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## REGULATORY OVERVIEW

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Our business in the PRC is subject to extensive supervision and regulatory control by the PRC government. This section sets out a summary of the major relevant laws, regulations, rules and policies which may have material impact on our business, particularly in relation to: (i) reforms of medical institutions that may affect our capabilities to implement our existing business strategies for the expansion of our hospital network; (ii) the classification and management of medical institutions, supervision of medical devices and pharmaceuticals in medical institutions, price of healthcare services, medical professionals, environmental protection and labor protection, and the governance of our day-to-day operations which may affect our costs of compliance; (iii) medical incidents which may affect our indebtedness arising from our day-to-day operations; (iv) foreign investors investing in the PRC; (v) taxation and foreign exchange matters which may affect our operating results and business; and (vi) overseas listing and H share “full circulation.”

### Regulations on the Reform of Medical Institutions

#### *Opinions of the Central Committee of the Communist Party and the State Council on Promoting Further Reform of the Healthcare System (《中共中央、國務院關於深化醫藥衛生體制改革的意見》)*

The Opinions of the Central Committee of the Communist Party and the State Council on Promoting Further Reform of the Healthcare System (《中共中央、國務院關於深化醫藥衛生體制改革的意見》) (the “**Opinions**”), which was promulgated by the State Council on March 17, 2009, advocates a range of measures to reform medical institutions in China and to establish a basic healthcare system covering urban and rural residents. The Opinions encourage private capital to invest in medical institutions (including investments by foreign investors), the development of private medical institutions and the reform of public medical institutions (including those established by state-owned enterprises) through private capital investment.

#### *Opinions on Accelerating the Development of Setup Medical Institutions by Social Capitals (《關於加快發展社會辦醫的若干意見》)*

Opinions on Accelerating the Development of Setup Medical Institutions by Social Capitals (《關於加快發展社會辦醫的若干意見》), which was promulgated by the National Health and Family Planning Commission (the “**NHFPC**”) and the State Administration of Traditional Chinese Medicine (the “**SATCM**”) on December 30, 2013, stipulates the policies to support the development of private-invested healthcare institutions, including but not limited to the (i) gradual relaxation of investment in healthcare institutions by foreign capital; (ii) relaxation of requirements for service sectors, allowing social capital’s investment in the areas which are not explicitly prohibited; and (iii) acceleration of the approval procedures regarding the establishment and operation of private hospitals.

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***Opinions of the General Office of the State Council on Encouraging Social Forces to Provide Multi-layered and Diverse Healthcare Services (《國務院辦公廳關於支持社會力量提供多層次多樣化醫療服務的意見》)***

Opinions of the General Office of the State Council on Encouraging Social Forces to Provide Multi-layered and Diverse Healthcare Services (《國務院辦公廳關於支持社會力量提供多層次多樣化醫療服務的意見》), which was promulgated by the General Office of the State Council on May 16, 2017, stipulates the policies to actively support social forces to go deep into the niche service market, such as specialized medical services, expand the effective supply of services, and foster professionalized advantages. A number of competitive branded service agencies will be formed at a rapid pace for such specialties including but not limited to medical imaging.

***Guiding Opinions of the General Office of the State Council on Promoting the Construction and Development of the Medical Treatment Partnership (《國務院辦公廳關於推進醫療聯合體建設和發展的指導意見》) and Administrative Measures for the Medical Treatment Partnership Groups (for Trial Implementation) (《醫療聯合體管理辦法(試行)》)***

According to Guiding Opinions of the General Office of the State Council on Promoting the Construction and Development of the Medical Treatment Partnership (《國務院辦公廳關於推進醫療聯合體建設和發展的指導意見》), promulgated by the General Office of the State Council on April 23, 2017 and came into effect on the same day, it is encouraged to explore the establishment of the Medical Treatment Partnership Groups (the “MTPS”) in various forms by region and at different levels, and promote the flow of quality medical resources to the grassroots and remote and poverty-stricken areas, and privately-invested medical institutions may be included in the MTPS according to their wishes.

According to Administrative Measures for the Medical Treatment Partnership Groups (for Trial Implementation) (《醫療聯合體管理辦法(試行)》) jointly promulgated by the National Health Commission of the PRC (the “NHC”) and SATCM on July 9, 2020 and came into effect on August 1, 2020, the MTPS includes but is not limited to urban medical groups, county-level medical communities, specialist alliances and telemedicine collaborative networks. The construction of urban medical groups and county-level medical communities should adhere to the government’s leadership and implement grid management according to the regional medical resource structure layout and the health needs of the masses. The urban medical groups and county-level medical communities should strengthen the sharing of resources within the MTPS by setting up medical imaging, examination and testing, pathological diagnosis and sterilization and supply centers, to provide homogeneous services for the medical and health institutions within the MTPS. Medical institutions invested by social capital are encouraged to join the MTPS on a voluntary basis.

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### ***Circular on Further Reforming and Improving the Examination and Approval of Medical Institutions and Physicians*** (《關於進一步改革完善醫療機構、醫師審批工作的通知》)

According to Circular on Further Reforming and Improving the Examination and Approval of Medical Institutions and Physicians(《關於進一步改革完善醫療機構、醫師審批工作的通知》), promulgated by the NHC and the SATCM on June 15, 2018 and came into effect on the same day, on the premise of ensuring medical quality and safety, medical institutions may entrust independently established medical test laboratories, pathological diagnosis centers, medical imaging diagnosis centers, medical sterilization supply centers or other qualified medical institutions to provide medical test, pathological diagnosis, medical imaging, medical sterilization supply and other services.

### ***Opinions on Further Improving the Medical and Health Service System*** (《關於進一步完善醫療衛生服務體系的意見》)

In March 2023, the General Office of the State Council of the PRC published the Opinions on Further Improving the Medical and Health Service System (《關於進一步完善醫療衛生服務體系的意見》), pursuant to which, the establishment of county-level medical communities (縣域醫共體) in the PRC shall be promoted, particularly: (i) the county-level medical communities (縣域醫共體) shall be developed in rural areas based on counties, with hospitals at county level taking the lead and several other medical and health institutions at county level, township health centers and community health service centers as member units, to push forward the construction of close county medical community, implement county and township integrated management, gradually realize the overall management of administration, personnel, finance, business, directory of drugs and information system, and establish community of responsibility, management, service and interest; and (ii) open and sharing imaging, electrocardiogram, pathological diagnosis and medical examination centers shall be established to promote the mutual recognition of grass-roots examinations, higher-level diagnosis and examination and examination results. The coordinated use of beds, registration resources and equipment within the medical communities and among the medical communities shall be strengthened.

The Company is of the view that, the Opinions on Further Improving the Medical and Health Service System would not have a material adverse impact on the Group's business operations and financial performance going forward, on the basis that: (i) such document advocates the establishment of open and shared medical imaging centers, and does not restrict the services of third-party medical imaging centers; (ii) according to the policies issued in recent years, the government encourages the establishment of third-party medical imaging centers, the establishment of the MTPS in various forms by region and at different levels, including but not limited to urban medical groups, county-level medical communities, specialist alliances and telemedicine collaborative networks, and the cooperation between third-party medical imaging centers and other

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hospitals, including but not limited to: a) in April 2017, the General Office of the State Council promulgated the Guiding Opinions of the General Office of the State Council on Promoting the Construction and Development of the Medical Treatment Partnership (《國務院辦公廳關於推進醫療聯合體建設和發展的指導意見》), encouraging the establishment of MTPS and privately-invested medical institutions may be included in the MTPS according to their wishes; b) in April 2019, the NHC and other departments issued the Opinions on Launching a Pilot Program to Promote the Development of Clinics (《關於開展促進診所發展試點的意見》), encouraging independent medical imaging centers to establish collaboration with clinics to realize medical resource sharing; c) in July 2020, the NHC and the relevant government department published the Administrative Measures for the Medical Treatment Partnership Groups (for Trial Implementation) (《醫療聯合體管理辦法(試行)》), medical institutions invested by social capital are encouraged to join the MTPS on a voluntary basis, and the urban medical groups and county-level medical communities should strengthen the sharing of resources within the MTPS by setting up centers such as medical imaging centers, to provide homogeneous services for the medical and health institutions within the MTPS; d) in December 2020, the NHC, the National Development and Reform Commission and other departments promulgated the Guiding Opinions on Further Regulating Medical Practices and Promoting Reasonable Medical Examination (《關於進一步規範醫療行為促進合理醫療檢查的指導意見》), encouraging the local regions to independently set up medical imaging centers according to the standards, and uniformly include such centers in the medical quality control system of the health departments, so as to provide examination services for medical institutions within the region and realize resource sharing.

### Regulations on the Classification of Medical Institutions

#### *Opinions on Implementing Classification Administration of Urban Medical Institutions (《關於城鎮醫療機構分類管理的實施意見》)*

The Opinions on Implementing Classification Administration of Urban Medical Institutions (《關於城鎮醫療機構分類管理的實施意見》), jointly promulgated by the Ministry of Health (the “MOH”), SATCM, Ministry of Finance (the “MOF”) and the National Development and Reform Commission (the “NDRC”) on July 18, 2000 and came into effect on September 1, 2000, provides that medical institutions in the PRC are mainly identified as for-profit medical institutions and not-for-profit medical institutions, and not-for-profit medical institutions are further divided into public not-for-profit medical institutions and private not-for-profit medical institutions. Not-for-profit medical institutions and for-profit medical institutions shall be classified based on their business objectives, service purposes and implementation of various financial, taxation, pricing and accounting policies. Also, governments shall not operate for-profit medical institutions. On the other hand, not-for-profit medical institutions must comply with the pricing guidance for medical service stipulated by governments from time to time, and the rules and policies issued by the NHC and the MOF including Hospital Finance System and Hospital Accounting System.

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For-profit medical institutions may distribute their profit to their investors as economic returns. Based on its marketing needs, for-profit medical institutions have the discretion to set the fees and prices for their medical and healthcare services. In establishing internal control system, they may apply the finance and accounting system and other policies suitable for corporate enterprise. Medical institutions shall file with relevant authorities of health written statements of their not-for-profit/for-profit status when they go through the application, registration and re-examination procedures in accordance with the relevant laws, and the handling authority of health shall, jointly with other relevant authorities, decide the not-for-profit/for-profit status for such medical institution based on the source of its investment and the nature of its business.

### ***Circular on Issuing the Basic Standards and Administrative Practices for Medical Imaging Diagnosis Centers (for Trial Implementation) (《關於印發醫學影像診斷中心基本標準和管理規範(試行)的通知》)***

According to Circular on Issuing the Basic Standards and Administrative Practices for Medical Imaging Diagnosis Centers (for Trial Implementation) (《關於印發醫學影像診斷中心基本標準和管理規範(試行)的通知》) promulgated by the NHFPC on July 20, 2016, a medical imaging diagnostic center, as a separately established medical institution, is an independent legal person entity, bearing the corresponding legal liability independently, and shall be subject to the examination and approval of the establishment by the health and family planning administrative department at the level of city divided into districts or above, and a medical imaging diagnosis center shall establish a cooperative relationship with the comprehensive hospitals at or above the second level in the region, establish a green channel for emergency treatment of critically ill patients, strengthen technical cooperation, and constantly improve technical level.

### **Regulations on the Management of Medical Institutions**

#### ***The Administrative Measures on Medical Institutions and Its Implementation Measures (《醫療機構管理條例》及其實施細則)***

The Administrative Measures on Medical Institutions (《醫療機構管理條例》), which were promulgated on February 26, 1994 by the State Council and last amended on March 29, 2022, and its Implementation Measures, which was promulgated by the MOH on August 29, 1994 and amended on November 1, 2006, June 24, 2008 and February 21, 2017, stipulate that clinics may practice after filing a record with the local health administrative department of the people's government at the county level and the establishment of other medical institution by any entity or individual must be reviewed and approved by relevant health administrative departments and obtain the Medical Institution Practicing Certificate (《醫療機構執業許可證》). Where a medical institution changes its name, premises, main person in charge, medical subjects or number of beds, it shall handle the change registration with the original registration authority or file with the



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original filing authority. The Medical Institution Practicing Certificate shall not be forged, altered, sold, transferred or lent. Where a medical institution violates the provisions thereof, and sells, transfers or lends the Medical Institution Practicing Certificate, it shall be penalized in accordance with the Basic Medical Care and Health Promotion Law of the PRC (《中華人民共和國基本醫療衛生與健康促進法》), pursuant to which, the health administrative department of the people's government at the county level or above shall order it to rectify and confiscate its illegal gains and may impose a fine of not less than five times but not more than 15 times of the illegal gains and if the illegal gains are less than RMB10,000, the fine shall be calculated as RMB10,000; where the circumstance is serious, the Medical Institution Practicing Certificate shall be revoked.

### ***The Administrative Measures for Verification of Medical Institutions (for Trial Implementation)*** **(《醫療機構校驗管理辦法(試行)》)**

The Administrative Measures for Verification of Medical Institutions (For Trial Implementation) (《醫療機構校驗管理辦法(試行)》), which were promulgated by the MOH and came into effect on June 15, 2009, stipulate that the Medical Institution Practicing Certificate is subject to periodic examinations and verifications by registration authorities. Verification period shall be 3 years for general hospitals, hospitals of traditional Chinese medicine, hospitals of western medicine and traditional Chinese medicine, hospitals of ethnic minority medicine and specialized hospitals, as well as sanitariums, rehabilitation hospitals, maternity and children's health care centers, emergency centers, clinical laboratories and specialized disease prevention institutions equipped with more than 100 beds, while the verification period shall be 1 year for other medical institutions. Medical institutions shall apply for such verification within three months before the expiration of such verification period. In the event that a medical institution fails to apply for verification as required and post re-verification procedures or unsuccessful in its re-verification application, the registration authorities may cancel its Medical Institution Practicing Certificate.

### ***Administrative Measures on the Radiotherapy*** (《放射診療管理規定》)

According to the Administrative Measures on the Radiotherapy (《放射診療管理規定》), which were promulgated by the MOH on January 24, 2006 and amended on January 19, 2016 by NHFPC, medical institutions engaged in the radio diagnosis and radiotherapy shall have conditions corresponding to the radiological diagnosis and treatment services. Prior to carrying out radiodiagnosis and radiotherapy, medical institutions shall submit relevant materials, including but not limited to the Medical Institution Practicing Certificate or the Approval Certificate for Establishment of a Medical Institution, the list of radiodiagnosis and radiotherapy equipment and apply for the License for Radiotherapy (《放射診療許可證》) issued by the competent public health administrative authorities. Medical institutions shall be respectively equipped with the corresponding equipment in carrying out different kinds of radiodiagnosis and radiotherapy. After

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obtaining the License for Radiotherapy, medical institutions shall undertake registration of the relevant diagnosis and treatment items with health administrative and registration authorities, which issued the Medical Institution Practicing Certificate. The License for Radiotherapy and the Medical Institution Practicing Certificate shall be verified at the same time. Where a medical institution intends to change radiodiagnosis and radiotherapy places, diagnosis and radiotherapy equipment or items of diagnosis and radiotherapy, it shall apply to the health administrative authority with the authority to examine and approve the changed items to go through the formalities for such change, and submit application materials, with the content of such change indicated in such application materials.

***Regulations on the Safety and Protection of Radioisotopes and Radiation-emitting Devices (《放射性同位素與射線裝置安全防護條例》) and Measures for Administration of the Safety Licensing of Radioactive Isotopes and Radioactive Equipment (《放射性同位素與射線裝置安全許可管理辦法》)***

According to the Regulations on the Safety and Protection of Radioisotopes and Radiation-emitting Devices (《放射性同位素與射線裝置安全防護條例》), which were promulgated by the State Council on September 14, 2005 and amended on July 29, 2014 and March 2, 2019, any entity which manufactures, sells or uses the radioisotope or the radioactive ray devices shall obtain the license in accordance with the provisions thereof. Where an entity holding the license changes its name, address or legal representative, it shall, within 20 days upon the alteration registration, apply to the original organ issuing the license for going through the formalities for altering the license.

According to the Measures for Administration of the Safety Licensing of Radioactive Isotopes and Radioactive Equipment (《放射性同位素與射線裝置安全許可管理辦法》), which were promulgated by the State Environment Protection Administration on January 18, 2006, and last amended on January 4, 2021 by the Ministry of Ecology and Environment, any entity conducts activities of production, sale, and use of radioactive isotopes and radial equipment within the territory of the PRC shall obtain the Radiation Safety Licenses (《輻射安全許可證》).

***The Notice on Accelerating the Mutual Recognition of the Examination Results (《關於加快推進檢查檢驗結果互認工作的通知》)***

Pursuant to the Notice on Accelerating the Mutual Recognition of the Examination Results (《關於加快推進檢查檢驗結果互認工作的通知》) promulgated by the NHC and took effect on July 13, 2021, provinces that have the conditions can jointly develop a work plan to gradually achieve mutual recognition of examination and test results among medical institutions located in those provinces and the state also encourages regions where conditions permit to incorporate the medical

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imaging diagnosis centers, medical test laboratories and others as set up independently into the mutual recognition system, to provide test and examination services for medical institutions within the regions and realize the sharing of resources.

***Administrative Measures on Internet Hospital (Trial) (《互聯網醫院管理辦法(試行)》) and Administrative Measures on Internet-based Diagnosis and Treatment (Trial) (《互聯網診療管理辦法(試行)》)***

According to the Administrative Measures on Internet Hospital (Trial) (《互聯網醫院管理辦法(試行)》), when a patient receives treatment at a physical medical institution, and the doctor receiving the patient invites another doctor for consultation through the internet hospital, the consulting doctor may issue diagnosis opinions and prescriptions; if the patient has not received treatment at a physical medical institution, the doctor may only provide follow-up diagnosis services for some of the common and chronic diseases through the internet hospital. An internet hospital shall strictly comply with the administrative provisions on prescriptions and abide by the relevant laws and regulations in the process of providing internet-based diagnosis and treatment. Pursuant to the Administrative Measures on Internet-based Diagnosis and Treatment (Trial) (《互聯網診療管理辦法(試行)》), the Internet-based diagnosis and treatment means that medical institutions, together with their registered physicians, use the Internet and other information technologies to conduct follow up diagnosis and treatment of certain common diseases and chronic diseases and to provide “Internet Plus” family doctor contracting services. Internet-based diagnosis services shall be provided by the medical institutions which have obtained a Practicing License for Medical Institutions. Internet-based diagnosis services provided by medical institutions shall be consistent with their diagnosis subjects.

### **Regulations on Pharmaceuticals in Medical Institutions and Medical Devices**

***The Measures for the Control of Radioactive Drugs (《放射性藥品管理辦法》)***

According to the Measures for the Control of Radioactive Drugs (《放射性藥品管理辦法》), promulgated by the State Council on January 13, 1989 and amended on January 8, 2011, March 1, 2017 and March 29, 2022, the use of radioactive drugs by a medical institution must meet the State regulations on safety of and protection from radioisotopes. The department in charge of supervision and administration of drugs of the province, autonomous region or municipality directly under the Central Government in the place where the medical treatment unit is located shall, according to the level of nuclear medical treatment technicians and the equipment conditions of such unit, issue the License for the Use of Radioactive Drugs (《放射性藥品使用許可證》) of the corresponding grade. No medical treatment unit without a license may use radioactive drugs on a clinical basis. The term of validity of a License for the Use of Radioactive Drugs is five years.



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Six months prior to the expiration, the medical treatment unit shall make a new application to the administrative department which originally issued the license, which shall, after examination and approval, issue a new license.

### ***Regulations on Supervision and Administration of Medical Devices*** (《醫療器械監督管理條例》)

In the PRC, medical devices are classified into three different categories, Class I, Class II and Class III, based on the invasiveness of and risks associated with each medical device. Class I medical devices refer to those devices with low risks and whose safety and effectiveness can be ensured through routine administration. Class II medical devices refer to those devices with moderate risks and whose safety and effectiveness shall be strictly controlled and administered. Class III medical devices refer to those devices with relatively high risks and whose safety and effectiveness must be strictly controlled and administered with special measures. According to the Regulations on Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) promulgated by the State Council on January 4, 2000 and lastly amended on February 9, 2021 and came into effect on June 1, 2021, to engage in the operation of Class II medical devices, an operating enterprise shall make a record-filing with the municipal level drug supervision and administration department, while to engage in the operation of Class III medical devices, an operating enterprise shall apply for the of Medical Devices Operation License (《醫療器械經營許可證》) to the municipal level drug supervision and administration department.

Meanwhile, medical institutions that use large-scale medical equipment are required to obtain the License for Deployment of Large-scale Medical Equipment (《大型醫用設備配置許可證》) issued by the health administrative authorities at province level or above. Any entity allocating and using large-scale medical equipment without permission shall be ordered by the health administrative authority at the county level or above to cease the use, given a warning, and its illegal gains be confiscated; and if the illegal gains are less than RMB10,000, a fine of not less than RMB50,000 but not more than RMB100,000 shall be imposed; and if the illegal gains are more than RMB10,000, a fine of not less than 10 times but not more than 30 times the illegal gains shall be imposed; where the circumstances are serious, the application for license for allocation of large-sized medical equipment filed by the relevant persons responsible and enterprises shall not be accepted within five years.

### ***Measures for the Supervision and Administration of Medical Devices Operation*** (《醫療器械經營監督管理辦法》)

Pursuant to the Measures for the Supervision and Administration of Medical Devices Operation (《醫療器械經營監督管理辦法》) which were promulgated on July 30, 2014 and amended on November 17, 2017 and March 10, 2022, an enterprise engaging in the operation of medical devices shall have business premises and storage conditions suitable for the operation

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scale and scope and shall have quality control department or personnel suitable for the medical devices it operates. An enterprise engaged in the operation of Class I medical devices is not required for license or record filing, the operation of Class II medical devices shall file with the municipal level drug supervision and administration department and provide proofing materials for satisfying the relevant conditions of engaging in the operation of medical devices, while an enterprise engaged in the operation of Class III medical devices shall apply for a Medical Devices Operation License to the municipal level drug supervision and administration department and provide proofing materials for satisfying the relevant conditions of engaging in the operation of such medical devices. Where matters stated on the Medical Devices Operation License of a Class III medical device operator change, or the business premises, mode of operation, business scope and warehouse addresses of a Class II medical device operator change, the operator shall apply to the competent drug supervision and administration department for filing of the change in a timely manner.

### ***Administrative Measures on the Deployment and Use of Large-scale Medical Equipment (for Trial Implementation)*** (《大型醫用設備配置與使用管理辦法(試行)》)

The Administrative Measures on the Deployment and Use of Large-scale Medical Equipment (For Trial Implementation) (《大型醫用設備配置與使用管理辦法(試行)》) jointly promulgated by the NHC and State Drug Administration on May 22, 2018 and came into effect on the same day, stipulates that the large-scale medical equipment refers to the large-scale medical devices that adopt complex technology, require large capital investment, have high operation costs, have significant impact on medical expenses, and have been included in the large-scale medical equipment catalogue management. The catalogue of large-scale medical equipment shall be proposed by the NHC in consultation with the relevant department under the State Council, reported to the State Council for approval, and issued for implementation. The State administers large-scale medical equipment through the classified and hierarchical allocation plan and through the issue of Licenses for Deployment of Large-scale Medical Equipment according to the catalog. The large-scale medical equipment allocation management catalog is divided into Category A and Category B. The large-scale medical equipment of Category A shall be allocated and managed by the NHC and issued with Licenses for Deployment of Large-scale Medical Equipment by it; the large-scale medical equipment of Category B shall be allocated and managed by provincial health administrative authorities and issued with Licenses for Deployment of Large-scale Medical Equipment by them. The NHC and provincial health administrative authorities shall respectively formulate the implementing rules for the allocation licensing management of Category A and Category B large-scale medical equipment. In case of any change in the information on the Licenses for Deployment of Large-scale Medical Equipment, the user of medical devices shall report the change to the original issuing authority within ten working days as of the date of such change.

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*The Notice of the Issuance of Large-scale Medical Equipment Allocation and Management Catalog (2018) (《關於發佈大型醫用設備配置許可管理目錄(2018年)的通知》) and The Notice of the Issuance of Large-scale Medical Equipment Allocation and Management Catalog (2023) (《關於發佈大型醫用設備配置許可管理目錄(2023年)的通知》)*

The Notice of the Issuance of Large-scale Medical Equipment Allocation and Management Catalog (2018) (《關於發佈大型醫用設備配置許可管理目錄(2018年)的通知》) (“**Catalog 2018**”) promulgated by the NHC on March 29, 2018, stipulates the Category A and Category B of large-scale medical equipment, according to the Catalog 2018, the PET/MR belongs to Category A of large-scale medical equipment, the PET/CT, 64 or more X-ray computed tomography scanners and 1.5T or more magnetic resonance imaging systems belong to Category B of large-scale medical equipment. On March 21, 2023, the NHC promulgated the Notice of the Issuance of Large-scale Medical Equipment Allocation and Management Catalogue (2023) (《關於發佈大型醫用設備配置許可管理目錄(2023年)的通知》) (“**Catalog 2023**”), which had replaced the Catalog 2018. In order to further implement the requirements for the reform, the NHC has actively promoted the adjustment of the classification of equipment with mature technology, stable performance and application specifications, such as switching from category A to category B or removing from category B.

Compared with the Catalog 2018, the adjustments mainly include, (i) the standard amount of initial allocation of Category A and Category B large medical equipment are raised, (ii) the number of administrative items of the Catalog 2023 is reduced from ten to six, among which the number of Category A items is reduced from four to two, and the number of Category B items from six to four, and (iii) the PET/MR was adjusted from Category A to Category B of large-scale medical equipment, PET/CT remains as the Category B of large-scale medical equipment, and the 64 or more X-ray computed tomography scanners, and 1.5T or more magnetic resonance imaging systems are excluded from the Catalog 2023 upon adjustment.

Such above adjustments mean that high-value equipment has higher accessibility and the threshold for admission of high-value equipment is lowered, which is conducive to the promotion of high-value equipment in hospitals. According to the Catalog 2023, the Category A of large-scale medical equipment configured and managed by the NHC includes: (i) heavy ion proton radiotherapy system (重離子質子放射治療系統), (ii) high-end radiotherapy equipment, including magnetic resonance -guided radiotherapy system (磁共振引導放射治療系統) and X-ray stereotactic radiosurgery treatment system (X射線立體定向放射外科治療系統) (including Cyberknife), and (iii) large medical devices equipped for the first time at a price per unit (set) of which is RMB50 million or above; the Category B of large-scale medical equipment configured and managed by the provincial health commission includes: (i) PET/MR, (ii) PET/CT, (iii) Laparoscopic surgical system (腹腔內窺鏡手術系統), (iv) conventional radiotherapy-type equipment (including medical linear accelerators (醫用直線加速器), spiral tomography

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radiotherapy systems (螺旋斷層放射治療系統), gamma ray stereotactic radiotherapy systems (伽瑪射線立體定向放射治療系統)), and (v) large medical devices equipped for the first time at a price of RMB30-50 million per unit (set).

### **Regulations on the Price of Healthcare Services**

#### ***Notice of Issues Related to the Implementation of Market Price Adjustment by Non-Public Medical Institutions (《關於非公立醫療機構醫療服務實行市場調節價有關問題的通知》)***

According to the Notice of Issues Related to the Implementation of Market Price Adjustment by Non-Public Medical Institutions (《關於非公立醫療機構醫療服務實行市場調節價有關問題的通知》) promulgated and implemented on March 25, 2014 by the NDRC, the NHFPC and the Ministry of Human Resources and Social Security (the "MHRSS"), the price of healthcare services provided by non-public medical institutions to be set with reference to the market level. Non-public medical institutions which are for-profit in nature may set the price list for their healthcare services at their own discretion. Non-public medical institutions which are non-profit in nature shall set the price list for their healthcare services according to the National Standard Price List of Healthcare Services (《全國醫療服務價格項目規範》). For non-public medical institutions qualified to become designated medical institutions covered by medical insurance, they should be included as a designated service provider covered by social insurance such as basic medical insurance for employees and urban residents, new-type rural cooperative medical insurance, work-related injury insurance and maternity insurance in accordance with relevant procedures and adopt the same payment policy as in public hospitals. To efficiently utilize funds, medical insurance agents should determine specific payment methods and standards with such non-public medical institution by ways of negotiation under the requirements of medical insurance payment system reform.

#### ***Regulations on Medical Insurance and Medical Liability Insurance for Urban Employees***

According to the Interim Measures for the Administration of Medical Insurance Designated Medical Institutions and the Provision of Basic Medical Insurance for Urban Employees (《城鎮職工基本醫療保險定點醫療機構管理暫行辦法》), which were promulgated by the MOH, the Ministry of Labor and Social Security and the SATCM on May 11, 1999, and the Decision of the State Council on Canceling the First Batch of 62 Items Subject to Administrative Examination and Approval of Local Governments Designated by the Central Government (《國務院關於第一批取消62項中央指定地方實行政審批事項的決定》), which was promulgated by the State Council on October 11, 2015 and the Guiding Opinions of the MHRSS on Improving the Management of Designated Medical Institutions and Pharmacies of Basic Medical Insurance through Agreements (《人力資源和社會保障部關於完善基本醫療保險定點醫藥機構協議管理的指導意見》) promulgated by MHRSS on December 2, 2015, and became effective on the same day, the license for qualifying a medical institution as a designated

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medical institution to provide medical services to urban employees with basic medical insurance was cancelled. Agencies and the medical institutions should strictly comply with the stipulations in the service agreement and perform the agreement seriously. The defaulting party shall be held liable to the violations of the agreement.

### **Regulations on Medical Practitioners of Medical Institutions**

#### ***The Law on Physicians of the PRC (《中華人民共和國醫師法》)***

Pursuant to the Law on Physicians of the PRC (《中華人民共和國醫師法》) promulgated by the Standing Committee of the National People’s Congress (the “SCNPC”) on August 20, 2021 and became effective on March 1, 2022, medical physicians in the PRC must obtain licenses of medical professional qualifications. Anyone who has been awarded the qualifications as a medical physician may apply to the competent health department under the local people’s government at or above the county level for registration. Physicians may, upon registration, work in medical and health institutions according to the registered place, category, and scope of business to engage in the corresponding medical and health services, while assistant practicing physicians should, under the supervision of practicing physicians, practice according to the registered categories and scope of practice at medical and health institutions.

#### ***Administrative Measures for the Registration of Practicing Physicians (《醫師執業註冊管理辦法》)***

Pursuant to the Administrative Measures for the Registration of Practicing Physicians (《醫師執業註冊管理辦法》) promulgated by the NHFPC on February 28, 2017 and became effective on April 1, 2017, medical physicians must register and obtain the Physician Practicing Certificate (《醫師執業證書》) before they commence practice, and those who are not registered or have not obtained the Physician Practicing Certificate are not allowed to engage in medical, preventive and healthcare services. The registration details of practicing physicians include place of practice, type of registered specialty and scope of practice. The place of practice refers to the county and provincial administrative region of the medical, preventive and healthcare institutions where the physician is practicing.

For a practicing physician who wants to practice in multiple institutions within the same place of practice, he/she shall determine a specific institution as the main practicing institution, apply for registration with the competent health authority which approved the aforesaid institution’s operation; as to other institutions where the practitioner is to practice, the practicing physician shall apply the record filing with the health authorities competent to approve the institutions’ operation and indicate the name of the institutions. If a practicing physician intends to



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practice in an additional institution beyond the registered place of practice, he/she shall apply for the registration of such practice to the competent health authority which approved the practice of such institution.

### ***Regulations on Nurses (《護士條例》)***

The Regulations on Nurses (《護士條例》) which were promulgated by the State Council on January 31, 2008, came into effect on May 12, 2008 and amended on March 27, 2020, provide that for nursing practice, a nurse must obtain the Nurse Practicing Certificate, which is valid for five years. The number of nurses deployed to a medical institution shall not be less than the standard number as prescribed by the competent health administration authority.

### ***Administrative Measures for the Registration of Practicing Nurses (《護士執業註冊管理辦法》)***

Pursuant to the Administrative Measures for the Registration of Practicing Nurses (《護士執業註冊管理辦法》) promulgated by the MOH on May 6, 2008, became effective on May 12, 2008 and amended on January 8, 2021, nurses must register and obtain the Nurse Practicing Certificate before they practice nursing at the registered practicing place.

### **Regulations on Medical Incidents**

### ***Civil Code of the PRC (《中華人民共和國民法典》)***

On May 28, 2020, the Civil Code of the PRC (《中華人民共和國民法典》) was adopted by the third session of the 13th National People's Congress and came into effect on January 1, 2021. According to the Civil Code of the PRC, where a patient has suffered damages in diagnosis and treatment activities, and the medical institution or its medical personnel have committed negligence, the medical institution shall bear compensation liability. Where medical personnel failed to perform medical treatment obligations corresponding to the prevailing medical standards in diagnosis and treatment activities and caused a patient to suffer damages, the medical institution shall bear compensation liability. Where a patient suffers damages due to defects in drugs or medical devices, the patient may seek compensation from the drug marketing permit holder and the manufacturer, or seek compensation from the medical institution. Where the patient seeks compensation from the medical institution, the medical institution shall have the right to seek recourse against the accountable drug marketing permit holder and the manufacturer after making compensation.

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### *The Regulations on Handling Medical Incidents (《醫療事故處理條例》)*

The Regulations on Handling Medical Incidents (《醫療事故處理條例》), which were promulgated by the State Council on April 4, 2002 and came into effect on September 1, 2002, provide a legal framework and specific regulations regarding the prevention, identification, compensation and penalties of or relating to cases involving personal injury to patients caused by medical institutions or medical personnel due to malpractice.

### **Regulations on Medical Advertisement**

#### *Advertising Law of the PRC (《中華人民共和國廣告法》)*

Pursuant to the Advertising Law of the PRC (《中華人民共和國廣告法》) (the “**Advertising Law**”) promulgated by the SCNPC on October 27, 1994 and last amended on April 29, 2021, advertisements shall not contain false statements that are deceitful or misleading to consumers and shall not publish medical, drugs, medical machinery or health food advertisements in disguised form of introduction of healthcare and wellness knowledge. Several types of advertisements are legally required to receive censorship, including but not limited to those relating to medical treatment, pharmaceuticals and medical devices, and shall be reviewed by the relevant authorities in accordance with relevant rules before being distributed by broadcasting, movies, television, newspapers, journals or otherwise. No such advertisement shall be published without being reviewed. If the advertisers published such advertisements without being reviewed in violation of the provisions, the market regulation departments shall order the cessation of the publishing of advertisements, order the advertisers concerned to eliminate the ill-effects within the corresponding scope, and impose a fine equivalent to an amount that is three times the amount of the advertising fees; where the advertising fees cannot be calculated or are significantly low, a fine of not less than RMB100,000 and not more than RMB200,000 shall be imposed; where the circumstance is serious, a fine of not less than three times and not more than five times the advertising fees shall be imposed; in case that the advertising fees cannot be calculated or are significantly low, a fine of not less than RMB200,000 and not more than RMB1 million shall be imposed; and the business licenses may be revoked, and the advertisement review authorities shall revoke the approval documents for advertisement review and shall not accept the relevant party’s application for advertisement review for one year.

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### *Administrative Measures on Medical Advertisement (《醫療廣告管理辦法》)*

Pursuant to the Administrative Measures on Medical Advertisement (《醫療廣告管理辦法》), which were jointly promulgated by the MOH and the State Administration of Industry and Commerce (the “SAIC”) on September 27, 1993 and amended on September 28, 2005 and November 10, 2006 and came into effect on January 1, 2007, any medical institution that intends to publish any medical advertisement shall apply for medical advertisement examination and obtain Medical Advertisement Examination Certificate.

### *Circular of the Ministry of Health on Strengthening the Medical Advertisement Administration (《衛生部關於進一步加強醫療廣告管理的通知》)*

According to the Circular of the Ministry of Health on Strengthening the Medical Advertisement Administration (《衛生部關於進一步加強醫療廣告管理的通知》), which was promulgated by the MOH on July 17, 2008 and became effective on the same date, the Medical Advertisement Examination Certificate (醫療廣告審查證明) shall be examined strictly, the medical advertisement monitoring system shall be gradually established and improved, and the penalty for illegal medical advertisement shall be increased.

### *Measures for the Administration of Internet Advertisement (《互聯網廣告管理辦法》)*

On February 25, 2023, the State Administration for Market Regulation (the “SAMR”) promulgated the Measures for the Administration of Internet Advertisement (《互聯網廣告管理辦法》), which took effect on May 1, 2023. Such measures explicitly include commercial advertisements that directly or indirectly promote goods or services by means of live Internet broadcasting and cross-border e-commerce advertisements in the scope of adjustment of such measures; further strengthen the system provisions in areas such as “one-click closure” of pop-up advertisements and implanted advertisements, and strengthened the responsibility of relevant subjects, etc. According to the Measures for the Administration of Internet Advertisement, advertisements for medical treatment, medical devices and other advertisements which are subject to examination as required by laws and administrative regulations shall be examined by the advertisement examination authorities prior to publication, and such advertisements shall not be published without going through examination. An Internet advertisement shall be identifiable and can make consumers recognize it as an advertisement, For goods or services ranked according to bidding, advertisement publishers shall mark the words “advertisement” prominently in order to make a clear distinction from the natural search results.

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### Regulations on Internet Security

Decision on the Protection of Internet Security (《關於維護互聯網安全的決定》) enacted by the SCNPC on December 28, 2000 and amended on August 27, 2009, which may subject violators to criminal punishment in China for any effort to: (i) gain improper entry into a computer or system of strategic importance; (ii) disseminate politically disruptive information; (iii) leak state secrets; (iv) spread false commercial information; or (v) infringe intellectual property rights.

In December 1997, the Ministry of Public Security issued the Administration Measures on the Security Protection of Computer Information Network with International Connections (《計算機信息網絡國際聯網安全保護管理辦法》), which were further revised on January 8, 2011 and prohibit using the internet in ways which, among others, result in a leakage of state secrets or a spread of socially destabilizing content. The Administrative Measures for the Hierarchical Protection of Information Security (《信息安全等級保護管理辦法》) effective from June 22, 2007 stipulate that the security protection of an information system may be graded into five levels and entities that operate the information systems at Grade II or above shall, within 30 days since the date when its security protection grade is determined, handle the record-filing procedures at the local public security authority.

On November 7, 2016, the SCNPC promulgated the Cyber Security Law of the PRC (《中華人民共和國網絡安全法》), which became effective on June 1, 2017. The Cyber Security Law of the PRC requires network operators to comply with laws and regulations and fulfill their obligations to safeguard security of the network when conducting business and providing services. The Cyber Security Law of the PRC further requires network operators to take all necessary measures in accordance with applicable laws, regulations and compulsory national requirements to safeguard the safe and stable operation of the networks, respond to cyber security incidents effectively, prevent illegal and criminal activities, and maintain the integrity, confidentiality and usability of network data.

The State Council promulgated the Regulations on Protection on the Safety of Critical Information Infrastructure (《關鍵信息基礎設施安全保護條例》) on July 30, 2021, effective from September 1, 2021, which provided that critical information infrastructure include important network facilities and information systems in public communication and information services, energy, transportation, water conservancy, finance, public services, e-government, national defense science and technology industry and other important industries and fields of which any damage, loss of function or data leakage may seriously endanger national security, national economy or people's livelihood and public interest. The critical information infrastructure operators must, in accordance with relevant laws, administrative regulations and mandatory national standards and based on the graded system for cybersecurity protection, adopt technical protection measures and other necessary measures to respond to network security incidents and prevent network attacks and

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crimes to ensure the safe and stable critical information infrastructure operation and maintain data integrity, confidentiality and availability. The protection work departments are responsible for organizing the identification of critical information infrastructure within their industries and sectors and notifying operators about the identification results. As of the Latest Practicable Date, the responsible authorities had not promulgated any implementation provisions or identification rules of critical information infrastructure operators and we had not received any notification from relevant regulatory authorities regarding our identification as a critical information infrastructure operator, nor had we been subject to or involved in cybersecurity review or received any investigation, inquiry, notice, warning or sanctions made by the CAC on such basis.

On December 28, 2021, the CAC and other twelve PRC regulatory authorities jointly revised and promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》), or the Cybersecurity Review Measures, which came into effect on February 15, 2022. The Measures for Cybersecurity Review (《網絡安全審查辦法》) which took effect on June 1, 2020 was abolished at the same time. Pursuant to the Cybersecurity Review Measures, critical information infrastructure operators procuring network products and services and network platform operators conducting data processing activities that affect or may affect national security shall conduct a cybersecurity review. In particular, if critical information infrastructure operators anticipate that its procurement of network products and services affect or may affect national security after the network products and services being put into use, it shall apply for cybersecurity review to the Cybersecurity Review Office. In addition, network platform operators holding personal information of more than 1 million users that seek for listing in a foreign country are obliged to apply for a cybersecurity review by the Cybersecurity Review Office. The Cybersecurity Review Measures also provide that the Cybersecurity Review Office of the CAC may initiate cybersecurity review against relevant operators if the authorities believe that the network products, network services or data processing activities of such operators affect or may affect national security. The Cybersecurity Review Measures set out certain risk factors which would be the focus in assessing the national security risk during a cybersecurity review.

### Regulations on Personal Information or Data Protection

On December 29, 2011, the Ministry of Industry and Information Technology (the "MIIT") issued Several Provisions on Regulating the Market Order of Internet Information Services (《規範互聯網信息服務市場秩序若干規定》), which provide that an Internet information service provider may not collect any user's personal information or provide any such information to third parties without such user's consent. Pursuant to the Several Provisions on Regulating the Market Order of Internet Information Services, Internet information service providers are required to, among others, (i) expressly inform the users of the method, content and purpose of the collection and processing of such users' personal information and may only collect such information necessary for the provision of its services; and (ii) properly maintain the users' personal information, and in case of



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any leak or possible leak of a user's personal information, online lending service providers must take immediate remedial measures and, in severe circumstances, make an immediate report to the telecommunications regulatory authority.

Pursuant to the Decision on Strengthening the Protection of Online Information (《關於加強網絡信息保護的決定》) issued by the SCNPC in 2012 and the Provisions on Protection of Personal Information of Telecommunication and Internet Users (《電信和互聯網用戶個人信息保護規定》) issued by the MIIT in 2013, any collection and use of a user's personal information must be subject to the consent of the user, be legal, rational and necessary and be limited to specified purposes, methods and scopes. An internet information service provider must also keep such information strictly confidential, and is further prohibited from divulging, tampering with or destroying any such information, or selling or providing such information to other parties. An internet information service provider is required to take measures to prevent the collected personal information from any disclosure, damage, tampering or loss.

Pursuant to the Ninth Amendment to the Criminal Law of the PRC (《中華人民共和國刑法修正案(九)》) issued by the SCNPC on August 29, 2015 and became effective on November 1, 2015, any internet service provider that fails to fulfil the obligations related to the internet information security administration as required by the applicable laws or administrative regulations, and refuses to rectify upon orders, shall be subject to criminal penalty. Pursuant to the Notice of the Supreme People's Court, the Supreme People's Procuratorate and the Ministry of Public Security on Legally Punishing Criminal Activities Infringing upon the Personal Information of Citizens (《最高人民法院、最高人民檢察院、公安部關於依法懲處侵害公民個人信息犯罪活動的通知》), issued on April 23, 2013, Article 253 of the Criminal Law of the PRC (《中華人民共和國刑法》), and the Interpretation of the Supreme People's Court and the Supreme People's Procuratorate on Several Issues regarding Legal Application in Criminal Cases Infringing Personal Information of Citizens (《最高人民法院、最高人民檢察院關於辦理侵犯公民個人信息刑事案件適用法律若干問題的解釋》), which was issued on May 8, 2017 and took effect on June 1, 2017, the following activities may constitute the crime of infringing upon a citizen's personal information: (i) providing a citizen's personal information to specified persons or releasing a citizen's personal information online or through other methods in violation of relevant national provisions; (ii) providing legitimately collected information relating to a citizen to others without such citizen's consent, unless the information is processed, not identifiable to a specific person and not recoverable; (iii) collecting a citizen's personal information in violation of applicable rules and regulations when performing a duty or providing services; or (iv) collecting a citizen's personal information by purchasing, accepting or exchanging such information in violation of applicable rules and regulations.

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The Method for Identifying the Illegal Collection and Use of Personal Information by Apps (《App違法違規收集使用個人信息行為認定方法》), promulgated jointly by the MIIT and three other departments in November 2019, specifies the practices of illegal collection and use of personal information, providing reference for regulatory authorities and offering guidance for App operators’ self-examination and self-correction under the current regulatory environment.

On May 28, 2020, the PRC Civil Code (《中華人民共和國民法典》) was issued by the NPC. The PRC Civil Code provides that natural persons’ personal information shall be protected by law, and the processing of personal information shall be subject to the principle of legitimacy, rightfulness and necessity, with no excessive processing.

On March 12, 2021, the MIIT, the CAC, the Ministry of Public Security and the SAMR jointly promulgated the Rules on the Scope of Necessary Personal Information for Common Types of Mobile Internet Applications (《常見類型移動互聯網應用程序必要個人信息範圍規定》), effective on May 1, 2021, which specifies that the scope of necessary personal information for medical consultation and appointment applications includes mobile phone numbers of registered users and descriptions of the patient’s condition, which need to be provided during a medical consultation.

On June 10, 2021, the SCNPC issued the Data Security Law of the PRC (《中華人民共和國數據安全法》) (the “**Data Security Law**”), which has taken effect on September 1, 2021. The Data Security Law applies to data processing activities, including the collection, storage, use, processing, transmission, sharing and disclosure of data, and security supervision of such activities within the territory of the PRC. The Data Security Law provides a national data security review system, under which data processing activities that affect or may affect national security shall be reviewed. In addition, it clarifies the data security protection obligations of organisations and individuals carrying out data activities and implementing data security protection responsibility. Data processors shall establish and improve the whole-process data security management rules, organise and implement data security trainings as well as take appropriate technical measures and other necessary measures to protect data security. Important data shall also be categorized and protected more strictly. Any organisational or individual data processing activities that violate the Data Security Law shall bear the corresponding civil, administrative or criminal liabilities depending on specific circumstances.

Pursuant to the PRC Personal Information Protection Law (《中華人民共和國個人信息保護法》) (the “**PIPL**”) promulgated by the SCNPC on August 20, 2021, effective as of November 1, 2021, personal information refers to all kinds of information related to identified or identifiable natural persons recorded by electronic or other means, excluding information after anonymisation processing. The handling of personal information includes the collection, storage, use, processing, transmission, provision, disclosure, and deletion, etc., of personal information. The activities of

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handling personal information of natural persons in the PRC shall be governed by the PIPL. Furthermore, a processor of personal information may process personal information only under any of the following circumstances: (a) where the consent of the individual concerned is obtained; (b) where it is necessary for the conclusion or performance of a contract to which the individual is a party, or for the implementation of human resources management in accordance with the labour rules and regulations established by law and the collective contract signed in accordance with the law; (c) where it is necessary for the performance of legal duties or legal obligations; (d) where it is necessary for the response to public health emergencies, or for the protection of the life, health and property of natural persons in an emergency; (e) where such acts as news reporting, public opinion monitoring and others are implemented for the public interest, and the processing of personal information is within a reasonable range; (f) where the personal information disclosed by the individual concerned or other personal information that has been legally disclosed is processed within a reasonable scope in accordance with the provisions of PIPL; and (g) other circumstances specified in laws and administrative regulations. The processing of personal information shall obtain the consent of the individual concerned in accordance with other relevant provisions of the PIPL, however, the consent of the individual concerned is not required under the circumstances set forth in items (b) to (g) of the preceding paragraph. Only where there is a specific purpose and sufficient necessity, and under circumstances where strict protection measures are taken, may personal information processors process sensitive personal information. The processing of sensitive personal information of an individual shall be subject to the individual’s separate consent. Personal information processors shall be subject to the liability for personal information processing activities, and adopt necessary measures to safeguard the security of the personal information. Otherwise, the personal information processors will be subject to orders of the regulatory authorities to rectify their operations, suspend or terminate the provision of services, or confiscation of illegal income, fines or other penalties.

On November 14, 2021, the CAC has publicly solicited opinions on the Regulations on Network Data Security Management (Draft for Comments) (《網絡數據安全管理條例(徵求意見稿)》), or the Draft Regulations on Network Data Security Management. Specifically, the Draft Regulations on Network Data Security Management address requirements including protection of personal information, security of important data, security management of cross-border data transfer, obligations of internet platform operators, and supervision and management. Under the Draft Regulations on Network Data Security Management, data is divided into three categories — common, important, and core — depending on its importance to national security, the public interest and, individual privacy. The scope of “important data” is similar to that in other rules and guidelines. Data processors should comply with the requirements of cybersecurity multi-level protection, strengthen the data processing system, data transmission network, data storage environment and other security protection. Data processors should establish a data security emergency response mechanism, and promptly start the emergency response mechanism in the event of a data security incident. The Draft Regulations on Network Data Security Management

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also set out detailed rules for data processors to apply when providing personal information to third parties, or sharing, trading or entrusting important data to third parties. In addition, Article 13 of the Draft Regulations on Network Data Security Management stipulates that data processors shall, in accordance with relevant state provisions, apply for cybersecurity review when carrying out the following activities:

- (i) the merger, reorganization or separation of internet platform operators that have acquired a large number of data resources related to national security, economic development or public interests, which affects or may affect national security;
- (ii) data processors that handle the personal information of more than one million individuals seeking to be listed abroad;
- (iii) data processors seeking to be listed in Hong Kong that affects or may affect national security; and
- (iv) other data processing activities that affect or may affect national security.

Data processors dealing with important data or listing offshore should carry out an annual data security assessment and submit the reports to the counterparties of the CAC at the districted-city level. The enforcement includes fines potential business suspension and/or revocation of business license, depending on the severity of the effects of violation. As of the Latest Practicable Date, the Draft Regulations on Network Data Security Management had not come into effect and the public comment period of the Draft Regulations on Network Data Security Management ended on December 13, 2021.

On July 7, 2022, the CAC promulgated the Measures on Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》) (the “**Measures on Security Assessment of Cross-border Data Transfer**”), which became effective on September 1, 2022. These Measures outline the requirements and procedures for security assessments on export of important data or personal information collected within the territory of mainland China. More specifically, these Measures provide that any of the circumstances below will require security assessment before any cross-border data transfer out of mainland China can occur: (i) a data processor provides important data out of mainland China; (ii) a critical information infrastructure operator or a data processor processing personal information of more than one million individuals provides personal information out of mainland China; (iii) a data processor, who has cumulatively provided personal information of 100,000 individuals or sensitive personal information of 10,000 individuals out of mainland China since January 1 of the previous year, provides personal information out of

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mainland China; or (iv) under other circumstances as stipulated by the CAC. The data processing entities need to carry out a self-assessment before they can apply through provincial CACs for a security assessment to be carried out and approved by the CAC at the central level.

Pursuant to the Regulations for Medical Institutions on Medical Records Management (《醫療機構病歷管理規定》) released on November 20, 2013, and effective from January 1, 2014, the medical institutions and medical practitioners shall strictly protect the privacy information of patients, and any leakage of patients' medical records for non-medical, non-teaching or non-research purposes is prohibited. Preservation time for outpatient (emergency) medical records in medical institutions shall be no less than 15 years from the last time patients seek consultation and treatment on. Preservation time for hospitalization medical records shall be no less than 30 years since the last time patients are discharged.

According to the Circular on Issuing the Basic Standards and Administrative Practices for Medical Imaging Diagnosis Centers (for Trial Implementation) (《關於印發醫學影像診斷中心基本標準和管理規範(試行)的通知》) promulgated by the NHFPC on July 20, 2016, medical imaging diagnosis centers shall strengthen the awareness of network and data security and conscientiously abide by the relevant laws and regulations on information security management. A firewall shall be set up and anti-virus software shall be installed for the operation of PACS/RIS information to prevent malicious attacks by foreign viruses. The PACS design and implementation project shall meet the national management of medical big data, including the requirements on uploading, multi-direction transmission and storage, so as to facilitate the access of various examination data. At the same time, different access authorities shall be set for the personnel on posts to protect the personal privacy of subjects, and it is not allowed to arbitrarily publicize or copy relevant materials of the subjects. The image data shall be kept for at least 10 years and shall be kept online for at least 3 years for quick reference, browsing and diagnosis. The image data information shall be uploaded timely as required by the health and family planning authority.

On February 15, 2017, the NHFPC and the General Office of the SATCM promulgated the Management Specification for the Application of Electronic Medical Records (for Trial Implementation) (《電子病歷應用管理規範(試行)》), effective on April 1, 2017, pursuant to which, medical institution shall be equipped with safety management systems and safety guarantee mechanisms of electronic medical records, and an electronic medical record system shall identify the identity of operators, save all previous operations, record operation time and information about operators, and ensure that all previous operations, operation time and operators' information are queryable and traceable.



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In December 2017, the China Food and Drug Administration promulgated the Administration and Supervision Measures of Online Sales of Medical Devices (《醫療器械網絡銷售監督管理辦法》), or the Online Medical Devices Sales Measures, which became effective in March 2018. According to the Online Medical Devices Sales Measures, the records of sale information of medical devices shall be kept for two years after the valid period of the medical devices, no less than five years in case of no valid period, or permanently in case of implanted medical devices.

The NHFPC released the Measures for Administration of Population Health Information (Trial) (《人口健康信息管理辦法(試行)》) on May 5, 2014, which refers the medical health service information as the population healthcare information and emphasizes that such information cannot be stored in offshore servers, and the responsible institutions shall not host or lease offshore servers.

Pursuant to the Management Measures of Standards, Safety and Service of National Health and Medical Big Data (Trial) (《國家健康醫療大數據標準、安全和服務管理辦法(試行)》), promulgated by the NHC on July 12, 2018, the medical institutions should establish relevant safety management systems, operation instructions and technical specifications to safeguard the safety of healthcare big data generated in the process of health management service or prevention and cure service of diseases. And it also stipulates that such healthcare big data should be stored in onshore servers and shall not be provided overseas without safety assessment.

On February 8, 2022, the NHC and the General Office of the SATCM promulgated the Regulatory Rules on Internet Medical Diagnosis and Treatment (Trial) (《互聯網診療監管細則(試行)》), effective on the same date. According to the Regulatory Rules on Internet Medical Diagnosis and Treatment (Trial), medical institutions should establish network security, data security, personal information protection, privacy protection and other systems, and sign agreements with relevant partners to clarify the rights and responsibilities of all parties. The electronic medical record information generated by medical institutions in the process of Internet diagnosis and treatment shall be in the same format and shared with the electronic medical record of the relying entity medical institutions, and the relying entity medical institutions shall carry out integrated quality control online and offline. Internet medical records are managed in accordance with the relevant provisions of the outpatient electronic medical records.

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On August 8, 2022, the NHC, the SATCM, and the National Bureau of Disease Prevention and Control jointly promulgated the Administrative Measures for the Cybersecurity of Medical and Healthcare Institution (《醫療衛生機構網絡安全管理辦法》) with immediate effect. The Administrative Measures for the Cybersecurity of Medical and Healthcare Institution require all the medical and health institutions to set up data life-cycle management systems and user participation-based cybersecurity management systems, including but not limited to strengthening system construction, implementing daily network maintenance and monitoring, conducting annual self-inspection and rectification, and classifying and grading data assets.

### Regulations on Intellectual Property Rights

#### *Trademark Law of the PRC and Its Implementing Rules (《中華人民共和國商標法》及其實施條例)*

Trademarks are protected by the Trademark Law of the PRC (《中華人民共和國商標法》) which was promulgated on August 23, 1982 and subsequently amended on February 22, 1993, October 27, 2001, August 30, 2013, April 23, 2019 and took effect on November 1, 2019 as well as the Implementation Regulation of the PRC Trademark Law (《中華人民共和國商標法實施條例》) adopted by the State Council on August 3, 2002 and revised on April 29, 2014. In the PRC, registered trademarks include commodity trademarks, service trademarks, collective marks and certification marks. The Trademark Office of National Intellectual Property Administration handles trademark registrations and grants a term of 10 years to registered trademarks, renewable every 10 years where a registered trademark needs to be used after the expiration of its validity term.

#### *Patent Law of the PRC and Its Implementing Rules (《中華人民共和國專利法》及其實施細則)*

According to the Patent Law of the PRC (《中華人民共和國專利法》), promulgated by the SCNPC on March 12, 1984 and further amended on September 4, 1992, August 25, 2000, December 27, 2008, October 17, 2020 and came into effect on June 1, 2021 and the Implementing Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), promulgated by the China Patent Bureau Council on January 19, 1985, and latest amended on December 11, 2023 and came into effect on January 20, 2024, the term “invention-creations” refers to inventions, utility models and designs. The duration of patent right for inventions shall be twenty years, the duration of patent right for utility models shall be ten years and the duration of patent right for designs shall be fifteen years, counted from the date of filing. In the event that a dispute arises due to a patent being exploited without the prior authorization of the patentee, that is to say an infringement upon the patent right of the patentee.

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### *Administrative Measures for Internet Domain Names (《互聯網域名管理辦法》)*

The Administrative Measures for Internet Domain Names (《互聯網域名管理辦法》), which was promulgated by the MIIT on August 24, 2017 and became effective on November 1, 2017, regulates the “.CN” and the “.zhongguo (in Chinese character)” shall be China’s national top-level domains. Any party that engages in internet information services shall use its domain name in compliance with laws and regulations and in line with relevant provisions of the telecommunications authority but shall not use its domain name to commit any violation.

### *Measures for the Registration of Computer Software Copyright (《計算機軟件著作權登記辦法》)*

The Measures for the Registration of Computer Software Copyright (《計算機軟件著作權登記辦法》), which was promulgated by the National Copyright Administration on February 20, 2002, and came into effect on the same day, regulates the registration of software copyright, the exclusive licensing contract and assignment contracts of software copyright. The National Copyright Administration is mainly responsible for the registration and management of national software copyright and designates the China Copyright Protection Center as the agency for software registration. The China Copyright Protection Center will grant certificates of registration to computer software copyright applicants.

### **Regulations on Environmental Protection Related to Medical Institutions**

#### *Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) and Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》)*

Pursuant to the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) promulgated by the SCNPC on December 26, 1989 and became effective on the same day, amended on April 24, 2014 and became effective on January 1, 2015, the waste discharge licensing system has been implemented in the PRC and entities that discharge medical sewage to water bodies directly or indirectly shall obtain a waste discharge license. Furthermore, installations for the prevention and control of pollution at a construction project must be designed, built and commissioned together with the principal part of the project.

Pursuant to the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》) promulgated by the SCNPC on October 28, 2002, became effective on September 1, 2003 and amended on July 2, 2016 and December 29, 2018, the State implements administration by classification on the environmental impact of construction projects according to the level of impact on the environment. The construction entity shall prepare an environmental impact report, or an environmental impact form or complete an environmental impact registration form (the “**Environmental Impact Assessment Documents**”) for reporting and filing purpose. If the

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Environmental Impact Assessment Documents of a construction project have not been reviewed by the approving authority in accordance with the law or have not been granted approval after the review, the construction entity is prohibited from commencing construction works.

***Regulations on the Management of Medical Waste (《醫療廢物管理條例》), and the Implementation Measures of the Management of Medical Waste (《醫療衛生機構醫療廢物管理辦法》)***

According to the Regulations on the Management of Medical Waste (《醫療廢物管理條例》), which was promulgated by the State Council on June 16, 2003 and amended on January 8, 2011, and the Implementation Measures of the Management of Medical Waste (《醫療衛生機構醫療廢物管理辦法》), which was promulgated by the MOH on October 15, 2003 and came into effect on the same day, medical or health institution shall register medical waste, manage medical waste under classification and undertake management of duplicate forms for transfer of hazardous waste in accordance with the Catalogue of Classified Medical Waste (《醫療廢物分類目錄》), and deliver medical waste to an entity for centralized disposal of medical waste and licensed by a relevant environment protection administrative department for dispose. Sewage generated by any health institution and excretion of its patients or suspected patients of infectious diseases shall be sterilized in strict accordance with the relevant provisions and shall not be discharged into sewage disposal systems until the discharging standards are met.

***The Law of the PRC on Prevention and Control of Radioactive Pollution (《中華人民共和國放射性污染防治法》) and Safety Management of Radioactive Waste (《放射性廢物安全管理條例》)***

The Law of the PRC on Prevention and Control of Radioactive Pollution (《中華人民共和國放射性污染防治法》) stipulates that, an entity generating radioactive waste liquid must, in accordance with the requirements of the national standards on the prevention and control of radioactive pollution, dispose or store the radioactive waste liquid which shall not be discharged to the environment. An entity generating radioactive solid waste shall, in accordance with the provisions of the competent administrative department of environmental protection under the State Council, deliver the radioactive solid waste it generates to the entity disposing the radioactive solid waste for disposition after having them treated, and shall assume the disposition expense.

In accordance with the Regulations on the Safety Management of Radioactive Waste (《放射性廢物安全管理條例》) which came into effect on March 1, 2012, China adopts the classified management of radioactive waste. According to the characteristics and the potential hazardous exposure of the human health and environment, radioactive waste are divided into high-level radioactive waste, medium-level radioactive waste and low-level radioactive waste. Entities of utilization of nuclear technology shall conduct relevant treatment procedures of the liquid radioactive waste (which was generated but couldn't be discharged after purification), and then

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transformed to solid radioactive waste. Entities of utilization of nuclear technology shall deliver disused radioactive sources and other solid radioactive waste generated by them to any qualified entity for centralized storage, or to a solid radioactive waste disposing entity possessing the applicable licenses for disposal.

### *The Regulations on Urban Drainage and Sewage Disposal (《城鎮排水與污水處理條例》)*

Enterprises that engage in the activities of industry, construction, catering, and medical treatment, etc., that discharges sewage into urban drainage facilities shall apply to the relevant competent urban drainage department for the permit for discharging sewage into drainage pipelines under relevant laws and regulations, including the Regulations on Urban Drainage and Sewage Disposal (《城鎮排水與污水處理條例》), which was promulgated on October 2, 2013 and came into force on January 1, 2014, and the Measures for the Administration of Permits for the Discharge of Urban Sewage into the Drainage Network (《城鎮污水排入排水管網許可管理辦法》), which was promulgated on January 22, 2015 and last amended on December 1, 2022 and took effect on February 1, 2023. Drainage entities covered by urban drainage facilities shall discharge sewage into urban drainage facilities in accordance with the relevant provisions of the State. Where a drainage entity needs to discharge sewage into urban drainage facilities, it shall apply for a drainage license in accordance with the provisions of these Measures. The drainage entity that has not obtained the drainage license shall not discharge sewage into urban drainage facilities.

### **Regulations on Foreign Investment in China**

#### *Company Law of the PRC (《中華人民共和國公司法》)*

The Company Law of the PRC (《中華人民共和國公司法》), which was amended by SCNPC on October 26, 2018 and came into effective on the same day, provides that companies established in China may take the form of limited liability company or joint stock company with limited liability. Each company has the status of a legal person and owns the assets itself. The Company Law of the PRC applies to foreign-invested companies unless relevant laws provide otherwise. Furthermore, the Company Law of the PRC was recently amended by the SCNPC on December 29, 2023 with respect to the registration, the capital contribution period and so on and will come into force on July 1, 2024, to improve the system for company registration and facilitates the establishment and exit channels of companies, to offer greater autonomy for companies in terms of corporate structure, improve the capital system for companies, boost the responsibility system of company shareholders and management personnel, and highlight social responsibility efforts of enterprises.



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### ***Foreign Investment Law of the PRC (《中華人民共和國外商投資法》)***

The Foreign Investment Law of the PRC (《中華人民共和國外商投資法》), which was promulgated on March 15, 2019 and became effective on January 1, 2020, is applicable to the investment activities in the PRC carried out directly or indirectly by foreign natural persons, enterprises or other organizations.

### ***Measures for the Reporting of Foreign Investment Information (《外商投資信息報告辦法》)***

Pursuant to the Measures for the Reporting of Foreign Investment Information (《外商投資信息報告辦法》) promulgated by the MOFCOM and the SAMR on December 30, 2019 and effective on January 1, 2020, a listed foreign-funded company may, when the change of foreign investors' shareholding ratio accumulatively exceeds 5% or the foreign party's controlling or relatively controlling status changes, report the information on the modification of investors and the shares held by them.

### ***Special Management Measures for Access of Foreign Investment (Negative List) (2021 Version) (《外商投資准入特別管理措施(負面清單)》〈2021年版〉)***

Foreign investors in the PRC are subject to certain restrictions regarding the types of industries they can invest in. The Special Management Measures for Access of Foreign Investment (Negative List) (2021 Version) (《外商投資准入特別管理措施(負面清單)》〈2021年版〉) was promulgated by the MOFCOM and the NDRC on December 27, 2021 and came into effect on January 1, 2022. The Negative List set out the restrictive measures in a unified manner, such as the requirements on shareholding percentages and management, for the access of foreign investments, and the industries that are prohibited for foreign investment. The Negative List covers 12 industries, and any field not falling in the Negative List shall be administered under the principle of equal treatment to domestic and foreign investment.

### ***Interim Administrative Measures on Sino-Foreign Equity Medical Institutions and Sino-Foreign Cooperative Medical Institutions (《中外合資、合作醫療機構管理暫行辦法》) and Its Supplementary Provisions***

The Interim Administrative Measures on Sino-Foreign Equity Medical Institutions and Sino-Foreign Cooperative Medical Institutions (《中外合資、合作醫療機構管理暫行辦法》), which was jointly promulgated by the MOH and the Ministry of Foreign Trade and Economic Cooperation on May 15, 2000 and came into effect on July 1, 2000, and its Supplementary Provisions allow foreign investors to partner with Chinese medical entities to establish a medical institution in China by means of equity joint venture or cooperative joint venture. Establishment of equity joint venture or cooperative joint venture shall meet certain requirements, among others,

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including the equity percentage of the Chinese partner in the joint venture shall not be less than 30%. Establishment of equity joint venture or cooperative medical institutions shall be subject to approval by relevant authorities.

### **Regulations on Employment and Social Security**

#### ***Labor Law of the PRC (《中華人民共和國勞動法》)***

The Labor Law of the PRC (《中華人民共和國勞動法》), which was promulgated by the SCNPC on July 5, 1994, came into effect on January 1, 1995, and was amended on August 27, 2009 and December 29, 2018, provides that an employer shall develop and improve its rules and regulations to safeguard the rights of its workers. Labor safety and health facilities must comply with relevant national standards. Workers engaged in special operations shall have received specialized training and obtained the pertinent qualifications.

#### ***Labor Contract Law of the PRC and its Implementation Regulations (《中華人民共和國勞動合同法》及其實施條例)***

The Labor Contract Law of the PRC (《中華人民共和國勞動合同法》), which was promulgated by the SCNPC on June 29, 2007, came into effect on January 1, 2008, and was amended on December 28, 2012, and came into effect on July 1, 2013, and the Implementation Regulations on Labor Contract Law (《中華人民共和國勞動合同法實施條例》) which was promulgated and came into effect on September 18, 2008 by the State Council, regulate the relations of employer and the employee, and contain specific provisions involving the terms of the labor contract.

### **Regulations on Supervision Over the Social Security and Housing Funds**

According to the Provisional Regulations on the Collection and Payment of Social Insurance Premium (《社會保險費徵繳暫行條例》), the Regulations on Work Injury Insurance (《工傷保險條例》), the Regulations on Unemployment Insurance (《失業保險條例》) and the Trial Measures on Employee Maternity Insurance of Enterprises (《企業職工生育保險試行辦法》), enterprises in China must provide benefit plans for their employees, which include basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and medical insurance. An enterprise must provide social insurance by processing social insurance registration with local social insurance agencies and must pay or withhold relevant social insurance premiums for or on behalf of employees.

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The PRC Law on Social Insurance (《中華人民共和國社會保險法》), which was promulgated by the SCNPC on October 28, 2010 and came into effect on July 1, 2011, and was amended on December 29, 2018 regulates basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and medical insurance, and has elaborated in detail the legal obligations and liabilities of employers who do not comply with relevant laws and regulations on social insurance.

The Regulations on the Administration of Housing Provident Fund (《住房公積金管理條例》), which were promulgated on April 3, 1999 and came into effective on the same date, and was amended on March 24, 2002 and March 24, 2019, stipulate that housing provident fund contributions paid by an individual employee and housing provident fund contributions paid by his or her employer shall all belong to the individual employee.

### **Regulations on Taxation**

#### ***Enterprise Income Tax***

According to the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) (the "EIT Law"), which was promulgated by the NPC on March 16, 2007, came into effect on January 1, 2008 and amended by the SCNPC on February 24, 2017 and December 29, 2018, and the Implementation Regulations on the EIT Law (《中華人民共和國企業所得稅法實施條例》), which was promulgated by the State Council on December 6, 2007 and came into effect on January 1, 2008, and amended by the State Council on April 23, 2019 and came into effect on the same date, a uniform income tax rate of 25% will be applied to domestic enterprises, foreign-invested enterprises and foreign enterprises that have established production and operation facilities in China. These enterprises are classified as either resident enterprises or non-resident enterprises. Resident enterprises refer to enterprises that are established in accordance with PRC laws, or that are established in accordance with the laws of foreign countries but whose actual or de facto control is administered from within the PRC. Non-resident enterprises refer to enterprises that are set up in accordance with the laws of foreign countries and whose actual administration is conducted outside the PRC, but who (whether or not through the establishment of institutions in the PRC) derive income from the PRC. Under the EIT Law and relevant implementing regulations, a uniform corporate income tax rate of 25% is applicable. However, if non-resident enterprises have not established institutions or places in the PRC, or if they have established institutions or places in the PRC but there is no actual relationship between the relevant income derived in the PRC and the institutions or places set up by them, enterprise income tax is set at the rate of 10%.

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### *Value-added Tax*

The Provisional Regulations on Value-added Tax of the PRC (《中華人民共和國增值稅暫行條例》), which were promulgated by the State Council on December 13, 1993, came into effect on January 1, 1994, and amended on November 10, 2008, February 6, 2016 and November 19, 2017, and the Detailed Implementing Rules of the Provisional Regulations on Value-added Tax of the PRC (《中華人民共和國增值稅暫行條例實施細則》), which were promulgated by the MOF on December 25, 1993 and came into effect on the same date, and was amended on December 15, 2008 and October 28, 2011, came into effect on November 1, 2011, set out that all taxpayers selling goods or providing processing, repairing or replacement services, sales of services, intangible assets and immovable assets and importing goods in China shall pay a value-added tax. A tax rate of 17% shall be levied on general taxpayers selling goods and services, leasing of tangible movable assets or importing goods whereas the applicable rate for the export of goods by taxpayers shall be nil, unless otherwise stipulated.

On November 16, 2011, the MOF and the State Administration of Taxation (the "SAT") promulgated the Trial Scheme for the Conversion of Business Tax to Value-added Tax (《營業稅改徵增值稅試點方案》), pursuant to which the government launched gradual taxation reforms from January 1, 2012, where a value-added tax is imposed in lieu of business tax on a trial basis in regions and industries showing strong economic performance, such as transportation and certain modern service industries.

The Notice of the Ministry of Finance and the State Administration of Taxation on Overall Implementation of the Pilot Program of Replacing Business Tax with Value-added Tax (《財政部、國家稅務總局關於全面推開營業稅改徵增值稅試點的通知》), which was promulgated by the MOF and the SAT on March 23, 2016 and came into effective on May 1, 2016, amended on July 1, 2017, December 25, 2017 and March 20, 2019 and became effective on April 1, 2019, all business taxpayers in the consumer service industry shall pay value-added tax instead of business tax from May 1, 2016. If the taxpayer of the pilot project has already enjoyed tax incentives of business tax according to relevant policies and regulations before the application of the pilot collection of value-added tax in lieu of business tax, he/she may, in the remaining period of tax incentives, enjoy tax incentives of value-added tax in accordance with the relevant provisions. Medical services provided by medical institutions shall be exempted from value-added tax.

According to the Notice of the Ministry of Finance and the State Administration of Taxation on Adjusting Value-added Tax Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》) issued on April 4, 2018 and became effective on May 1, 2018, the value-added tax rates of 17% and 11% applicable to the taxpayers who have VAT taxable sales activities or imported goods are adjusted to 16% and 10%, respectively.

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According to the Notice on Relevant Policies for Deepening Value-Added Tax Reform (《關於深化增值稅改革有關政策的公告》) issued on March 20, 2019 and became effective on April 1, 2019, the value-added tax rate was reduced to 13% and 9%, respectively.

### Regulations on Foreign Exchange

On January 29, 1996, the State Council promulgated the Administrative Regulations on Foreign Exchange of the PRC (《中華人民共和國外匯管理條例》) which became effective on April 1, 1996 and were amended on January 14, 1997 and August 5, 2008. Foreign exchange payments under current account items shall, pursuant to the administrative provisions of the foreign exchange control department of the State Council on payments of foreign currencies and purchase of foreign currencies, be made using self-owned foreign currency or foreign currency purchased from financial institutions engaging in conversion and sale of foreign currencies by presenting the valid document. Domestic entities and domestic individuals making overseas direct investments or engaging in issuance and trading of overseas securities and derivatives shall process registration formalities pursuant to the provisions of the foreign exchange control department of the State Council.

On November 19, 2012, the SAFE issued the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment (《關於進一步改進和調整直接投資外匯管理政策的通知》), or the SAFE Circular 59, which came into effect on December 17, 2012 and was revised on May 4, 2015, October 10, 2018 and partially abolished on December 30, 2019. The SAFE Circular 59 aims to simplify the foreign exchange procedure and promote the facilitation of investment and trade. According to the SAFE Circular 59, the opening of various special purpose foreign exchange accounts, such as pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts, the reinvestment of RMB proceeds derived by foreign investors in the PRC, and remittance of foreign exchange profits and dividends by a foreign-invested enterprise to its foreign shareholders no longer require the approval or verification of SAFE, multiple capital accounts for the same entity may be opened in different provinces as well. Later, the SAFE promulgated the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》) in February 2015, which was partially abolished in December 2019, prescribed that the bank instead of SAFE can directly handle the foreign exchange registration and approval under foreign direct investment while SAFE and its branches indirectly supervise the foreign exchange registration and approval under foreign direct investment through the bank.

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On May 10, 2013, the SAFE issued the Administrative Provisions on Foreign Exchange in Domestic Direct Investment by Foreign Investors (《外國投資者境內直接投資外匯管理規定》), or the SAFE Circular 21, which became effective on May 13, 2013, amended on October 10, 2018 and partially abolished on December 30, 2019. The SAFE Circular 21 specifies that the administration by SAFE or its local branches over direct investment by foreign investors in the PRC must be conducted by way of registration and banks must process foreign exchange business relating to the direct investment in the PRC based on the registration information provided by SAFE and its branches.

According to the Notice on Relevant Issues Concerning the Administration of Foreign Exchange for Overseas Listing (《關於境外上市外匯管理有關問題的通知》) issued by the SAFE on December 26, 2014, the domestic companies shall register the overseas listed with the foreign exchange control bureau located at its registered address in 15 working days after completion of the overseas listing and issuance. The funds raised by the domestic companies through overseas listing may be repatriated to China or deposited overseas, provided that the intended use of the fund shall be consistent with the contents of the document and other public disclosure documents.

According to the Notice of the State Administration of Foreign Exchange on Reforming the Management Mode of Foreign Exchange Capital Settlement of Foreign Investment Enterprises (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》), or the SAFE Circular 19 promulgated on March 30, 2015, coming effective on June 1, 2015 and partially abolished on December 30, 2019 and March 23, 2023, foreign-invested enterprises could settle their foreign exchange capital on a discretionary basis according to the actual needs of their business operations. Whilst, foreign-invested enterprises are prohibited to use the foreign exchange capital settled in RMB (a) for any expenditures beyond the business scope of the foreign-invested enterprises or forbidden by laws and regulations; (b) for direct or indirect securities investment; (c) to provide entrusted loans (unless permitted in the business scope), repay loans between enterprises (including advances by third parties) or repay RMB bank loans that have been on-lent to a third party; and (d) to purchase real estates not for self-use purposes (save for real estate enterprises).

On June 9, 2016, SAFE issued the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》), or the SAFE Circular 16, which came into effect on the same day. The SAFE Circular 16 provides that discretionary foreign exchange settlement applies to foreign exchange capital, foreign debt offering proceeds and remitted foreign listing proceeds, and the corresponding RMB capital converted from foreign exchange may be used to extend loans to related parties or repay inter-company loans



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(including advances by third parties). However, the interpretation and implementation of SAFE Circular 16 shall be determined in accordance with the relevant laws and regulations in effect at that time in practice.

On October 23, 2019, SAFE promulgated the Notice on Further Facilitating Cross-Board Trade and Investment (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》), which became effective on the same date (except for Article 8.2, which became effective on January 1, 2020). The notice cancelled restrictions on domestic equity investments made with capital funds by non-investing foreign-funded enterprises. In addition, restrictions on the use of funds for foreign exchange settlement of domestic accounts for the realization of assets have been removed and restrictions on the use and foreign exchange settlement of foreign investors’ security deposits have been relaxed. Eligible enterprises in the pilot area are also allowed to use revenues under capital accounts, such as capital funds, foreign debts and overseas listing revenues for domestic payments without providing materials to the bank in advance for authenticity verification on an item-by-item basis, while the use of funds should be true, in compliance with applicable rules and conforming to the current capital revenue management regulations.

According to the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (《關於優化外匯管理支持涉外業務發展的通知》) issued by the SAFE on April 10, 2020, eligible enterprises are allowed to make domestic payments by using their capital funds, foreign credits and the income under capital accounts of overseas listing, without submitting the evidentiary materials concerning authenticity of such capital for banks in advance, provided that their capital use is authentic and in compliance with administrative regulations on the use of income under capital accounts. The bank in charge shall conduct post spot checking in accordance with the relevant requirements.

### Regulations on Overseas Listing

The CSRC promulgated the Trial Administrative Measures on the Overseas Securities Offering and Listing of Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “**Overseas Listing Trial Measures**”) and five relevant guidelines on February 17, 2023, which took effect on March 31, 2023. The Overseas Listing Trial Measures comprehensively reform the regulatory regime for overseas offering and listing of PRC domestic companies’ securities, either directly or indirectly, into a filing-based system.

According to the Overseas Listing Trial Measures, the PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to fulfill the filing procedure with the CSRC and report relevant information. The Overseas Listing Trial Measures provide that an overseas listing or offering is explicitly prohibited, if any of the following applies: (i) such securities offering or listing is explicitly prohibited by provisions in

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PRC laws, administrative regulations or relevant state rules; (ii) the proposed securities offering or listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with laws; (iii) the domestic company intending to be listed or offer securities in overseas markets, or its controlling shareholder(s) and the actual controller, have committed crimes such as corruption, bribery, embezzlement, misappropriation of property or undermining the order of the socialist market economy during the latest three years; (iv) the domestic company intending to be listed or offer securities in overseas markets is currently under investigations for suspicion of criminal offenses or major violations of laws and regulations, and no conclusion has yet been made thereof; or (v) there are material ownership disputes over equity held by the domestic company’s controlling shareholder(s) or by other shareholder(s) that are controlled by the controlling shareholder(s) and/or actual controller. As advised by our PRC Legal Advisor, we do not fall under any of the circumstances specified in the Overseas Listing Trial Measures under which overseas offering and listing are prohibited. In addition, we had not received any inquiry, notice, warning, or order prohibiting us from getting listed on the Stock Exchange from the CSRC or any other PRC government authorities. According to the Overseas Listing Trial Measures, initial public offerings or listings in overseas markets shall be filed with the CSRC within three working days after the relevant application is submitted overseas. We had filed with the CSRC within three working days after we submit the A1 application to Hong Kong Stock Exchange.

On February 24, 2023, the CSRC and other relevant government authorities promulgated the Provisions on Strengthening the Confidentiality and Archives Administration of Overseas Securities Issuance and Listing by Domestic Enterprises (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》) (the “**Provision on Confidentiality**”), which took effect on March 31, 2023. Pursuant to the Provision on Confidentiality, where a domestic enterprise provides or publicly discloses to the relevant securities companies, securities service institutions, overseas regulatory authorities and other entities and individuals, or provides or publicly discloses through its overseas listing subjects, documents and materials involving state secrets and working secrets of state organs, it shall report the same to the competent department with the examination and approval authority for approval in accordance with the law, and submit the same to the secrecy administration department of the same level for filing. Domestic enterprises providing accounting archives or copies thereof to entities and individuals concerned such as securities companies, securities service institutions and overseas regulatory authorities shall perform the corresponding procedures pursuant to the relevant provisions of the State. The working papers formed within the territory of the PRC by the securities companies and securities service institutions that provide corresponding services for the overseas issuance and listing of domestic enterprises shall be kept within the territory of the PRC, and those that need to leave the PRC shall go through the examination and approval formalities in accordance with the relevant provisions of the State.

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## REGULATORY OVERVIEW

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### Regulations on H Share Full Circulation

According to the Overseas Listing Trial Measures and related guidelines, “full circulation” refers to the conversion of domestic unlisted shares, which are held by shareholders of domestic companies directly offering and listing overseas, into overseas listed shares, so as to be circulated on overseas trading venues. Applications of “full circulation” shall comply with relevant regulations of the CSRC and the shareholders of domestic unlisted shares shall authorize the domestic company to report the “full circulation” with CSRC by filing materials on key compliance issues. Contents of the filing shall include (i) whether the “full circulation” has fulfilled adequate internal decision-making procedures, obtained necessary internal approvals and authorizations; (ii) whether the “full circulation” involves any approval or filing procedures related to state-owned asset administration, industry supervision and foreign investment, and if so, whether such approval or filing procedures have been performed in accordance with the law.