

个人信息保护法律热点问题

新修订的《医疗机构病历管理规定》加强对患者个人信息的保护

国家卫生计生委和国家中医药管理局对2002年发布的《医疗机构病历管理规定》进行了修订，修订后的规定（以下简称“新规定”）于2013年12月17日发布，并将自2014年1月1日起施行。

新规定有以下几点值得关注：

- 确定了电子病历与纸质病历有同等效力，以及电子病历的保存规范；
- 要求医疗机构及其医务人员严格保护患者隐私，禁止以非医疗、教学、研究等目的泄露患者的病历资料；
- 对查阅、借阅和复制病历等行为规定了更为具体的要求和程序。

这些变化与今年11月国家卫生计生委发布的《人口健康信息管理办法（实行）》（征求意见稿）的精神是一致的。该征求意见稿中规定电子病历属于人口健康信息的一种，收集该等信息应当说明用途并征得其同意，任何单位、个人不得擅自复制、更改、删除该等信息。

新规定的可操作性更强，要求更为具体详细。但新规定之中没有创设行政处罚则，其执行力是否会受到影响仍待观察。

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Protection of Personal Information

Amended Medical Records Administration Measures Strengthens Protection for Patients' Personal Information

The amended *Medical Records Administration Measures of Medical Institutions* (the "New Measures") was issued by the National Health and Family Planning Commission ("NHFPC") and the State Administration of Traditional Chinese Medicine on December 17, 2013, and will become effective from January 1, 2014.

The following points in the New Measures are notable:-:

- It has included electronic medical records as a new type of medical records, in addition to paper-based medical records, and set forth the requirements for keeping electronic medical records;
- It strictly prohibits the leakage of patients' medical records information for purposes of teaching or research, or which are not related to medical treatment;

- It has included more specific and stricter requirements and procedures for reviewing, borrowing or copying medical records.

These changes are consistent with the *Measures for Administration of Personal Health Information* issued this November by NHFPC for public comments, which has included electronic medical records as a type of personal health information and requires data subject's consent for collection, and prohibit duplication, amendment or deletion of such information by any person without proper authorization.

The New Measures includes more practical and specific requirements on protection of patients' privacy rights compared with the 2002 version. However, there is no specific administrative penalty being provided thereunder, and it is still to be tested in practice.

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