

个人信息保护法律热点问题

国家卫生计生委出台《人口健康信息管理办法（试行）》征求意见稿

2013年11月18日，国家卫生和计划生育委员会于网站上发布《人口健康信息管理办法（试行）》（征求意见稿）（以下简称“意见稿”），向社会公开征求意见，征求意见截止12月20日。这是中国首次特别对个人健康信息通过单独的规定进行管理和保护。

人口健康信息的定义

意见稿第六条规定，“人口健康信息”是指依据国家法律法规和工作职责，在卫生计生服务和管理过程中产生的电子数据信息，包括以下四类：

- 全员人口信息，主要指人口基本信息、家庭户及户成员信息、计划生育服务管理相关信息，流动人口计划生育服务管理信息；
- 电子健康档案，主要是居民健康管理过程的记录；
- 电子病历，主要指医务人员在医疗活动中使用医疗机构信息系统生成的文字、符号、图表、图形、数据、影像等数字化信息，并能实现存储、管理、传输和重现的医疗记录；
- 其他信息，是指各类卫生计生服务和管理中相关生产性信息、管理决策信息以及人口健康信息管理系统产生的信息。

人口健康信息保护的要求

重点关注以下方面：

信息收集

- 责任单位应依照规定程序和国家相关标准采集与其履行职责相适应的人口健康信息。

- 采集人口健康信息，应当说明用途，并征得被采集对象的同意。

信息管理

- 不得将人口健康信息相关系统委托给具有商业利用人口健康信息目的的机构运营。
- 不得擅自复制、更改、删除、泄露人口健康信息。
- 责任单位应建立痕迹管理制度，任何建立、修改和访问人口健康信息的用户，都应通过严格的实名身份鉴别和授权控制，做到行为可管理、可控制、可追溯。
- 人口健康信息的主管部门为县级以上卫生计生行政部门。

信息利用

- 单位或个人利用人口健康信息，应当向责任单位申请同意，并不得用于商业目的或危害公民权益、社会秩序和国家安全的任何用途。
- 利用单位或个人根据需要，可以对数据进行二次分析或者对数据的格式进行转换。但未经主管部门许可，不得以任何形式将分析、转换后的数据对外发布和提供。

信息转移

- 利用单位或个人不得将获得的人口健康信息擅自提供给他人利用，不得超出申请用途范围利用。

- 不得用境外的服务器存储人口健康信息，包括托管在境外的服务器和租赁的境外服务器。

简评

意见稿对“人口健康信息”做出了比较宽泛的定义，针对人口健康信息提出的保护方案和力度都非常大，同时给出了详细、具体的保护方案。

但意见稿的法律责任一章中，仅规定了行政处分，而并未特别规定相应的行政处罚。

如果意见稿出台，在没有明确罚则、而是依赖现有民法、刑法规定的情况下，是否能够有效推行，也仍然是一个有待实践的问题。

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Protection of Personal Information

NHFPC issued Draft Measures for Administration of Personal Health Information for Public Comments

National Health and Family Planning Committee (“NHFPC”) issued a Draft of *Measures for the Administration of Personal Health Information (For Trial Implementation)* (the “**Draft Measures**”) on its website for public comments with a deadline on December, 20th. This is the first time the Chinese government has proposed a distinguished and unified framework for the administration and protection of personal health information.

Definition of Personal Health Information

Article 6 of the Draft Measures provides, “Personal Health Information” is electronic data information produced in the process of health and family planning service and management in accordance with national laws and administrative duties, which includes the following four types of information:

- Population information, mainly referring to the basic population information, numbers of families and family member information, relevant information of family planning service and management, management

information of transient population family planning;

- Electronic health archives, mainly referring to the records of health situation formed in the course of health management of residents;
- Electronic medical records, mainly referring to digital information generated by medical personnel using information systems of medical institutions in their medical activities, such as words, symbols, charts, designs, data and images, which can be stored, managed, transferred and reproduced; and
- Other information, referring to the relevant production information, management decision information related to various health and family planning service and management, and information generated by personal health information management system.

Requirements of protection for Personal health information

Major requirements set forth in the Draft Measures are as follows:

Collection of Information

- Responsible entities such as medical institutions should only collect personal health information appropriate according to their duties and responsibilities, following the relevant procedures and national standards.
- Responsible entities must inform the person whose information is collected of the purpose for collecting his personal health information and obtain his consent.

Information Management

- Institutions having commercial purposes of using personal health information should not be entrusted to operate such information.
- It is not allowed to duplicate, amend, delete or leak personal health information without authorization.
- Responsible entities should establish trace management system and set up strict rules on user real-name identity verification and access controls for establishing, amending or visiting personal health information, so that the activities of relevant persons having access to such information are manageable, controllable and traceable.
- The health and family planning administrative departments at or above the county level are in charge of the administration of personal health information.

Information Utilization

- Entities or individuals should apply to responsible entities for consent to use

personal health information, and are not allowed to use such information for commercial purposes or any purposes infringing others' rights, social order or State security.

- Entities or individuals may conduct second-time analysis on the data or change its format if necessary, provided that they are not allowed to publicize or provide to others such analyzed or transformed data without authorization of the administration in charge.

Transfer of Information

- Entities or individuals should not provide personal health information they obtained to others or use it beyond purposes as they originally applied for.
- No Personal health information may be stored in any server located outside of China, including servers under custody or rented outside of China.

Brief Comments

The Draft Measures has provided a broad definition of "personal health information" with detailed and specific rules for the administration and protection of such personal health information. However, the Draft Measures has not provided any specific administrative penalty for breach and only mentioned that the penalties under other laws and regulations may be applicable. It will be of question whether the Draft Measures could be efficiently and effectively enforced once it is published. We will follow up with the legislation process.

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