**The Document of** **General Office of the People's Government of Hainan Province**

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**Notice by General Office of the People's Government of Hainan Province on Issuing the Measures of Hainan Province for Working Faster to Develop the Digital Therapy Industry**

The people’s governments of all cities, counties and autonomous counties; and all agencies directly under the provincial government:

With the approval of the provincial government, the Measures of Hainan Province for Working Faster to Develop Digital Therapy Industry is hereby issued to you for your diligent implementation.

General Office of the Hainan Provincial People’s Government

September 29, 2022

**The Measures of Hainan Province for Working Faster to Develop its Digital Therapy Industry**

Delivering his landmark speech at a ceremony marking the 30th anniversary of the founding of Hainan Province and the Hainan Special Economic Zone, General Secretary Xi Jinping said that Hainan should deepen supply-side structural reform and leverage its strengths to actively develop the next generation of its information technology sector and digital economy with all necessary resources for innovation. For the purposes of thoroughly implementing the guiding principles of this speech; seizing historic opportunities; building Hainan into an innovation hub of digital therapy across the globe, a region where innovation resources converge, and an industrial center of digital therapy after two or three years of effort; making digital therapy a new engine for the high-quality development of the health industry in Hainan; promoting the leapfrog development of healthcare in Hainan; and achieving a two-year increase in average life expectancy during the 14th Five-Year Plan period, the following measures are hereby formulated.

1. **Establishing a Clinical Research Demonstration Center of Digital Therapy Topping the Whole Country**
2. **A number of Clinical Trial Centers Concerning Digital Therapy should be opened.** Boasting advantages in branches of medicine, a number of tertiary hospitals across the province have been selected to build clinical trial centers of digital therapy. These include: the Clinical Research and Translation Center for Digital Therapy in Hainan Boao Lecheng International Medical Tourism Pilot Zone; the Clinical Trial Center for Digital Therapy on Mental Disorders; the Clinical Trial Center for Digital Therapy on Children with Attention-Deficit Hyperactivity Disorder and Autism; the Clinical Trial Center for Digital Therapy on Tumors; the Clinical Trial Center for Digital Therapy Concerning Ophthalmology; the Clinical Trial Center for Digital Therapy on Sleeping Problems, etc.
3. **We should promote major breakthroughs in technologies of digital therapy and relevant clinical translation.** We should encourage medical institutions and higher learning institutions to conduct scientific research into digital therapy and promote related clinical translations. We should actively apply for special funds for science and technology, such as special funds for key research and development programs and the natural science funding at the provincial level, and attract superior forces to make major breakthroughs in core technologies of digital therapy via various mechanisms, such as utilizing an open competition mechanism to select the best candidates to lead key research projects. Promoting international cooperation on science and technology, we should develop a cooperation platform for scientific projects concerning digital therapy across the globe. To boost research, development and innovation in digital therapy products, we can make use of research and development vouchers for the biomedical industry of Hainan province and other support policies on research, development and innovation across the province; and give subsidies and awards to enterprises, higher learning institutions and medical institutions in stages, according to their progress made in research, development and industrialization related to digital therapy products at different periods. When it comes to job opportunities, promotions, awards and honors, medical institutions should give priority to employees actively undertaking clinical researches on digital therapy. Performance-based salaries should be properly weighted toward clinical trial researchers of digital therapy in public hospitals. Included in the total performance-based salaries of public hospitals in that year, cash rewards for applying scientific and technological advances in digital therapy made by the employees are not limited by the total amount of the salaries, and are not involved in the base of the total salaries or social insurance payment base.
4. **We should work faster to establish a public service and management platform for digital therapy.** Creating links that are exclusive to the digital therapy industry on the websites of related government organs, we support enterprises, medical institutions, clinical doctors and other participants of digital therapy in their demand for clinical trials, and will help them acquire resources they need as soon as possible. We will develop a publicity system for clinical trials regarding digital therapy, so that digital therapy enterprises can promptly update the progress and results of clinical trials which can be regarded as supporting documents by approval organs. Attracting a number of CROs and CDMOs concerning digital therapy to Hainan, we should promote the establishment of the provincial CDMO platform for digital therapy, and boost clinical trial and market-oriented cooperation between platforms, such as CDMO, and local hospitals providing offline or online services.
5. **Accelerating the Processes of Registration and Approval Related to Digital Therapy Products**
6. **We should formulate guidelines on classified supervision, registration, and approval regarding digital therapy products.** We should set up columns on the websites of relevant government organs, and fill the columns with regulatory policies and guidelines on registration and approval concerning digital therapy products. Guidelines for classification and identification of digital therapy products should be drawn up and released through the website columns, according to guidelines issued by the National Medical Products Administration on classification of software products regarding medical devices and on registration and technology review of mobile medical devices, and classification and identification results made by the Center for Medical Device Standardization Administration, etc. Additionally, we should classify and specify regulatory policies, supervising documents and operating guidelines related to key parts of developing digital therapy products, such as clinical trials, registration, evaluation, approval and updating.
7. **We should create special channels for instructions on how to register the second category of medical devices concerning digital therapy products.** Releasing information regarding consulting hotlines and e-mail addresses for regulatory policies on digital therapy via websites of relevant government organs, we should develop a rapid response mechanism for exclusive instructions on how to register the second category of medical devices concerning digital therapy products, assign proper staff members to technology consultation of digital therapy products, and technically they should make replies within 10 working days after consultation. Additionally, we should conduct training for enterprises in registration and policies concerning digital therapy products, help enterprises to improve their applying standards and application materials, and increase the approval rate.
8. **We should formulate criteria for digital therapy development and set up green channels for approving specified categories of digital therapy.** We should giving priority to developing a number of digital therapy products in urgent need for clinical use in Hainan and the ones having a solid theoretical foundation, reliable technologies, and bright prospects; and create green channels to approve the products. Formulating approval procedures prioritizing digital therapy applications, we should develop requirements and procedures for applications that can be prioritized. If an enterprise applies for registering a digital therapy product and provides registration and application materials according to the requirements for medical devices, relevant government organs should complete evaluation and approval within three months, not counting the time a enterprise spends in making corrections and supplements to its materials and experts spend on technology evaluation. If an application is not approved, the applicant should be notified of relevant reasons and suggestions.
9. **We should develop a filing system of digital therapy and encourage applications of real world data to registration and approval regarding digital therapy products and to relevant clinical verification before market launch.** As for digital therapy products in the field of public health, we should rapidly apply them after filing without violating relevant state requirements of evaluation and approval, if they have low risks and can be used for screening and intervention. Encouraging researches into real world, we should fully leverage the leading role of Research Base for Medicines and Medical Devices Regulatory Science of National Medical Products Administration and Hainan Key Laboratory for Real World Data Research and Evaluation of National Medical Products Administration, fully use the experience of franchised medical devices that had been approved for market launch according to policies on real world researches, and boost utilization of real world data in application and registration of digital therapy products and in relevant regulatory decisions and clinical verification after market launch.
10. **Broadening the Application of Digital Therapy Products**
11. **We should establish application bases for digital therapy.** Selecting qualified medical institutions as the province’s first group of diagnosis and treatment centers of digital therapy, we should gradually bring digital therapy into the scope of common diagnosis and treatment paths for diseases in all qualified medical institutions. In addition to “2+3” health service package of Hainan province and other measures, we should improve supply capacities for medical services provided by community-level medical institutions and disease management capacities for patients and their families by making use of digital therapy. We should encourage medical institutions to publicize digital therapy, and help patients and the public to raise their awareness of digital therapy and their capacity for using it.
12. **We should promote the integrated development of digital therapy and internet hospitals.** Encouraging medical institutions to integrate digital therapy with internet hospital platforms, we should authorize doctors of internet hospitals to give patients digital therapy prescriptions. We should encourage internet hospitals to strengthen applications of digital therapy products, and improve their service capacities for prevention and treatment of special diseases and health intervention. We should also encourage doctors to use digital therapy to manage patients outside hospitals, and achieve comprehensive management of patients outside hospitals with the help of services provided by internet hospitals, such as follow-up prescriptions, prescription circulation and medical logistics. We should supervise the development of digital therapy through the oversight and management platform for internet hospitals in Hainan.
13. **Demonstration zones of digital therapy application should be built, topping the whole country.** We should integrate digital therapy into the whole process of the reform and development related to medical and health services in Hainan, coordinate efforts to establish a provincial system of tiered diagnosis and treatment and centers for diagnosis and treatment, and support efforts to apply high-clinical-value digital therapy products in urgent need for clinical use to five centers including urban medical groups, county medical communities and chest pain centers. We should encourage doctors of secondary and tertiary hospitals to diagnose complicated and refractory diseases with the help of digital therapy data, and help the medical staff of community-level medical institutions to manage patients with chronic diseases and track their condition. Making greater efforts to apply information technology to regional medical centers, we should add digital therapy data to databases of regional electronic medical record and electronic health record, and achieve comprehensive supervision for digital therapy by making use of a provincial platform called the Network of Coordinated Medical Service, Medical Insurance, and Pharmaceutical Reforms.
14. **We should encourage people from all walks of life to strengthen applications of digital therapy products.** Encouraging relevant government organs, public welfare foundations and other institutions or organizations to purchase digital therapy products, we should emphasize key groups, major diseases and diversified and mult-tiered demand for digital health, expand the scope of applications of digital therapy products to the treatment for psychological diseases and behavior and cognition problems, effectively improve intervention and screening of chronic diseases, empower community family doctors with digital therapy technology, innovate new service models, and improve residents’ capacity for health intervention.
15. **Encouraging the Exploration of Various Payment Models**
16. **We should encourage the exploration of product innovation concerning a combination of digital therapy and commercial insurance.** A pilot reform project has been rolled out in Hainan Boao Lecheng International Medical Tourism Pilot Zone to explore health management service with special medicines insurance covering digital therapy expenses. We encourage insurance companies to provide clients with health manage services concerning digital therapy in accordance with relevant laws and regulations, and reasonably price the services according to real world data collected through digital therapy and relevant regulations. Creating an upgraded edition of medical insurance covering all of the people of Hainan, we need to regard some digital therapy products as health management services and bring them into the scope of insurance products. Encouraging insurance agencies to add digital therapy products to their insurance product systems, we should also encourage product developers of insurance agencies to take training courses in digital therapy made by medical authorities and to raise their awareness of digital therapy.
17. **We should bring digital therapy into the scope of technical code and charges related to medical service programs.** According to the real demands for diagnosis and treatment of particular diseases, we should develop a pricing mechanism of digital therapy for clinical use and make reasonable charges for digital therapy. Medical institutions should apply to Hainan Provincial Healthcare Security Administration for prices of medical services concerning digital therapy, and the prices should be disclosed and charged after expert discussion and completion of relevant procedures. In accordance with strategic purchase principles concerning medical insurance of being commensurate with the level of economic growth in the province, reflecting social equity of medical insurance and increasing value, we should study the possibility of making digital therapy products and relevant medical services reimbursable under the medical insurance plan if the products and services have high clinical value and good economic returns, and are affordable for medical insurance funds and people covered by the insurance. Additionally, we should bring digital therapy products utilized by medical institutions into the scope of medical service revenues.
18. **We should explore the combination of digital therapy and the reform of medical insurance payment models.** According to progress in the reform of medical insurance payment models across the province, we should select medical institutions that have applied digital therapy and accumulated relevant data, support applications of digital therapy to medical cost control and health management, develop an effective mechanism for integrating digital therapy with disease-related payment, and promote the building of an efficient and effective payment mechanism based on value and data.
19. **Promoting the Publicity of Digital Therapy and the Building of Industrial Clusters**
20. **We need to develop high-quality industrial clusters for digital therapy.** We should make an enterprise list by sorting out digital therapy enterprises and the potential candidates at home and abroad, and then attract targeted businesses covering the industrial chain. Leveraging the strengths of policies concerning Hainan Free Trade Port and the whole process of developing digital therapy, we could attract innovation resources by utilizing high-level data platforms, such as electronic prescription centers. We could also establish a number of innovation hubs and industrial clusters for digital therapy in Hainan Free Trade Port, based on the Hainan Boao Lecheng International Medical Tourism Pilot Zone, Hainan Resort Software Community, the Haikou National Hi-tech Industrial Development Zone, Haikou Fullsing Internet Industrial Park, and so on.
21. **Overseas digital therapy enterprises should be actively attracted.** Taking targeted policies and measures for different overseas enterprises regarding digital therapy, we should actively guide overseas digital therapy enterprises in cooperation with local medical institutions, and achieve deep integration of overseas digital therapy with the local industrial chain. Leveraging the strengths of the pilot program for real world data research conducted in Hainan Boao Lecheng International Medical Tourism Pilot Zone, we could import a number of overseas digital therapy products at a high level, carry out trials on overseas products, and support agencies in approving products by using real world data.
22. **We should work faster to develop Hainan into an innovation island for digital therapy**. We could pool resources for government policies, industry leaders, capital, innovation, technologies and talents by holding a Digital Therapy World Congress in Hainan. Publishing annual reports of digital therapy across the world (in multiple languages), we could establish a demonstration and experience center for digital therapy, and build a large museum of digital therapy with recognizable features by using technologies and means, such as virtual reality, holographic displays, large digital screens and exhibitions.
23. **Well-regulated Development and Other Supporting Measures**
24. **We should attract associations or branches related to digital therapy, formulate industry standards and establish a platform for information exchange.** Setting up an expert committee or a relevant organization of digital therapy, we should create industry standards for digital therapy, organize training courses and symposiums on digital therapy on a regular basis, help clinical doctors and relevant parties to raise their awareness of digital therapy, and steadily develop digital therapy to create an expert consensus regarding diagnosis, treatment and management of specialist diseases. Supporting the founding of the international digital therapy industry alliance, we should work with relevant enterprises at home or abroad to host discussion activities about policies and regulations, evaluation and approval, medical value and medical insurance payment models related to digital therapy, and provide state-of-the-art theory guidelines and practice experience for building innovative business models.
25. **We should enhance supervision of data security and strengthen the use of data resources.** Formulating policy guidelines on date security related to digital therapy, we should use the provincial platform for sharing and exchanging administrative information, add public health data collected by digital therapy products to the provincial big data resource center for coordinated medical service, medical insurance, and pharmaceutical reforms under the premise of strengthening data security and privacy protection according to the law, and steadily expand open access to health medical data in an orderly way. We should strengthen special guidelines on approving technologies concerning user information protection in relation to digital therapy products, and those who are responsible for data leaks would be strictly held accountable. Creating channels for user complaints and mechanisms of regular inspection and spot checks, we need to promptly investigate and prosecute relevant violations of laws and regulations.
26. **We should make greater efforts to train and attract digital therapy personnel.** Encouraging relevant colleges and universities in Hainan to set up courses and majors of digital therapy, we will support the development of crossover disciplines related to digital therapy. We should make more efforts to train personnel of related crossover disciplines, such as the internet, big data, artificial intelligence and bioinformatics, and provide human resources support for the development of the digital therapy industry. A provincial academy of digital therapy should be established with the help of Hainan Medical University. Implementing supporting policies on permanent residency, buying vehicles, housing and medical service related to talent, we should encourage higher learning institutions and enterprises to actively attract medium-level and high-level talents at home or abroad. Additionally, we should actively help talents of the digital therapy industry to be covered by talent programs at all levels, and support the high-level talents we are badly lacking in the field of digital therapy in enjoying the preferential individual income tax policies of the Hainan Free Trade Port according to relevant regulations.
27. **We should leverage the strength of the investment fund for the development of the Hainan Free Trade Port, and promote the development of the digital therapy industry by making equity investments.** We should fully play the leveraging role of the investment fund for the development of the Hainan Free Trade Port, cooperate with industrial and financial capital in a way guided by the government, and operate the fund in a market-oriented manner. Promoting the establishment of a healthcare sub-fund, we should invest in the digital therapy industry, and support the development of digital therapy enterprises in Hainan.

The General Office of the Hainan Provincial People’s Government

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