New Chinese Requirements on Management of Health Information

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On May 5, 2014, China’s National Health and Family Planning Commission (“NHPC”) promulgated the Administrative Measures for Population Health Information (For Trial Implementation) (“Health Information Measures”) governing the collection, use, and management of “Population Health Information” by medical, health care, and family planning services. According to the NHPC, the Health Information Measures are intended to “standardize and strengthen population health information collection, management and utilization, as well as to protect information security and individual privacy.”

NHFPC officials have informed us that the new regulations apply to both public- and private-sector entities, although it remains unclear which specific entities are targeted.

The Measures also prohibit storing “Population Health Information” on overseas servers for the first time, a cross-border prohibition that has been applied to health information in China.

Key Definitions

“Population Health Information”
Under the Health Information Measures, “Population Health Information” (renkou jiankang xinxi) is defined as “basic demographic information, information collected from the provision of medical and health care services, including and health planning services, and other population health information generated by medical, health care, and family planning service agencies of all types and at all levels.”

While various PRC laws and regulations have included provisions related to personal health information, the Health Information Measures are China’s first regulations that are primarily focused on such data.

“Responsible Entities”
The Health Information Measures state that “medical, health care and family planning service agencies of all types and levels” are the “Responsible Entities” for the collection, use, management, storage, and privacy protection of Population Health Information.

We have confirmed with the NHPC that this term applies to both public- and private-sector entities.

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Substantive Provisions

The Health Information Measures include a mix of broad prescriptions and more specific, targeted requirements. Among the measures, a more detailed provision provides an overview of common data protection standards for Responsible Entities to follow:

- **Data Quality Assessment**: Responsible Entities must conduct an assessment of the importance and necessity of the data collected, and maintain data quality over time.

- **Data Use and Maintenance**: Responsible Entities must ensure data is maintained in a true-to-actual, true-to-date, and valid state.

- **Data Storage, Disaster Recovery, and Management**: Responsible Entities must establish procedures for data storage, disaster recovery, and management.

- **Data Access and Management**: Responsible Entities must ensure appropriate data access and management, including the establishment of a trace management system.

- **Data Security**: Responsible Entities must implement appropriate security safeguards for data collected.

- **Data Protection**: Responsible Entities must protect data from unauthorized access or disclosure.

- **Data Sharing**: Responsible Entities must ensure that data is shared in accordance with the relevant national standards and regulations.

- **Data Submission**: Responsible Entities must submit data to the relevant authorities in accordance with the provisions of the Measures.

- **Data Utilization**: Responsible Entities must utilize data in an appropriate manner, in accordance with the relevant national standards and regulations.

In addition, Responsible Entities must develop and implement appropriate data protection policies and procedures, and must ensure that all employees are trained in data protection policies.

Significantly, the Health Information Measures prohibit the storage of Population Health Information collected in China on servers outside China, as well as the hosting of any servers outside China that are used to store or transmit such information. The Measures also prohibit the transfer of Population Health Information collected in China to third parties without the patient’s consent, this prohibition is the first of its kind in China.

**Rationale**

While the promulgation of the Health Information Measures seems to be part of China’s general strategy to promote comprehensive utilization of health information, the Measures also reflect broader goals contained in this document.

**Substantive Provisions**

These include:

- **Data Quality Assessment**: Responsible Entities must conduct an assessment of the importance and necessity of the data collected, and maintain data quality over time.

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**Remedial Provisions**

Exhibitors violating the Health Information Measures may be subject to administrative sanctions, depending on the extent of the violation. The magnitude of fines is determined by the nature and extent of the violation, and varies from RMB 10,000 to RMB 100,000. Violators may be required to make corrections or may be subject to public criticism or administrative sanctions.

**Legislative Background**

While various PRC laws and regulations have included provisions related to personal health information, the Health Information Measures are China’s first regulations that are primarily focused on such data.

The provisions of the Health Information Measures build on a foundation of existing laws and regulations, and allow for a more comprehensive approach to data protection. The National Health and Family Planning Commission (NHFPC) is responsible for implementing the Measures.

In 2013, the NHFPC released a policy paper entitled Guidelines of the National Health and Family Planning Commission on Promoting the Development of Information Systems in the Field of Health Information. This policy paper sets out guidelines for the development of health information systems in China.

**NOTES**

1. The Ministry of Health and the National Population and Family Planning Commission merged in 2013 to create the NHFPC.


3. The Measures also prohibit storage on overseas servers of Population Health Information collected in China. The first time a cross-border prohibition has been applied to health information in China.
Article 8. We have been unable to confirm which national requirements are referenced here, but this may refer to a set of national standards entitled Information Security Technology — Baseline for Classified Protection of Information Systems.

Article 10.

Article 11.

Article 15.

Article 7.

Article 18.

The text of the Administrative Measures for Population Health Information (For Trial Implementation) is available, in Chinese, at http://www.moh.gov.cn/guihuaxxs/s10741/201405/783ec8adebc6422bbebdf79db3868d0b.shtml.


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