmacists must practise medicine in accordance with the 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.

Foreigners who wish to practise medicine in China (e.g., foreign-registered physicians) must 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 who intend to practise nursing also need to pass a qualification examination and complete the registration process. Prior to registration, candidates must 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 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 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.

Appeals against refusal to grant or revocation 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 that 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 of receiving this 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 of being informed of the revocation or initiate a lawsuit within six months of 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 December 2022 was more than twice that of public medical institutions,¹³ 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 latest Special Administrative Measures (Negative List) for the Access of Foreign Investment (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, Macau 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 minimum total investment amount (20 million yuan), the minimum percentage of Chinese capital or equity (30 per cent) and the maximum term of operations of Sino-foreign joint venture medical institutions (20 years). In addition, the local Medical Institution Organisation Plan should also be complied with when establishing foreign-invested medical institutions.

13 According to statistics published by the National Bureau of Statistics on 28 February 2023.

VI MARKETING AND PROMOTION OF SERVICES

i Advertising and promotions

The medical and healthcare industries are highly regulated with respect to advertising and promotional activities, including interactions between specific entities and individuals.

In addition to general regulatory requirements, advertisements for medical services, drugs and medical devices are all subject to special requirements including prior review as specified in the Advertising Law and the Anti-Unfair Competition Law.

For medical service advertising, the content of the advertisement is limited to basic information consistent with the healthcare provider's practice licence, including the provider's first name, form of ownership, address, classification, number of hospital beds, scope of clinical subjects, service hours and contact phone number of the medical institution, in accordance with the Measures for the Administration of Medical Advertisements.

Drug and medical device advertising is also highly regulated and subject to special requirements under the Interim Measures for the Administrative Review of Advertisements for Drugs, Medical Devices, Dietary Supplements and Formula Food for Special Medical Purposes. For example, off-label information may not be included in advertising and promotional materials for drugs and medical devices, which could constitute false advertising in violation of the Advertising Law or false or misleading commercial promotion with respect to performance and function in violation of the Anti-Unfair Competition Law. In addition, the following are prohibited in both drug and medical device advertising as specified in the Advertising Law:

- 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 other products;
- d* the use of spokespersons to endorse or provide testimonials; and
- e* advertising disguised as health and well-being advice.

ii Anti-Bribery Requirements

The medical and healthcare industries have long been a top priority for law enforcement with respect to anti-bribery and anti-corruption. According to the Anti-Unfair Competition Law, business operators are prohibited from bribing the following entities or individuals in order to seek transaction opportunities or competitive advantages:

- a* any employee of the counterparty in transactions;
- b* any entity or individual entrusted by the counterparty in transactions to handle relevant affairs; and
- c* other entities or individuals who can use their position or power to influence transactions.

Specifically, regulators closely scrutinise kickbacks to medical practitioners in the form of off-the-book and secretive benefits, such as cash or property, offered in return for purchasing products or services. Fourteen ministries and departments, including the NHC and the

NMPA, have long jointly named anti-bribery issues as a law enforcement focus, and, in 2023, they have emphasised actions against bribery through donations, academic activities and conferences, and rebate and kickbacks in medical products transactions.¹⁴

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, 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 procure healthcare insurance for their employees and, accordingly, commercial insurance agencies procure healthcare services for their policyholders, including but not limited to medical examinations.

Commercial insurance agencies influence procurement of healthcare services 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.

¹⁴ See the Notice of Key Highlights of Correcting Bad Practices in the Field of Purchase and Sales of Drugs and Medical Services in 2023, Articles 5–6 (promulgated by 14 ministries and departments of China on 8 May 2023).

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.

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.¹⁵

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. 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, must apply to the competent healthcare security agencies 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.¹⁶ Given the positive effect of

15 See Opinions 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).

16 See Circular on 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).

the pilot policy, in 2023 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 450 drugs in 2023.¹⁷

In recent years, city-customised commercial medical insurance has realised explosive growth, with about 750 million participants covered by April 2023.¹⁸ 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. In 2023, the National Healthcare Security Administration issued a written response that provided that medical insurance plans would cover the costs of internet medical services provided by eligible medical institutions once they fulfil certain requirements.

IX DIGITAL HEALTH DEVELOPMENTS

The digitalisation of the healthcare system in China accelerated following the 14th Five-Year Plan for National Informatisation issued in 2021 and the 14th Five-Year Plan for Informatisation of National Health promulgated in 2022, which outline the blueprints for digital healthcare of China. Since then, a series of laws and policies have been adopted to boost the development of digital healthcare. Driven by recent legislative developments, technology innovation and the impact of covid-19, China's healthcare system is gradually marching into the new era of 'digital governance'.

i Digitalisation of medical services

Regulators have taken many actions to promote the informatisation and digitalisation of medical services in China. 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.¹⁹ The government has emphasised the establishment of comprehensive smart hospital information systems that integrate electronic medical records, smart services and smart management. In addition, the Ministry of Science and Technology has issued multiple initiatives to promote the development and application of artificial intelligence

17 According to the Notice on the Centralised Medical Procurement and Price Management in 2023 (promulgated by the National Healthcare Security Administration on 22 February 2023).

18 According to the speech presented by Yu Hua, the chairman of the Insurance Association of China, on the ending ceremony of the fifth 'Healthy China' forum on 26 April 2023.

19 See Evaluation and Grading Criteria for Electronic Medical Records (for Trial Implementation) (NHC, promulgated 3 December 2018); the Evaluation and Grading Criteria for Smart Hospital Services (for Trial Implementation) (NHC, promulgated 5 March 2019); and the Evaluation and Grading Criteria for Smart Hospital Management (for Trial Implementation) (NHC, promulgated 15 March 2021).

technologies in the healthcare sector. Efforts have been made to explore intelligent medical imaging-aided diagnosis, clinical-aided diagnosis and treatment, medical robotics, internet hospitals, intelligent management of medical equipment, smart hospitals and smart public health services.²⁰ Empowered by artificial intelligence, smart diagnosis and treatment is selected as one of the first 10 fields where the demonstration and application of artificial intelligence is strongly encouraged and supported.²¹ At the local level, Hainan Province has adopted the first full-life-cycle medical industry policy in China to support and accelerate the development of digital therapeutics. A multitude of specific and noteworthy policies have been implemented, such as building a leading centre for digital clinical research and trials, accelerating the registration of digital therapeutics products, promoting relevant application fields and exploring multiple payment methods.²²

During the digitalisation of medical services, the government has raised the issue of cybersecurity among healthcare providers. Medical and healthcare institutions are also required to comply with laws and regulations on cybersecurity and data security management, especially with respect to the important data and personal information.²³

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, which aims to establish a unified national healthcare security information platform and the nationwide implementation of electronic medical insurance cards.²⁴ 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.²⁵ 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.

20 See Guiding Opinions on Accelerating Innovation in Scenarios to Promote High-level Economic Development through High-level Application of Artificial Intelligence (Ministry of Science and Technology et al., promulgated 29 July 2022).

21 See Notice on Supporting the Development of Demonstration and Application Scenarios for New-Generation Artificial Intelligence (Ministry of Science and Technology, promulgated 12 August 2022).

22 See Circular on Issuing the Several Measures in Hainan Province to Accelerate the Development of the Digital Therapy Industry (General Office of the People's Government of Hainan Province, promulgated 29 September 2022).

23 See Notice on Promulgation of the Administrative Measures for the Cybersecurity of Medical and Healthcare Institutions (NHC et al., promulgated 8 August 2022).

24 See 14th Five-Year Plan for National Informatisation (Central Cyberspace Affairs Commission, promulgated December 2021).

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

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.

‘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,²⁶ 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 mentioned above, expenses incurred from remote consultation services and remote patient monitoring services can be partially paid by local medical insurance funds.

X CORONAVIRUS

Following the outbreak of the covid-19 pandemic in January 2020, China conditionally approved multiple applications for registration of covid-19 vaccines pursuant to the Vaccine Administration Law and the Drug Administration Law. Meanwhile, the NMPA 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. The Regulations on the Supervision and Administration of Medical Devices 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 emergency that seriously threatens public health.

Apart from the impact on drug and medical device registrations, covid-19 also affected medical services and medical insurance. During the pandemic, medical institutions were encouraged to prescribe medicines online for patients infected with covid-19 and to deliver them through qualified third parties under certain circumstances.²⁷ Notably, the government downgraded covid-19 administrative measures from a Class A infectious disease to a Class B

26 See, e.g., Guiding Opinions on Improving the ‘Internet Plus’ Medical Service Prices and Medical Insurance Payment Policies (National Healthcare Security Administration, promulgated 17 August 2019).

27 See Notice on Provision of Internet Medical Services for covid-19 (Joint Prevention and Control Mechanism of the State Council, promulgated 11 December 2022).

infectious disease on 8 January 2023, which was followed by a series of easing measures.²⁸ Medicines used for covid-19, such as Azvudine tablets and lung cleaner, have been listed on the National Reimbursement Drug List,²⁹ and the cost of other medicines used to treat covid-19 outside the list may be covered temporarily by medical insurance funds under certain circumstances.³⁰

XI FUTURE OUTLOOK AND NEW OPPORTUNITIES

In January 2023, it was reported that the population of China fell for the first time in 60 years. The Report on the Work of the Government, delivered on 5 March 2023, calls for pursuing a proactive national strategy in response to population aging and refining policies in support of childbirth. The legitimate rights and interests of women, children, the elderly and people with disabilities will be protected. The report also mentions that more quality medical resources will be made available and weighted toward the community level and that traditional Chinese medicine shall be revitalised.

‘Internet Plus’ and medical big data remain popular and are undergoing rapid development in China. The Opinions on Promoting the Development of ‘Internet plus Healthcare’, promulgated by the State Council in April 2018, marked the beginning of promoting the application of the internet and big data technology in medical services by the state. Since then, numerous policies have been issued to promote this trend, and, recently, concepts of protecting important data and improving data security monitoring have been promoted along with the trend of ‘Internet Plus’. Furthermore, the application of the internet, blockchain, the internet of things, artificial intelligence, cloud computing and big data will be accelerated, a healthcare data security system will be constructed and the data security protection capabilities of the healthcare institutions will be improved, according to the Opinions on Further Improving the Medical and Health Service System, promulgated by the CPC Central Committee and the General Office of the State Council in March 2023.

‘ChatGPT’ is the key word in 2023 with respect to the digitalisation of the healthcare system in China. Although ChatGPT has not been officially launched in China, it has brought heated discussions in all industries and areas, including healthcare. It is predicted that ChatGPT may be used in the future for information retrieval, assisted diagnosis, pharmaceutical development and writing research studies, especially in the areas of improving self-service, timeliness and big data. The use of artificial intelligence technologies such as ChatGPT can also facilitate an intelligent shift in data sharing, healthcare decision-making and service delivery in cyberspace.

28 See Notice on the Promulgation of the Overall Plan for Classifying covid-19 as Class B Infectious Disease and Subjecting covid-19 to Corresponding Preventive and Control Measures (Joint Prevention and Control Mechanism of the State Council, promulgated on 26 December 2022).

29 See National Reimbursement Drug List (2022) (National Healthcare Security Administration and the Ministry of Human Resources and Social Security, promulgated 13 January 2023).

30 See Circular on Further Improving the Security of Medical Expenses for Patients Infected with covid-19 (National Healthcare Security Administration, Ministry of Finance, and the National Bureau of Disease Control and Prevention, promulgated 29 March 2023).

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. Therefore, foreign capital still cannot participate in gene detection and diagnosis projects in China.

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.