

CLIENT ALERT

Beat by Beat: Harnessing e-Health to Optimize Health Care Delivery in China

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This alert is part of our Beat by Beat Series, which explores global digital health developments.

Crowell & Moring International LLC (CMI), the global policy and regulatory affairs consulting affiliate of Crowell & Moring LLP, recently established an office in Shanghai to support global businesses facing cross-border business needs, as well as international trade, policy, and regulatory issues. This new Shanghai presence expands CMI's ability to serve clients in China and builds on CMI's more than 30 years of experience advising global businesses operating in the Asia-Pacific. For more information click [here](#).

While it is still riding the long wave of an economic boom that lifted millions from poverty, China is facing unique new challenges driven by rapid urbanization, population and demographic trends, and rising expectations among its growing middle class. These winds of change are driving reform efforts in Beijing across myriad industries, including the marketplace for digital health innovation. To ensure adequate health care for its 1.4 billion citizens, China is focusing on digital solutions and is updating its rules around data privacy, telehealth, and other e-healthcare products.

China's Health System

China has one health care practitioner for every 6,666 people, creating major challenges for access to care. Long lines are common outside large hospitals in big cities. Specialist doctors typically work in public hospitals located in large cities, which can be difficult to access for the 900 million people that live in rural areas.

Telemedicine and other tech-enabled diagnostic and treatment platforms could create a better experience for patients and increase efficiency for providers, making the provision of health care in China more accessible and affordable. For patients, the implementation of telemedicine could speed access to care despite geographical barriers, delivering solutions in the comfort of their own home. On the provider side, digital health technologies can offer better access to information and training to support practitioners in rural areas. In addition to telemedicine, the use of electronic health records or secure data-sharing platforms could increase operational efficiency and reduce administrative cost across China's expansive health care system, which is ranked 144th in the world.

China has experimented with telemedicine since the 1980's and now has several telemedicine networks operating in the country; however, a lack of investment in telecommunications infrastructure and workforce development, as well as unclear financial incentives and no national telemedicine regulations, have slowed the progress of innovation. The regulatory landscape is evolving, however, and showing signs that may auger a new, innovative horizon for digital health.

China's New e-Healthcare Rules

On September 14, 2018, the National Health Commission (NHC) and the National Administration of Traditional Chinese Medicine (NATCM) released three new rules on internet-based medical services and telemedicine. The rules cover the areas of e-diagnosis, internet-based hospitals, and telemedicine services, and allow commercial companies to collaborate with hospitals and clinics to provide health services online.

e-Diagnostic Rule

Under the e-diagnostic rule, licensed doctors and nurses in China may provide e-diagnostic services. These practitioners must be listed in the national health care professionals system and have at least 3 years of independent clinical practice experience. Services are only available to patients for follow-up visits for certain common and chronic diseases and controlled substances may not be prescribed.

Internet-based Hospital Rule

The internet-based hospital rule provides a framework for medical institutions to become accredited e-hospitals. These facilities must satisfy hardware and software requirements, such as having two sets of servers, uninterruptible power supply, and a high-speed internet connection. Furthermore, the hospital must have appropriately licensed health care practitioners on staff.

Telemedicine Service Standard

Hospitals providing medical services via remote connection to patients must enter into collaboration agreements that identify the scope and conditions of the collaboration, service procedures, the rights and obligations of the parties, and allocation of medical malpractice risks. Collaboration agreements must be reviewed by a local health care regulator and address data privacy issues.

China's Data Privacy System

China's Personal Information Security Specification took effect on May 1, 2018. Using the European Union's General Data Protection Regulation (GDPR) as a model, China sought to formulate a less rigid data protection regime that would not undermine efforts to develop cutting-edge technologies, such as artificial intelligence, which rely on access to massive datasets. Health data is treated as "sensitive personal information" under this regime, including records generated as a result of medical treatment of individuals. Network operators (including all companies that own or administer a network) are required to be transparent about the purpose, method, and scope of proposed data collection and use, and obtain consent from the individual. "Explicit consent" is required from data subjects for any collection of sensitive personal information. Some exemptions to consent requirements exist when necessary for contract signing and performance, and when necessary for maintaining a safe and stable operation of product and service provided. When information collected is inaccurate, an individual can request correction.

Previously in December 2017, China also issued a draft Basic Medical Health Care and Health Promotion Law, which provides that the state protects the privacy of individuals related to their health and ensures the security of personal health information.

Under this law, no organization or individual may acquire, use or disclose personal health information of individuals, except as required by law or with the consent of such individuals. This law is still pending.

New Cybersecurity Law

Products and services may also be potentially regulated by China’s new Cybersecurity Law and implementing regulations. Under certain circumstances (which can be hard to discern from the written legislation), the storage, transmission and use of data by “critical information infrastructure operators” may be subject to burdensome in-country storage and transmission restrictions that can impact businesses with digital health components.

Impact on Health Marketplace

As of February 2019, China reported that it had achieved full telemedicine coverage in county-level hospitals located in counties identified as highest-need. While telemedicine has found a foothold in the market, other factors continue to stall the adoption of the technology, as telemedicine and other e-healthcare technologies are in tension with the traditional medical culture in China, which strongly favors face-to-face interactions.

The Xiamen Regional Health Information Platform provides a case study of integrated and digitized care that could be a wave of the future. The system improved service efficiency and quality across the city’s health care delivery system by facilitating information sharing, and providing integrated health information to patients and providers. All population groups in Xiamen are able to use a mobile app to get real-time information on wait times in emergency rooms, make appointments, get prescriptions dispensed, access their EHR, and make payments. Each patient is provided a unique identifier that is the same as their health insurance number. The system monitors all interactions between the patient and provider, and stores relevant health data.

As the Chinese digital health landscape continues to evolve, companies making strategic investments need to keep in mind the limitations to participating in the marketplace. For telehealth and other e-healthcare platforms, this likely means partnering with existing providers to reach target populations. As the Chinese government seeks to accelerate technology innovation to drive improved health outcomes and lower costs, industry, patient groups, researchers, and other stakeholder have a critical role to play in shaping policies related to the issues of commercial participation, data collection, management, privacy, security, and usability.

Learn more about our [Digital Health team here](#) and our [Policy Roadmap](#) that lays out ten of the most important policy issues facing governments as they look to the role of digital technology in health care.

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