

IN-DEPTH

Healthcare Law

CHINA



LEXOLOGY

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In-Depth: Healthcare Law (formerly The Healthcare Law Review) provides a global introduction to healthcare economies and their legal frameworks. It covers both diverse areas of practice and the common challenges and approaches across key jurisdictions, including the role of insurance or public payers; models of commissioning; the interplay between primary, secondary and social care; and the regulatory and licensing arrangements for healthcare providers and professionals.

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China

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Introduction

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.

Year in review

The year 2023 saw significant developments in China's healthcare sector, ranging from regulatory advancements in the digitalisation of medical services, records and medical insurance to a new anti-corruption campaign targeting areas of non-compliance such as misconduct by drug enterprise executives, illegal kickbacks related to drug sales and the use of medical insurance funds. Behind these developments, legal compliance remains a cornerstone for enterprises operating in the sector and necessitates vigilance on the part of practitioners.

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, healthcare education, vaccinations, healthcare administration for special at-risk groups, traditional Chinese medicine health management, infectious diseases and public healthcare emergency reporting and treatment and health and family planning supervision. 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. Both public and non-public medical institutions 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.^[4]

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 2023, the number of people participating in basic medical insurance schemes reached 1.334 billion, with the coverage stabilising at over 95 per cent of the population of China.^[5]

iii Funding and payment for specific services

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]

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] and the NHC is continuously improving the healthcare system in accordance with the requirements of the graded medical treatment system.

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]

According to the Guidelines for Community and Home Integrated Healthcare and Nursing Services (for Trial Implementation) promulgated in November 2023, the NHC is vigorously developing the integration of community and home healthcare and nursing services, pursuant to which medical institutions may provide healthcare services for the elderly (such as healthcare visits and home sickbeds), either at their home or in community healthcare service centres.

iv 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. Personal health data is considered a sensitive form of information; thus, healthcare providers are subject to significant regulatory requirements for how they process data during the provision of services. The relevant provisions of law 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, Guidelines to the Filing of the Standard Contract for Outbound Transfer of Personal Information (First Edition), 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).

v 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 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. 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.

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:

1. developing medical institutions, medical technology applications, medical quality, medical safety and medical service policies and organisational standards;
2. developing medical personnel practice and service standards;
3. formulating medical institution and healthcare industry administrative measures and exercising supervision;
4. participating in drug and medical equipment clinical trial administration;
5. leading the oversight of nationwide medical institution assessments and developing public hospital operating oversight and performance evaluations and assessments; and
6. 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.

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 licence or clinics that operate without the appropriate filing or whose medical treatment activities exceed the scope specified in a licence 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 licences revoked (if any). Furthermore, according to the Criminal Law, unlawfully practicing medicine without the requisite qualifications can lead to up to three years of imprisonment, criminal detention, public surveillance and fines.

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 as a result of 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 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 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.

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.

Ownership of healthcare businesses

i Limitations on ownership of healthcare businesses

According to the Regulations on the Administration of Medical Institutions, the setup of any medical institution shall be in compliance with the plan for setting up medical institutions and the basic standards for medical institutions by the NHC. Additionally, both national and local NHCs have specific requirements for different types of medical institutions, such as basic standards for certain departments within general hospitals.

ii Barriers for inbound investment in healthcare by foreign businesses

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.

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:

1. assertions or guarantees as to efficacy and safety;
2. efficacy rates or cure rates;
3. comparisons of the safety or efficacy of drugs or medical devices with other products;
4. the use of spokespersons to endorse or provide testimonials; and
5. advertising disguised as health and well-being advice.

Additionally, for prescription drug advertising, the Advertising Law imposes even more stringent restrictions, permitting advertising only in professional publications jointly designated by the NMPA and NHC.

Recent developments

With the rise of the internet healthcare industry and the development of online sales of drugs and medical devices, the regulation of internet advertising has gained increasing attention and importance in recent years. The SAMR released the Measures on the Administration of Internet Advertising, which entered into force on 1 May 2023. The Measures have clarified and refined the compliance requirements for internet advertising, reiterating the stringent regulatory requirements for advertisements for medical services, drugs and medical devices in the context of internet advertising.

In addition, following the implementation of the Provisions for Supervision and Administration of Online Drug Sales, the NMPA has been continuously enhancing the regulation of drug information displays in online drug sales. For example, it is prohibited to display details of a prescription drug on a homepage or landing page, such as its packaging, labelling and related information. Additionally, before the prescription verification is completed, it is not permitted to display any information, such as the instructions, or to provide any related service for purchasing prescription drugs. Under these regulations, online platforms are also responsible for the compliance of online drug advertising and promotion, not only drug distributors.

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. 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.^[11]

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 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 procure healthcare insurance for their employees and, accordingly, commercial

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

For government procurement, the applicable laws mainly include the Law on Basic Medical and Healthcare and the Promotion of Health, the Government Procurement Law, and the Implementing Rules on the Government Procurement Law. 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.

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.

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.^[12]

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, as well as the expenses for medical service facilities that meet the standards set by the government, 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.

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.^[13] Given the positive effect of the pilot policy, in 2024 China has continued its nationwide expansion of the centralised medical procurement policy, actively advancing centralised procurement at the national, provincial and provincial alliance levels, and continuously expanding the coverage of drug procurement. Diversified reimbursement systems are evolving. For instance, city-customised commercial insurance with government backing is emerging, potentially covering innovative therapies like CAR-T products. By 2024, healthcare authorities across numerous provinces had integrated a sizable roster of designated online medical institutions within their jurisdictions into basic medical insurance coverage schemes, thereby bringing the 'Internet + Medical Insurance' model to fruition.

Digital health developments

The digitalisation of the healthcare system in China accelerated following the 14th Five-Year Plan for National Informatisation issued in 2021, the 14th Five-Year Plan for Informatisation of National Health promulgated in 2022, and the Layout of National Digital Development rolled out in 2023, which outline the blueprints for digital healthcare in China. Since then, a series of laws and policies have been adopted to boost the development of digital healthcare. Driven by recent legislative developments, policy inspiration, technology innovation and consumer demands, 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.^[14] The government has emphasised the establishment of comprehensive smart hospital information systems that integrate electronic medical records, smart services and smart management. In addition, government authorities have issued multiple initiatives to promote the development and application of artificial intelligence technologies, blockchain, the Internet of Things, cloud computing and big data in the healthcare sector.^[15] The application of digital twin technology in clinical research has also been encouraged.^[16] 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.^[17]

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 throughout the process of medical treatment and drug purchase.^[18] 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.^[19] 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. It is reported that more than 90 per cent of the regions across China had launched the DRG/DIP reform by the end of 2023.^[20]

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,^[21] 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.

Special considerations

i Two-invoice system

China launched a pilot programme for a two-invoice system in 2016 and rolled it out for nationwide implementation in 2018.^[22] This programme aimed to regulate and streamline the pharmaceutical procurement process and ensure the safe and steady supply of drug products at reasonable and affordable prices. The two-invoice system means that, during the distribution process from a drug manufacturer to the end-user medical institutions,

only up to two VAT invoices can be issued, usually with one issued by the manufacturer to the distributor and the other issued by the distributor to the end-user medical institutions.

Some provinces and cities in China have also enacted local regulations stipulating that a Contract Manufacture Organisation (CMO) or Contract Sales Organisation (CSO) appointed by the marketing authorisation holder to deliver the pharmaceutical product can be deemed as the manufacturer of the product, and the delivery of the product to such CMO or CSO will not be deemed to constitute 'one invoice', as long as such CMO or CSO, as applicable, would mainly provide services without acquiring the ownership of the product or issuing invoices for such product.

ii Anti-corruption campaign

Since the middle of 2023, China's healthcare sector has witnessed a sharp escalation and uprising momentum of rigorous inspection and investigation regarding anti-corruption. Following the Key Points of Work on Rectifying Misconduct in the Fields of Medical Product Purchase and Distribution and Medical Services in 2023 jointly issued by the NHC and other 13 government authorities on 11 May 2023, which aims at rectifying unethical practices in the healthcare sector, the NHC, the Central Commission for Discipline Inspection (CCDI) and the National Supervisory Commission (NSC) have held several conferences to announce the commencement of a year-long and nationwide anti-corruption campaign.^[23]

iii Sci-tech ethics review

China has unveiled its trial guideline on the review of sci-tech ethics in 2023, driven by the rapid development of sci-tech innovation and the growing ethical risks and challenges in the sci-tech field.^[24] Sci-tech activities are required to go through the sci-tech review procedure where they involve human research participants, human biological samples and personal data, and experimental animals as well as those that may impose potential ethical risks on health, ecological environment, public order and sustainable development.

Outlook and conclusions

i Technological integration and digitalisation

The integration of technology into healthcare is accelerating, driven by initiatives like 'Internet Plus' and the rapid development of medical big data. Policies promoting the application of internet technologies, blockchain, the internet of things, artificial intelligence (AI), cloud computing, and big data are shaping the future of healthcare. Notably, AI technology is being integrated into drug development processes, particularly in drug discovery and preclinical research stages. Additionally, brain-computer interface (BCI) technology is advancing rapidly, with significant breakthroughs in 2023, suggesting that BCI will soon see broader clinical applications.

ii Emphasis on patient-centred and integrated care

The 'patient-centred' approach is being reinforced across various aspects of healthcare, including drug development, medical services, doctor-patient communication, and clinical trials. In 2023, the National Medical Products Administration issued guidelines emphasising patient-centred drug development. Furthermore, with the aging population, integrated medical and elderly care has become a focus, covering home-based care, community care, wellness, elderly disease prevention, and early intervention. In 2023, health management and smart elderly care startups experienced a surge in capital, indicating a robust future for this sector in the years to come.

iii Enhancing anti-corruption efforts

China has continued to enhance its anti-corruption efforts. Legal and policy developments, such as the passing of the 'Criminal Law Amendment (XII)' on 29 December 2023, which imposes harsher penalties for bribery in the healthcare sector, have further strengthened the framework for combating corruption. As these measures continue into 2024, they are expected to yield long-term benefits, fostering an environment of transparency and accountability in the sector.

iv Conclusions

Reflecting on the evolving landscape of China's healthcare sector, it becomes evident that legal compliance remains a cornerstone for organisations operating within this domain. Looking ahead, the Chinese healthcare sector is poised for further transformation, driven by technological advancements, regulatory refinements and a persistent focus on quality and compliance.

Endnotes

- 1 Min Zhu, Aaron Zhou, Li Zhang and Aaron Gu are partners at Han Kun Law Offices. [^ Back to section](#)
- 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. [^ Back to section](#)
- 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. [^ Back to section](#)
- 4 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). [^ Back to section](#)

- 5** See Statistical Bulletin on the Development of Medical Security Undertakings in 2023 published by the National Healthcare Security Administration on 11 April 2024. [^ Back to section](#)
- 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). [^ Back to section](#)
- 7** China Health Industry Bluebook (2017), page 16 (China National Pharmaceutical Industry Information Centre, 2017). [^ Back to section](#)
- 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). [^ Back to section](#)
- 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). [^ Back to section](#)
- 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). [^ Back to section](#)
- 11** 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). [^ Back to section](#)
- 12** 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). [^ Back to section](#)
- 13** 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). [^ Back to section](#)
- 14** See Evaluation and Grading Criteria for Electronic Medical Records (for Trial Implementation) (NHC, promulgated on 3 December 2018); the Evaluation and Grading Criteria for Smart Hospital Services (for Trial Implementation) (NHC, promulgated on 5 March 2019); and the Evaluation and Grading Criteria for Smart Hospital Management (for Trial Implementation) (NHC, promulgated on 15 March 2021). [^ Back to section](#)
- 15** See Opinions on Further Improving the Medical and Health Service System (CPC Central Committee and the General Office of the State Council, promulgated on 23 March 2023). [^ Back to section](#)

- 16** See Three-Year Action Plan (2023–2025) for the Innovative Development of the Metaverse Industry (Ministry of Industry and Information Technology, et al, promulgated on 29 August 2023) ^ [Back to section](#)
- 17** 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 on 29 September 2022). ^ [Back to section](#)
- 18** See 14th Five-Year Plan for National Informatisation (Central Cyberspace Affairs Commission, promulgated on December 2021); the Circular of the National Healthcare Security Administration on Further Advancing the Informatisation and Standardisation of Medical Insurance (National Healthcare Security Administration, promulgated on 17 February 2022); the Circular of the General Office of the State Medical Security Administration on Implementing 16 Convenience Measures Concerning Medical Insurance Services (National Healthcare Security Administration, promulgated on 25 May 2023). ^ [Back to section](#)
- 19** See Notice on the Issuance of a Three-year Action Plan for the Reform of DRG/DIP Payment Methods (National Healthcare Security Administration, promulgated on 19 November 2021). ^ [Back to section](#)
- 20** See Statistical Express on the Development of Medical Security in 2023, available at http://www.nhsa.gov.cn/art/2024/4/11/art_7_12348.html. ^ [Back to section](#)
- 21** See, e.g., Guiding Opinions on Improving the 'Internet Plus' Medical Service Prices and Medical Insurance Payment Policies (National Healthcare Security Administration, promulgated on 17 August 2019). ^ [Back to section](#)
- 22** See Implementing Opinions on Promoting the 'Dual Invoicing System' for the Drug Procurement by Public Medical Institutions (for Trial Implementation) (NHC et al, promulgated on 26 December 2016). ^ [Back to section](#)
- 23** Available at https://www.ccdi.gov.cn/toutiaon/202307/t20230728_278985.html; <http://www.nhc.gov.cn/ylyjs/pqt/202307/7baafcfc244af69a962f0006cb4e9c.shtml>. ^ [Back to section](#)
- 24** See the Notice on Promulgation of the Measures for the Review of Sci-tech Ethics (for Trial Implementation) (the Ministry of Science and Technology et al, promulgated on 7 September 2023). ^ [Back to section](#)

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