

**海南自由贸易港博鳌乐城国际医疗
旅游先行区条例**

**Regulations of Hainan Free Trade Port on Bo'ao
Hope Pilot Zone of International Medical Tourism**

海南自由贸易港博鳌乐城国际医疗旅游 先行区条例

(2020年6月16日海南省第六届人民代表大会常务委员会
第二十次会议通过)

第一章 总 则

第一条 为了促进海南自由贸易港博鳌乐城国际医疗旅游先行区(以下简称先行区)发展,根据有关法律、行政法规,结合本省实际,制定本条例。

第二条 先行区应当按照海南自由贸易港建设的有关要求,对标国际最高标准,创新体制机制,在产业政策、招商引资、医疗创新、旅游服务、跨境服务贸易等方面先行先试,以高水平开放推动国际医疗旅游和高端医疗服务发展,建设世界一流的国际医疗旅游目的地和医疗科技创新平台。

第三条 省人民政府应当加强对先行区建设的组织领导,决定先行区建设中的重大事项,建立考核和评估机制。

省人民政府推进先行区建设领导机构负责先行区建设的指导、督导、推进和协调工作,研究先行区建设中的重大问题。

省人民政府有关部门按照职责分工负责先行区建设的具体指导、协调和服务工作。

Regulations of Hainan Free Trade Port on Bo'ao Hope Pilot Zone of International Medical Tourism

(Adopted at the 20th Session of the Standing Committee of the 6th Hainan Provincial People's Congress on June 16, 2020)

Chapter I General Provisions

Article 1 For the purposes of promoting the development of Bo'ao Hope Pilot Zone of International Medical Tourism (hereinafter referred to as the "Pilot Zone") in Hainan Free Trade Port (hereinafter referred to as "HFTZ"), the Regulations on Bo'ao Hope Pilot Zone of International Medical Tourism are enacted pursuant to applicable laws and administrative regulations and in the light of the actual circumstances of this Province.

Article 2 Pursuant to the applicable requirements for the development of the HFTZ, the Pilot Zone shall adhere to the highest international standards, engage in governance innovation, and be a leader in industry policies, investment promotion, medical innovation, tourism services, and cross-border service trade, so as to promote the development of international medical tourism and high-end medical services with a high level of openness and build a world-class international medical tourism destination and medical science and technology innovation platform.

Article 3 The provincial people's government shall improve the organization and leadership of the development of the Pilot Zone, decide on major issues, and implement an assessment and evaluation system.

The provincial people's government shall enable the lead agency of the Pilot Zone to be responsible for guiding, overseeing, promoting, and coordinating the development of the Pilot Zone, and studying major issues.

The appropriate agencies of the provincial people's government shall be responsible for the guidance, coordination, and service of the development of the Pilot Zone pursuant to their respective functions and duties.

第四条 在先行区设立管理机构。管理机构是在先行区履行相应行政管理和公共服务职责的法定机构，具体负责先行区综合协调、开发建设、运营管理、产业发展、投资促进、制度创新、企业服务等工作，依照授权或者委托行使相应的行政审批权和行政处罚权。

先行区管理机构按照精简高效的原则，在薪酬总额范围内，自主决定机构设置、岗位设置、人员聘用、薪酬标准等，依照有关规定任命的人员除外。

先行区管理机构的高级管理人员及其他工作人员可以从境外选聘。

第五条 先行区管理机构可以依法组建开发运营公司，委托开发运营公司负责先行区内的产业投资、基础设施和公共服务设施的建设及运营，参与园区管理服务的组织与实施。

第六条 琼海市人民政府及其有关部门负责行使先行区的社会管理职能，具体范围由省人民政府规定。

琼海市人民政府及其有关部门应当在规划编制、招商引资、基础设施建设、体制创新、政策实施等方面支持先行区的发展。

第七条 省和琼海市人民政府及其有关部门应当依法将相关管理权限下放或者委托先行区管理机构行使。

不宜下放或者委托行使的管理权限，省和琼海市人民政府有关部门可以按照规定在先行区设立驻区机构。

省人民政府有关部门、先行区管理机构、驻区机构应当明确在先行区的管理权限，依法编制权力清单、责任清单，经批准后向社会公布。

Article 4 An administrative agency shall be created in the Pilot Zone. The administrative agency shall be the statutory agency that performs the appropriate administrative duties and provides public services in the Pilot Zone and is specifically responsible for the integrated coordination, development and construction, operation management, industrial development, investment promotion, institutional innovation, service for entities in the Pilot Zone, and shall exercise the administrative review and penalty authority through the authorization or delegation of power.

Under the principle of streamlining and efficiency, the administrative agency shall independently determine the organization, positions, employment, and salary standards as limited by the salary cap, except for those appointed pursuant to applicable regulations.

The senior administrative officers and other administrative agency employees in the Pilot Zone may be hired from other countries or regions.

Article 5 The administrative agency of the Pilot Zone may incorporate a development and operations company pursuant to law, delegate the development and operations company to be responsible for the development and operation of industrial investment, infrastructure, and public services facilities in the Pilot Zone, and participate in the organization and enforcement of the industrial park administration.

Article 6 The Qionghai Municipal People's Government and its appropriate agencies shall be responsible for the social administration of the Pilot Zone, which shall be specified by the provincial people's government.

The Qionghai Municipal People's Government and its appropriate agencies shall support the development of the Pilot Zone in planning, attracting investment, infrastructure development, institutional innovation, and policy enforcement.

Article 7 The provincial and Qionghai municipal people's governments and their appropriate agencies shall devolve or delegate the appropriate administrative powers to the administrative agency of the Pilot Zone pursuant to law.

If it is not appropriate to devolve or delegate the administrative powers, the appropriate agencies of the provincial and Qionghai municipal people's governments may establish local branch offices in the Pilot Zone pursuant to the rules.

The appropriate agencies of the provincial people's government, the administrative agency of the Pilot Zone, and the local branch offices shall clarify the administrative powers in the Pilot Zone, prepare the list of powers and duties pursuant to law, and publish such upon approval.

第二章 开发建设

第八条 先行区管理机构负责组织编制先行区控制性详细规划以及产业发展规划等，经批准后实施。

先行区周边地区相关规划应当与先行区控制性详细规划以及产业发展规划等相衔接。

第九条 先行区应当严格落实生态环境保护制度和生态保护红线管理制度，严格资源节约利用和环境准入门槛，完善生态环境保护基础设施和措施，坚持绿色低碳循环发展。

第十条 先行区应当加强路网、电网、光网、气网、水网、生产和生活配套服务等基础设施的整体规划和同步建设，促进产城融合发展。

琼海市人民政府和先行区管理机构应当建立开发建设协调机制，统筹先行区与周边地区基础设施、公共服务设施和其他配套设施的建设与管理，推动区域一体化布局和联动发展。

第十一条 省人民政府应当通过债券资金、专项资金、补助等多种方式对先行区予以财政扶持。

第十二条 先行区土地利用应当符合先行区控制性详细规划和产业发展需要，实施严格的节约集约用地制度，提升土地利用效益。

第十三条 省人民政府应当统筹安排先行区年度新增建设用地计划指标，优先保障重点产业、重点项目年度新增建设用地计划指标。

Chapter II Development and Construction

Article 8 The administrative office of the Pilot Zone shall be responsible for organizing the preparation of the detailed regulatory planning and industrial development planning of the Pilot Zone, and the enforcement of such plans upon approval.

The appropriate planning of the surrounding areas of the Pilot Zone shall be connected with the detailed regulatory planning and industrial development planning of the Pilot Zone.

Article 9 The Pilot Zone shall strictly enforce the environmental protection system and the bright-line administrative rules for environmental protection, strictly enforce the resource conservation and utilization and minimum requirements for environmental protection, improve the environmental protection infrastructure and measures, and adhere to pursuing green, low-carbon, and circular development.

Article 10 The Pilot Zone shall improve the comprehensive planning and development of infrastructure such as road networks, power grids, optical networks, gas networks, water networks, production and living supporting services, and promote the integrated development of the industry and city.

The Qionghai Municipal People's Government and the administrative agency of the Pilot Zone shall establish the development and construction coordination system, coordinate the development and management of infrastructure, public services facilities, and other supporting facilities in the Pilot Zone and its surrounding areas, and promote regional integration layout and inter-connective development.

Article 11 The provincial people's government shall give financial support to the Pilot Zone through issuing bonds, special funds, and allowances.

Article 12 The land use in the Pilot Zone shall meet the needs of detailed regulatory planning and industrial development in the Pilot Zone, and enforce the strict land conservation rules to improve land use efficiency.

Article 13 The provincial people's government shall make comprehensive and coordinated arrangements for land use quota for the Pilot Zone, and give priority to the land use quota for the key industries and the annual increased land needs for key projects.

在先行区可以采取划拨、出让、租赁、作价出资或者入股等灵活多样的供地方式。允许以出让、租赁、作价出资或者入股等方式利用农村集体经营性建设用地进行产业项目建设。

第十四条 在先行区有偿供应的土地上配建的属于先行区管理机构资产的产业用房、办公、商业、公寓、停车位等物业，用于先行区的产业扶持、公共服务设施、人才住房等。

第三章 产业发展

第十五条 支持将公立医院品牌、商标、专利、技术、服务、管理等以特许经营的形式提供给先行区医疗机构使用，鼓励公立医院入驻先行区。

第十六条 鼓励境内外资本在先行区投资举办医疗机构，放宽境外资本股比限制。民办医疗机构在医疗服务准入、社会保险定点、职称评定、等级评审、科研教学和学科建设等方面与公立医院享有平等待遇。

支持在先行区引进和培育具有国际先进水平的健康管理机构、医疗旅游保健中心、第三方医学检测机构等医疗机构。

第十七条 支持在先行区建设先进技术临床医学研究中心、临床试验机构和重点实验室等医学科研机构，联合世界知名医学院设立医学院校。鼓励国内外重点科研院所和医学院校、国家重点实验室、知名企业在先行区设立分支机构。

支持在先行区引进和培育医疗健康领域国际学术交流平台、国际性医疗组织，鼓励举办医疗健康领域国际会议和会展活动。

The flexible and diverse land supply methods such as allocation, transfer, lease, capital contribution, or shareholding can be adopted in the Pilot Zone. It is allowed to use rural collective development land for industrial project development by means of transfer, lease, capital contribution, or shareholding.

Article 14 The industrial buildings, office buildings, commercial buildings, apartments, parking spaces, and other properties that belong to the administrative agency of the Pilot Zone, which are paid and built in the Pilot Zone, are used for industrial support, public services facilities, and talent housing in the Pilot Zone.

Chapter III Industrial Development

Article 15 The brands, trademarks, patents, technology, services, management of public hospitals shall be supported to be franchised to the health care institutions in the Pilot Zone. The public hospitals are encouraged to provide services in the Pilot Zone.

Article 16 The domestic and foreign capital shall be encouraged to invest in the health care institutions in the Pilot Zone, and the restrictions on the share ratio of foreign capital shall be relaxed. Private health care institutions enjoy equal treatment with public hospitals in terms of medical service access, social insurance designation, professional title evaluation, grade evaluation, scientific research and teaching, and discipline development.

The international advanced health care institutions, medical tourism health care centers, third-party medical testing institutions, and other health care institutions shall be introduced and cultivated in the Pilot Zone.

Article 17 Construction of clinical research centers with advanced technology, clinical trial institutions and key laboratories, and other medical research institutions in the Pilot Zone shall be supported, as shall achieve establishment of medical colleges in joint efforts with world-renowned medical schools. Domestic and international key scientific research institutes and medical colleges, national key laboratories, and well-known companies shall also be encouraged to set up branches in the Pilot Zone.

International medical and health academic exchange platforms and international medical organizations shall receive support to be introduced and developed in the Pilot Zone, and the international medical care and health conferences and exhibitions shall also be encouraged to be held in the Pilot Zone.

第十八条 支持在先行区建设国家医药成果转移转化试点示范基地，探索开展重大新药创制国家科技重大专项成果转移转化试点，鼓励建设产业化生产基地、医药技术成果转移转化服务平台和交易中心。

第十九条 先行区医疗机构可以在先行区进行干细胞、免疫细胞治疗、单抗药物、基因治疗、组织工程等新技术研究和转化应用。

第二十条 鼓励开展先行区临床真实世界数据应用研究，探索将临床真实世界数据用于药品、医疗器械产品注册，缩短上市时间。

第二十一条 先行区可以建立区域性制剂中心，承担或者接受委托开展先行区医疗机构制剂的配制。

医疗机构制剂可以在先行区调剂使用，具体办法由省人民政府药品监督管理部门制定。

对医疗机构中药制剂委托配制、应用传统工艺配制的中药制剂实施备案管理。

省人民政府药品监督管理部门应当对先行区医疗机构制剂的注册、配制、使用等加强管理，确保制剂安全有效。

第二十二条 旅游文化主管部门应当会同先行区管理机构、卫生健康管理等部门促进医疗与旅游的融合发展，依托全省旅游资源，指导发展高端体检、健康管理、医疗服务、中医养生保健、特色康养等医疗健康产品服务，加强医疗健康养生产品开发和旅游路线设计，发展医养结合、休闲养生、健康农业等医疗旅游延伸项目。

鼓励国内外旅行社等机构为先行区开展专业化医疗旅游中介服务，加大医疗旅游宣传推介力度，提供医疗旅游全流程服务。

Article 18 The national pilot bases for the transfer and transformation of medical achievements shall be supported to be established in the Pilot Zone. The pilot projects for the transfer and transformation of national major scientific and technological achievements for the creation of major new drugs shall be explored, and the industrialized production bases, service platforms, and trading centers for the transfer and transformation of medical technological achievements shall also be encouraged to be established in the Pilot Zone.

Article 19 The health care institutions in the Pilot Zone may carry out research, transformation, and application of new technologies such as stem cells, immune cell therapy, monoclonal antibody drugs, gene therapy, and tissue engineering in the Pilot Zone.

Article 20 The real-world clinical data application research shall be encouraged to be conducted in the Pilot Zone to explore the use of real-world clinical data in the registration of drugs and medical devices and shorten the time to market.

Article 21 The Pilot Zone may establish regional preparation centers and undertake or accept the delegation to compound the preparations in health care institutions in the Pilot Zone.

The finished medical products can be prepared within the Pilot Zone, and specific rules shall be enacted by the medical products administration agency of the provincial people's government.

The drug master file administration shall be implemented for finished traditional Chinese medicine products produced by other entities or prepared via traditional methods.

The medical products administration agency of the provincial people's government shall improve the administration of the registration, compound, and use of the finished medical products in the Pilot Zone to ensure the safety and effectiveness of preparations.

Article 22 The competent agency for tourism and culture shall promote the integration of medical treatment and tourism in collaboration with the administrative agency of the Pilot Zone and health administration agencies, and guide the development of high-end medical examination, health management, medical services, health care with traditional Chinese medicine, special health care and other medical and health products and services, improve the development of medical and health care products and the design of tourism routes, and develop medical tourism extension projects such as a combination of medical care, leisure and health care, and healthy agriculture.

The domestic and foreign travel agencies and other organizations shall be encouraged to carry out specialized medical tourism intermediary services for the Pilot Zone to enhance the promotion of medical tourism and provide full-range medical tourism services.

第二十三条 先行区应当促进中医药传承与文化传播，推进中医药科研和创新，推动中医药国际合作和服务贸易发展。

第二十四条 拟在先行区使用的临床急需进口药品（不含疫苗）、医疗器械，可以在获批前批量储存先行区保税仓库，一次入库、多次通关，保障获批后即提、即用。

允许先行区医疗机构患者经备案承诺，按照本省有关规定将符合条件的进口药品带离先行区使用。

允许先行区扩大境外进口保健食品、保健用医疗器材范围。在符合有关规定的条件下，允许先行区进口使用境外上市但境内未上市的特医食品。

第二十五条 外籍医务人员、患者及陪同人员到先行区诊疗，享受海南自由贸易港出入境、停留居留便利化政策措施。

第二十六条 先行区建立保险业金融机构与先行区医疗机构的合作机制，鼓励开发多样化、特色化、个性化商业健康保险产品，简化管理手续，探索建立与国际商业保险付费体系相衔接的商业健康保险服务。

支持保险业金融机构与境外机构在先行区合作开发跨境商业健康保险产品。

第二十七条 在先行区依照海南自由贸易港有关规定实行跨境资金流动自由化便利化制度，放宽外商直接投资、跨境融资、个人跨境交易等方面限制，简化外汇登记、外债登记、资金汇出入和结购汇等手续。

第二十八条 先行区的企业和个人依照海南自由贸易港税收制度的有关规定，享受关税、企业所得税及个人所得税等方面的优惠政策。

Article 23 The Pilot Zone shall promote the inheritance and dissemination of traditional Chinese medicine to facilitate scientific research and innovation of traditional Chinese medicine, and promote the development of international cooperation and service of traditional Chinese medicine.

Article 24 The imported medical products (vaccines excluded) and medical devices urgently needed for clinical use in the Pilot Zone may be stored in batches in the bonded warehouse of the Pilot Zone before being approved. Customs declaration of the imported medical products and devices may be made separately after stored in the bonded warehouse altogether, so that they may be picked up and used immediately once being approved.

The patients in health care institutions in the Pilot Zone shall be allowed to take conforming imported medical products out of the Pilot Zone pursuant to the applicable laws of this Province.

The Pilot Zone shall be allowed to increase the variety of imported health food and medical equipment for health care. Pursuant to applicable rules, it shall also be allowed to import food for special medical purposes used overseas but not in China.

Article 25 The foreign medical personnel, patients, and their accompanying personnel, going to the Pilot Zone for medical treatment, shall enjoy the facilitated policies and measures with regard to entry and exit, and stay and residence in the HFTZ.

Article 26 The Pilot Zone shall establish a collaboration system between insurance financial institutions and health care institutions in the Pilot Zone, encourage the development of diversified, featured, and personalized commercial health insurance products, simplify the procedures for claims settlement, and explore the establishment of commercial health insurance services interconnected with the international commercial insurance payment system.

The insurance financial institutions and foreign institutions shall receive support to cooperate in respect of cross-border commercial health insurance in the Pilot Zone.

Article 27 In the Pilot Zone, the system of liberalization and facilitation of cross-border capital flows shall be enforced pursuant to applicable rules in the HFTZ. The restrictions on foreign direct investment, cross-border financing, and cross-border transactions by individuals shall be relaxed. The procedures for foreign exchange registration, foreign debt registration, capital remittance, and purchase of foreign exchange shall be simplified.

Article 28 The entities and individuals in the Pilot Zone shall enjoy preferential policies in terms of customs duties, corporate income tax, and personal income tax pursuant to the applicable rules of the tax system of the HFTZ.

第二十九条 执业医师（含境外）主要执业机构在先行区的，可以直接在先行区其他医疗机构执业。

护士（含境外）可以在先行区多点执业。

第三十条 先行区应当引进境内外高层次人才和急需紧缺人才，自主认定先行区高层次人才，可以对急需紧缺人才结合实际适当放宽文凭、年龄、职称等条件限制。

相关管理部门应当优化人才保障机制，在人才签证、停留和居留、人才移民、住房、医疗、就业、项目与奖励申报、教育等方面提供便利。

先行区依据国家和本省有关规定自主开展卫生系列高级专业技术职称评审工作。

国有企业事业单位医疗卫生、旅游等专业技术和管理人才可以在先行区按规定兼职兼薪。

第四章 服务管理

第三十一条 在先行区实施和深化极简审批改革，鼓励先行区管理机构结合实际需要，探索改革做法，创新管理模式。

先行区管理机构对权限范围内的审批事项，应当简化审批流程，压缩审批时限，提高行政审批服务效能。

先行区管理机构应当建立招商项目落地保障机制，实行项目全程跟踪服务责任制，对重大招商项目提供全程代办协办等优质便捷服务，及时协调解决项目审批、开工建设和生产经营中的问题。

Article 29 The medical practitioner (non-China's mainland medical practitioners included), whose major practicing institution is within the Pilot Zone, may directly practice in other health care institutions in the Pilot Zone.

The nurses (non-China's mainland nurses included) may practice in one or more institutions in the Pilot Zone.

Article 30 The Pilot Zone shall introduce domestic and foreign high-level talents and urgently needed talents, independently evaluate high-level talents in the Pilot Zone, and appropriately relax restrictions on diploma, age, professional title, and other conditions for urgently needed talents in consideration of reality.

The appropriate administrative departments shall optimize the talent guarantee system and provide convenience in talent visa, stay and residence, migration, housing, medical care, employment, project and reward application, and education.

Pursuant to state provisions and rules of this Province, the Pilot Zone independently carries out the evaluation of senior titles in respect of the health professionals.

The professionals and managers of the state-owned entities and institutions, such as in medical, health care, or tourism, may have part-time jobs and part-time remunerations pursuant to the rules in the Pilot Zone.

Chapter IV Service Management

Article 31 The reform of expedited review shall be enforced and improved, and the administrative agency of the Pilot Zone shall be encouraged to explore reforms and innovate administration in light of actual needs.

The administrative agency of the Pilot Zone shall simplify the review procedures, reduce the time limit, and improve efficiency.

The administrative agency of the Pilot Zone shall establish the guarantee system for investment projects, enforce the responsibility system for tracking services throughout the project, provide high-quality and convenient services such as full-time agency or co-sponsorship for major investment projects, and coordinate and solve the problems in project approval, development, production, and operation in a timely manner.

第三十二条 省人民政府卫生健康管理部门应当会同先行区管理机构制定先行区医疗机构设置标准及实施办法。

先行区管理机构会同省人民政府卫生健康管理、药品监督管理等部门,根据各自职责对入驻项目进行产业合规审查和医疗技术先进性评估。

先行区管理机构应当建立先行区不良市场主体退出机制,保障医疗旅游产业健康发展。

第三十三条 对在先行区兴办的医疗机构,不再核发《设置医疗机构批准书》,仅核发《医疗机构执业许可证》。

对先行区医疗机构设置申请和甲类大型医用设备配备申请,可以一并审批。

第三十四条 先行区应当完善医学伦理审查体系,加强临床研究与应用伦理审查。

省人民政府卫生健康和药品监督管理部门驻区机构应当加强对先行区医疗机构及从业人员遵守医学伦理规范行为的监管。

第三十五条 省人民政府知识产权管理部门应当会同先行区管理机构及其他有关部门加强先行区医疗健康领域知识产权保护,健全多元化知识产权争端解决与维权援助机制和涉外知识产权执法协作机制,鼓励医疗机构积极申请国际专利,注册国际商标。

第三十六条 先行区医疗机构应当建立医疗废物管理责任制,全面落实医疗废物管理责任。

省人民政府卫生健康和药品监督管理部门驻区机构、琼海市人民政府生态环境管理部门按照职责分工对先行区医疗废物管理实施监督管理。

Article 32 The health administration agency of the provincial people's government shall, together with the administrative office of the Pilot Zone, enact standards and rules for health care institutions in the Pilot Zone.

The administrative agency of the Pilot Zone shall, jointly with the health administration agency, medical products administration agency of the provincial people's government, conduct industrial compliance review and medical technology advancement evaluation on the projects pursuant to their respective functions and duties.

The administrative agency of the Pilot Zone shall establish an exit system for noncompliant organizations in the Pilot Zone to ensure the healthy development of the medical tourism industry.

Article 33 In respect of the health care institutions in the Pilot Zone, the Approval for Establishing Health Care Institution shall be no longer issued, and only the Practice License of Health Care Institution shall be issued.

The application for setting up health care institutions in the Pilot Zone and the application for Class A large medical equipment may be jointly reviewed.

Article 34 The Pilot Zone shall improve the medical ethics examination system and improve the ethics examination of clinical research and application.

The local branch office of the health administration agency and medical products administration agency of the provincial people's government shall improve the oversight of the health care institutions' and employees' adherence to the medical ethics in the Pilot Zone.

Article 35 The intellectual property administrative agency of the provincial people's government shall, in collaboration with the administrative agency of the Pilot Zone, and other appropriate agencies, improve the protection of intellectual property rights concerning the medical treatment and health in the Pilot Zone, improve the diversified dispute resolution and protection assistance system and collaboration system for foreign intellectual property law enforcement, and encourage health care institutions to actively apply for international patents and register international trademarks.

Article 36 The health care institutions in the Pilot Zone shall establish the accountability system for medical waste management and completely enforce the accountability system for medical waste management.

The local branch office of the health and medical products administration agency of the provincial people's government, and the environmental administration agency of the Qionghai Municipal People's Government shall oversee and manage the medical waste in the Pilot Zone according to their respective functions and duties.

第三十七条 省人民政府卫生健康和药品监督管理部门驻区机构应当加强对先行区药品、医疗器械的监督检查，及时查处违法行为，确保药品和医疗器械质量安全。

先行区建立药品和医疗器械追溯管理平台，对药品和医疗器械进口、审批、使用、监管等全流程实行追溯管理，实现卫生健康管理部门、药品监督管理部门、海关及先行区内所有医疗机构联网共享。

第三十八条 省人民政府卫生健康和药品监督管理部门驻区机构应当对先行区医疗机构运行、医疗健康从业人员、医疗技术临床应用、医疗卫生服务行业秩序、医疗健康产业等实施全方位监管，保障医疗质量和医疗安全。

省人民政府卫生健康和药品监督管理部门驻区机构应当加强对先行区医疗机构业务合作的监管，建立先行区医疗机构对外合作备案管理制度。

第三十九条 先行区管理机构应当会同省和琼海市人民政府有关部门按照国家有关规定建立医疗机构及从业人员信用记录，依法及时公布、公示和共享医疗机构及从业人员的信用信息，实行守信联合激励和失信联合惩戒。

鼓励医疗行业协会对先行区医疗机构开展医疗质量、服务能力等评价。

第四十条 省人民政府卫生健康管理、药品监督管理等部门应当会同先行区管理机构建立防范医疗风险为主的预警体系，健全突发事件应急预案及处置机制，监督指导医疗机构加强医疗风险管理和完善医疗风险的识别、评估和防控措施，防范各类风险。

Article 37 The local branch office of the health and medical products administration agency of the provincial people's government shall improve the oversight and inspection of medical products and medical devices in the Pilot Zone, investigate and punish illegal acts in a timely manner, and ensure the quality and safety of medical products and medical devices.

The Pilot Zone shall establish a traceability management platform for medical products and medical devices, and enforce traceability management for the whole process of import, review, usage, and oversight of drugs and medical devices, so as to achieve interconnectivity and sharing among health administration agencies, medical products administration agencies, customs, and all health care institutions in the Pilot Zone.

Article 38 The local branch office of the health and medical products administration agency of the provincial people's government shall oversee the operation of health care institutions, medical and health practitioners, clinical application of medical technology, medical and health service industry order, and medical and health industry in the Pilot Zone in an all-round way to ensure medical quality and safety.

The local branch office of the health and medical products administration agency of the provincial people's government shall improve the oversight of the business collaboration of health care institutions in the Pilot Zone and establish the record management system for foreign collaboration of health care institutions in the Pilot Zone.

Article 39 The administrative office of the Pilot Zone shall jointly with the appropriate agencies of the provincial people's government and Qionghai Municipal People's Government establish credit records for health care institutions and practitioners pursuant to state provisions, issue, publish, and share the credit information on health care institutions and providers in a timely manner pursuant to law, and enforce joint incentives for honesty and joint punishment against dishonesty.

The medical industry association is encouraged to evaluate the medical service quality and capability of health care institutions in the Pilot Zone.

Article 40 The health and medical products administration agencies of the provincial people's government shall, jointly with the administrative office of the Pilot Zone, establish the warning system prioritizing medical risk prevention, improve emergency response plans and emergency response system, oversee and guide health care institutions to improve medical risk management, improve the identification, evaluation, prevention, and control measures concerning medical risks, and prevent various risks.

第五章 法律责任

第四十一条 先行区管理机构、省和琼海市人民政府有关部门及其工作人员在先行区服务管理工作中有滥用职权、玩忽职守、徇私舞弊等行为的，对直接负责的主管人员和其他直接责任人员依法给予处分；构成犯罪的，依法追究刑事责任。

第四十二条 先行区建立创新容错机制，对有下列情形之一的，可以按照国家和本省有关规定从轻、减轻处理或者免除责任：

- （一）在推进先行区改革创新中因缺乏经验、先行先试出现的失误；
- （二）尚无明确限制的探索性试验中的失误；
- （三）为推动改革发展的无意过失；
- （四）法律法规规定的其他从轻、减轻或者免除责任的情形。

第六章 附 则

第四十三条 本条例自公布之日起施行。

Chapter V Legal Liability

Article 41 If the administrative agency of the Pilot Zone, the appropriate agencies of the provincial people's government and Qionghai Municipal People's Government, and their employees commit abuse of position, dereliction of duty, or play favoritism and commit irregularities, the person directly in charge and other employees subject to direct liability shall be penalized pursuant to law. If a crime is constituted, criminal liability shall be imposed pursuant to law.

Article 42 The Pilot Zone shall establish the innovative fault-tolerant system. Under any of the following circumstances, the punishment may be attenuated, mitigated, or exempted pursuant to state provisions and rules of this Province:

- (a) fault in promoting reform and innovation in the Pilot Zone results from inexperience and pilot trial;
- (b) fault in explorations that are not clearly limited;
- (c) negligence for the purpose of promoting reform and development; or
- (d) other circumstances subject to extenuated, mitigated, or exempt from liability pursuant to law.

Chapter VI Supplementary Provision

Article 43 These Regulations shall come into force as of the issuance date.

